Unlock the potential for patients and budgets with Negative Pressure Wound Therapy

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Summary

Over 300 expert delegates and 37 speakers representing Europe, United States, the Middle East, Canada, Africa, Asia and Australia came to Berlin for the 6th International Negative Pressure Wound Therapy Expert Meeting. All four work-streams (Plastic and Reconstructive Surgery, Cardiothoracic Surgery, General Surgery, and Orthopaedic Surgery) comprised presentations on the complications associated with surgical incisions, commonly surgical site infection (SSI) and wound dehiscence and how the prophylactic application of Negative Pressure Wound Therapy (NPWT) can prevent them. With organisations driving down costs and cutting resources, and an increasingly high-risk patient population, identifying the at-risk patient and implementing strategies such as the use of PICO™ Single-use NPWT System to prevent complications, is key to sustainable healthcare.

The event, chaired by Michael Sugrue (Ireland), James Stannard (USA), Richard Ingemansson (Sweden) and Maurizio Nava (Italy), presented a unique opportunity to discuss, debate, share practice, and to present data on this new indication of NPWT on closed incisions.

The key messages from the meeting are:

• **Surgical Site Complications are underestimated.** The main reason for this is that there is not a unique definition of what should be reported. Surgical Site Infections are well defined by the CDC, with the distinction of what is a superficial, deep and organ/space infection, but the same is not true for the overall incisional complications. Another reason for being underestimated is the fact that a high percentage of SSC happen after the patient discharge.

• **Surgical Site Complications have a high human and economic cost for the healthcare authorities,** but this cost can be avoided if sustainable strategies for prevention are put in place. In order to be sustainable, prevention has to be targeted only at high-risk patients, therefore their identification is critical. The implementation of a “surgical wound risk score” would be a big step forward toward affordable surgical site complications prevention.

• **NPWT devices like PICO NPWT System are becoming increasingly accepted in surgical practice,** because there is increasing evidence in various surgical specialties that they **provide a significant reduction of surgical site complications**29, a reduction of seroma formation29, and a better scarring32,33.

• **Several high level studies are in progress** and in the next few months these should provide a definitive body of evidence to drive systematic prophylactic use of incisional NPWT in high-risk patient populations, in order to reduce Surgical Site Complications, facilitating an earlier discharge and therefore reducing the cost of treatment and improving patients outcomes29, 33.
Opening Plenary

Michael Sugrue presented the state-of-the-art use of Negative Pressure Wound Therapy (NPWT) in open wounds, making an extensive review of the literature and sharing his clinical experience, particularly on the use of NPWT in the Open Abdomen. Prof. Sugrue reminded how, in the US, approximately 500,000 surgical site infections (SSI) occur per annum, 40-60% of which are considered preventable.

A SSI has been proven to affect long-term survival, so the surgeons have to consider a multi-factorial strategy, including a precise timing of antibiotic administration, good bowel and skin preparation, double gloving, careful fascial closure technique, and the appropriate use of NPWT, in order to achieve better outcomes. Evidence-based recommendations for the treatment variables of Negative Pressure Wound Therapy, the use of NPWT in chronic wounds, traumatic wounds and reconstructive surgery, and most recently in open abdominal wounds have been published, and are now available in the public domain, but the awareness of this therapeutic option is still relatively limited.

Prof. Stannard reviewed studies exploring iNPWT’s role in perfusion and the use of prophylactic iNPWT, an approach which seems to have demonstrable benefits such as faster healing (particularly in high-risk knee and ankle fracture repair areas), and quicker discharge. He reported success in management of haematoma and surgical incisions and granulation. Results to date show a 45% greater reduction in wound depth, and faster healing compared to control.

Prof. Lavery went on to discuss instillation and intermittent irrigation (NPWTi). Phillips et al. studied periodic instillation of antibacterial agents with NPWT in a swine model and concluded that NPWTi with active antimicrobial agents, enhances the reduction of CFUs by destruction and removal of biofilm bacteria. Conversely, Davis et al. looked at continuous irrigation in a swine model and concluded that NPWT with simultaneous irrigation further reduced bioburden over control and NPWT-treated wounds; NPWT with simultaneous irrigation therapy (normal saline or PHMB), had a positive effect on bioburden in a porcine model. Prof. Lavery presented the unpublished data from his recent prospective, randomised, comparative effectiveness study comparing the instillation of saline with 1% polyhexanide (PHMB). There was a reduction in days to final surgery with NPWT (but only in normal saline group). A further study is underway using continuous instillation. Finally, he presented some data from an on-going study of pulsed UVA light (fibre-optic delivery system) under NPWT to reduce bioburden and accelerate granulation. Results to date show a 45% greater reduction in wound area, a 50% greater reduction in wound depth, and faster healing compared to control.

After these presentations, the four session chairs discussed the agenda for each of the work streams, based on the key deliverables of the meeting:

- An understanding of incisional complication incidence in the four specialties and practice protocols to minimise or manage them;
- A potential clinical algorithm which may aid identification of high-risk situations (patients or type of surgery) where the prophylactic use of NPWT may be considered;
- The notion that NPWT, and in particular products such as the PICO® Single Use NPWT System, should be considered in high-risk patients.
This work stream focused on breast cancer surgery, breast reconstruction and aesthetic breast surgery. The main complication is wound infection and/or dehiscence, so the factors which impede healing must be considered.

**Breast surgery**

Giuseppe Catanuto (IT) outlined the main oncoplastic surgery techniques (simple wide local excision, simple wide local excision +/- nac [nipple-areola complex] repositioning, uni/bilateral therapeutic mammoplasty, conservative mastectomy). Surgeons must assess risk factors, oncological needs and patient expectation, and adapt their surgical strategy accordingly.

Maurizio Nava (IT) presented a workflow infographic to aid peri-operative surgery decision making. He outlined his practice for avoiding complications – short-term antibiotic treatment (in low risk patients), frequent glove changes during surgery, washing the pocket or the surgical bed with saline and Amikacine, and pre-medicated absorbable wires.

Given the plethora of both published and unpublished data to be presented at the meeting, Nicola Rocco (IT) injected a note of caution; knowing how to evaluate evidence is critical because randomised doesn’t always infer validity, and results do not necessarily apply to your patient group. Consider using the Consolidated Standards of Reporting Trials (CONSORT) statement as a guide.

The unpublished results of a multi-national, prospective randomised clinical trial on the use of PICO™ to prevent post-surgical incision healing complications in 200 patients undergoing reduction mammoplasty were presented by Robert Galiano (US).

They showed a statistically significant reduction of incision healing complications of 38% and a significantly better scar quality in the PICO group within the first three post-operative months. The latter outcome may suggest the use of PICO in surgeries where there may be a higher interest in the cosmetic outcome (i.e. in visible parts of the body).

**Breast reconstruction**

Risal Djohan (US) gave an overview of breast conservation and full or partial mastectomy (with or without reconstruction - implant or autologous) techniques. Early onset complications include dehiscence and skin necrosis; late complications include sensory loss and scar hypertrophy. These may be ameliorated by pre-operative weight loss and a well-vascularised quality flap; vascularity can be assessed intra-operatively by the use of indocyanine green.

The challenges of using autologous flaps for breast reconstruction were outlined by Gemma Pons (ES). While a number of ‘donor’ sites can be used to create flaps, the abdominal perforator flap is considered the ‘gold standard’. The approach depends on clinical indication and patient preference, but the aim is to provide a safe procedure. Dr. Pons suggested that PICO may be a useful prophylactic intervention for both reconstruction and flap sites.

Clinical experience of PICO in complex breast reconstructions was presented by John Murphy (UK). He postulated that ‘simple’ wounds (T-junction, Wise pattern wounds) in high risk patients, and linear wounds in patients undergoing breast reconstruction where cost of failure is high (e.g. implant + Acellular Dermal Matrix or ADM), are actually complex wounds. Results from his study showed no wound breakdown nor adverse skin reactions, and high patient satisfaction with PICO, mainly driven by a scarring which seems subjectively better that the standard of care. PICO appears to be cost-effective, with an average cost in UK of £144 per dressing vs. the cost of a wound breakdown which ranges £840 - £1260, if the implant is not affected, while in case of loss of the implant, the price of a new reconstruction is over £10000 (over £13000, when ADM is used).
Aesthetic breast reconstruction

Gemma Pons (ES) emphasised that in aesthetic surgery, the patient’s primary concern is the quality and location of the scarring; she is using microsurgical approaches to improve outcomes.

The challenges of reduction mammoplasty and mastopexy were reviewed by Risal Djohan (US), comparing the patient satisfaction, the revision rate and the complications of the various technique, according to the literature.

Maurizio Nava (IT) outlined the surgical techniques appropriate to breast augmentation, emphasising the need to do a careful planning of the surgery and manage patient’s expectations. He concluded that breast augmentation is usually not associated with wound breakdown, except the mastopexy-augmentation technique which has some potential for poor wound healing, as well as vertical, inverted T and peri-areolar incisions, where the use of a device like PICO™ may provide some benefit.

The session concluded with Rene van der Hulst (NL), who presented the results of an extension of the study presented by Dr. Galiano. Scar quality was assessed in 32 original study patients at 180 and 365 days, measuring viscoelasticity, skin surface hydration and trans-epidermal water loss. A significant improvement in VAS at day 180 was noted, although only a small difference was seen in elasticity, and no difference was seen in the other two parameters. PICO addresses the factors that ensure better scar appearance, minimising tension, dead space (preventing seroma formation), tissue injury, and contamination.

Plastic Surgery workstream: key points

- Surgical site infection (SSI) and wound dehiscence can delay adjunctive (radiation or chemotherapy) therapy and have long-term morbidity, mortality and resource implications.
- Precise pre-operative planning that takes into account clinical and patient need is required to prevent post-operative complications.
- Peri-operative risk factors must be considered, to define the level of risk of the individual patient and to utilise the most appropriate approach to the management of the surgical incision.
- The post-operative use of PICO in breast reduction surgery has been proven to significantly reduce the incidence of dehiscence (38% reduction) and to provide a better cosmetic outcome at 42 and 90 days post surgery, compared to standard postoperative management. (Galiano et al., - unpublished results)
- In complex breast reconstructions, no wound breakdown or adverse skin reactions, were seen using PICO. Patient satisfaction was high and, subjectively, scarring was better.

Gaps in knowledge centre on long-term scar outcome (after 90 days), where additional evidence is required and identifying the patients eligible for the use of iNPWT (i.e. high-risk patients, revision surgery onco-plastic procedures).

Structure of the PICO dressing.
Data on the use of iNPWT in cardiothoracic surgery are now emerging: this stream focused on the incisional complications of cardiothoracic surgery and how these patients may be stratified according to the individual risk level, developing the concept that patients with a higher risk factor may require a specific approach from a postoperative management point of view.

Richard Ingemansson (SE) opened with an overview of the incidence of sternal wound complications such as deep sternal wound infection (DSWI), superficial sternal wound infection (SSWI), sternal dehiscence, pseudoarthrosis, sternal pain, subxyphoid hernia; DSWI has an incidence of 1-4% of cases with a 7-35% mortality, while SSWI has an incidence of 4-7%, with a mortality of 1-2%. He has proposed a practical classification for risk factors related to cardiothoracic surgery: major (diabetes mellitus, BMI<18 or >40, dialysis), intermediate (use of bilateral mammary arteries, chronic lung disease [GOLD class>2], long-term immunosuppressive therapy, previous chest wall radiotherapy, chronic kidney disease, 35<BMI<39), and minor (cardiac re-operation, female gender, age>75 years, acute myocardial infarction, hospitalized for at least 7 days before surgery).

Johan Nilsson (SE) explained how risk stratification can aid identification of patients at risk of post-operative complications (and associated costs), thereby ensuring they undergo the most appropriate intervention. This is important when comparing mortality rates; high rates may be considered to be a result of poor surgical skills, but the acuity of the patient pre-operatively is a key determinant of clinical outcome. Available risk calculators are based on database patient information, but few exist for Surgical Wound Infection (SWI) risk in cardiac patients. To obtain a true picture of SWI rates, Örjan Friberg (SE) postulated that longer post-operative follow-up is required. Most organisations report a 1-2% infection rate, whereas the real incidence is likely to be 5-8% at 30 days and 6-10% at 2-3 months. Prophylactic local placement on the incision of a collagen sponge with gentamycin can help reduce sternal infection, as can meticulous surgical technique, minimising oedema and rigid fixation of the sternum.

Onnen Grauhan (DE) presented his clinical experience of using NPWT prophylactically in high risk (obese) patients undergoing a sternotomy procedure; he concluded that NPWT over clean, closed incisions, for 6-7 postoperative days significantly reduces the wound infection incidence after median sternotomy\textsuperscript{11}. His ‘all comers’ study observed 237 patients treated with prophylactic NPWT (192 ‘standard’; 45 ‘high risk’ – all treated with KCI Prevena\textsuperscript{TM}21 with a total of 3 wound infections (one in the standard group, two in the high-risk one), which compared very favorably with their historical control group of 3508 patients, showing an incidence of 1.3% vs. an historical value of 3.4% (p<0.05). Professor Grauhan concluded that NPWT provides a “sterile” wound environment, supports improved wound healing through improved microcirculation, drainage, and stabilisation of the wound edges.

Pascal Dohmen (DE) discussed the costs associated with Surgical Site Infection (SSI) in cardiothoracic surgery, explaining that the more complex the procedure, generally, the greater the risk of SSI. Cardiothoracic procedures SSI rates are between 3.2 and 25%, with an incidence of mediastinitis between 0.3 and 3%, and mortality, if MRSA is present, around 75% within three years. An SSI will prolong patients’ hospital stay by up to 10 days, with associated direct costs to the European healthcare system of €19.0 billion p.a.\textsuperscript{22}.

A review of the various strategies to minimise complications (endoscopic vein-graft harvesting, triclosan sutures, use of skin staples vs. sutures, use of microbial sealant) including the liberal use of NPWT at the first signs of disturbed wound healing, has been provided.

Of course of Prof. P. Dohmen

Healing of groin incisions post femoral artery surgery is challenging as they are inherently ‘unclean’, according to Stefan Acosta (SE). Complications include graft infection, SSI and amputation. Dr. Acosta presented the preliminary data from an RCT where iNPWT was compared to a standard dressing to prevent SSI. Early results show SSI rate of 4.7% (PICO\textsuperscript{TM}) and 11% (standard care), even if not statistically significant at this point.

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of operations</th>
<th>Incidence of SSI</th>
<th>No. of patients with a fever, elevated WBC and a change in WBC &gt;10%</th>
<th>No. of patients with a fever, elevated WBC and a change in WBC 10-20%</th>
<th>No. of patients with a fever, elevated WBC and a change in WBC 20-40%</th>
<th>No. of patients with a fever, elevated WBC and a change in WBC 40-60%</th>
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<tr>
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<td>516</td>
<td>21</td>
<td>3.6 (2.25.5)</td>
<td>516</td>
<td>209</td>
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<tr>
<td>France</td>
<td>2 236</td>
<td>43</td>
<td>2.3 (2.2-3.8)</td>
<td>2 236</td>
<td>22 616</td>
<td>31</td>
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<tr>
<td>Sweden</td>
<td>21 609</td>
<td>842</td>
<td>3.0 (2.9.2)</td>
<td>21 609</td>
<td>27 002</td>
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<tr>
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<td>376</td>
<td>35</td>
<td>4.1 (2.6.7)</td>
<td>376</td>
<td>7 987</td>
<td>6 807</td>
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<tr>
<td>Italy</td>
<td>1 553</td>
<td>68</td>
<td>6.1 (4.9.8)</td>
<td>1 553</td>
<td>17 585</td>
<td>15 987</td>
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<tr>
<td>U.K.</td>
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<td>1 170</td>
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Data source: CDC, HCUP-Net SSI patient-based data 2010-2013.
Carlos Velasco (ES) presented the preliminary results of a study testing the use of PICO™ to reduce the incidence of incisional complications after sternotomy compared to standard care (dry dressing). High risk patients (n=362) undergoing isolated or combined myocardial revascularisation surgery were included. Incisions were examined at day 7 and one month post surgery. Analysis so far shows a reduction in both the severity and number of infections (5.8% vs 10.8). Total treatment costs (including treatments, antibiotic therapy, hospitalization and surgery) were estimated to be €81k in the PICO group and €255k in the control group.

Martin Oberhoffer (DE) concluded the session by outlining the complications of vascular graft failure in CABG. There is an increasing trend towards use of artery grafts rather than veins as these survive longer but there is a cost: the use of arteries often taken from the chest, increases the chance of SSWI. Skeletisation of the artery may reduce the chances of SSI but other strategies are needed. He presented preliminary results from a study of the use of PICO in the reduction of SSWI in patients undergoing total arterial revascularisation (BIMA). In the first 100 patients (control), SWI rate was 11.9%; in the following 100 patients (PICO), SWI was 6.9%. Dr. Oberhoffer concluded that based on these results to date, prophylactic use of PICO for the reduction of SWI in high-risk CABG patients is promising and the cost−effectiveness calculations may justify the use of PICO, although the patient number is too low to detect a statistically significant effect.

Cardiothoracic Surgery workstream: key points

- SSI rates in cardiothoracic surgery are about 5-7% (10-15% in leg donor sites/groin incisions). Risk factors for SSI are well described; however there is no clarity on assessment parameters and also limited adoption of the many risk assessment tools described for cardiothoracic surgery.
- One speaker (R. Ingemansson) has suggested a pragmatic and practical classification of risk factors in major, intermediate and minor. It may be a subject of future discussion and validation from a Cardiothoracic Surgery Expert Panel.
- The role of SSI preventive strategies is huge in this specialty: the high risk of any surgical complication, should suggest the consideration of prophylactic incisional NPWT in high risk patients.
- SSIs cause direct (hospital stay, investigations, drugs, etc) and indirect costs which are generally patient related, such as loss of earnings and reimbursement; indirect costs are eight times higher than direct costs.
- A number of independent studies on PICO are ongoing in this indication and are showing very positive preliminary results, both in sternotomy and groin incisions. Gaps in knowledge relate to the still relative low number of studies proving the benefits of iNPWT in this indication. More level I evidence is required.
This stream was divided into two sessions: one focused on the management of the Open Abdomen (OA) where NPWT has an established role in the management of this serious condition, and one focused on the incisional complications of colorectal surgery, where evidence is accumulating about the prophylactic role of incisional NPWT to reduce the incidence of Surgical Site Complications.

**Open abdomen**

In this opening session, Stefano Rausei (IT) presented evidence based on 20 years experience in OA management, concluding that NPWT in OA management is superior to other techniques as it allows easy observation of the abdomen, partially prevents fascial and wound margin retraction, and prevents intra-abdominal hypertension. The existing guidelines on the use of NPWT in the OA were presented by Andreas Bruhin (CH) based on a recent paper. A common four-stage classification of the OA has been suggested, and Dr. Bruhin discussed the management of each one. He concluded that NPWT is key to providing an individualised approach and provides different benefits at different stages, such as wound and fluid management, down-staging of pro-inflammatory cytokines, facilitation of primary fascial closure, splinting skin grafts, and avoiding/managing entero-atmospheric fistulas.

The use of mesh-mediated fascial traction with NPWT in the OA was presented by Thordur Bjarnason (SE). In general, the management of OA should provide a cover to retain and protect bowel, room for expansion of abdominal volume, removal of toxins, debris, bacteria and excess fluid from the wound, the prevention of abdominal wall adhesion, and retraction of edges. As many patients require prolonged OA, a novel technique was explored - vacuum-assisted wound closure and mesh-mediated fascial traction (VAWCM). After treatment of 111 consecutive patients, the authors concluded that VAWCM provided a high fascial closure rate after long-term treatment of OA and should be considered when the anticipated duration of the OA is above one week. (Note that Smith & Nephew doesn't promote the use of RENASYS™ AB with mesh-mediated fascial traction as there have been no studies yet to demonstrate use in combination)

Salomone Di Saverio (IT) presented a paper which proposed a clinical algorithm for the management of the open abdomen and took the audience through an original technique for the management of concomitant enteroastrpheric fistulas. Incidence ranges from 2% - 50% depending on the underlying condition.

**Surgical Site Complications in colorectal surgery**

Day two began with an outline of the incidence of SSIs in colorectal surgery from Gregory Sergeant (BE). This is extremely high and varies between 15% and 30%; the average time to diagnosis is 7 days (in-patient) and 14 days (post discharge). Procedure, environment and patient preventative interventions were presented, including NPWT for contaminated wounds. Judith Tanner (UK) in a post-discharge survey, found that of 105 patients, 27% developed a SSI, costing £8,960 (in-patient) and £1,406 (in community). A larger study showed that variation in data collection leads to underestimation of SSI rates.

Although the mechanisms of NPWT action used prophylactically on closed incisions are not fully understood, there is a good consensus in the existing literature that they relate to protection, reduction of lateral tension, reduction of oedema, and improved perfusion, as presented by Elizabeth Huddleston (UK) in a survey of animal studies, in vitro and clinical investigations. The mechanisms through which NPWT could influence contaminated wounds following colorectal surgery were also addressed.

Pauline Whitehouse (UK) presented a pathway for high-risk laparotomy incisions which included the prophylactic use of PICO. Prior to the introduction of iNPWT, 7.69% of patients developed a Surgical Wound Infection (SWI) (estimated treatment cost £10k per patient); after PICO, incidence was 1.96% (p=0.049). The potential saving if PICO was used on all laparotomies is £45,760 (one hospital, performing about 102 laparotomies per year).

The preliminary results of a multi-centre RCT which explored the combined use of NPWT and antimicrobial (ACTICOAT® Antimicrobial barrier silver dressing, Smith & Nephew) in colorectal and high risk surgery patients compared to standard treatment were presented by Sebastian Smolarek (IE). The aim is a 50% reduction in SSI rate (CDC criteria). To date, 30% patients have developed an SSI across both groups (no statistical difference), and length of stay is the same in both, although very few patients have yet been recruited.

<table>
<thead>
<tr>
<th>Without PICO protocol</th>
<th>With PICO protocol</th>
<th>p value</th>
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<tbody>
<tr>
<td>Worthing Hospital</td>
<td>May – November 2013 (7 months)</td>
<td>May – November 2014 (7 months)</td>
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<tr>
<td>9/37 (2.4%)</td>
<td>2/102 (1.9%)</td>
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<tr>
<td>St Richard’s Hospital, Chichester</td>
<td>January – December 2013 (12 months)</td>
<td>January – September 2014 (9 months)</td>
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<tr>
<td>33/340 (13.75%)</td>
<td>16/191 (8.38%)</td>
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Comparison of SSI rate after laparotomy in two UK hospitals, before and after implementing the protocol including PICO (courtesy of Dr. Pauline Whitehouse)
Age is commonly cited as a risk-factor for colorectal SSI, which in elderly patients can affect mortality. Identifying those patients where prophylactic NPWT can be used may reduce SSI. Gianluca Pellino (IT) presented the results of a “NPWT in colorectal surgery” literature review (submitted for publication) which demonstrated that NPWT reduced the incidence of SSIs. Pellino et al’s 2013 study\textsuperscript{28} showed that using NPWT prophylactically significantly reduced the development of seroma and SSI, compared to conventional dressings. An extension to this study\textsuperscript{29} showed that PICO\textsuperscript{\textregistered} is safe and effective, and facilitates better closure and shorter hospital stay. Dr. Pellino closed with the results of his latest study, which assessed the efficacy of PICO in preventing SSC in patients undergoing breast or colorectal surgery, compared with conventional dressings\textsuperscript{30}. The secondary aim of this open label controlled study was to assess the efficacy and safety in elderly patients. Results showed that PICO significantly reduced SSC in both arms of the study and no significant differences were observed according to age. The authors conclude that PICO is an effective tool to prevent SSC in patients undergoing general surgery and that its use may be recommended in frail, elderly patients, with a higher risk of complications.

Recognized mechanisms of action of incisional NPWT

- Protects the incision from external contamination\textsuperscript{32}
- Holds closed incision edges together and helps reduce tensile forces across the incision\textsuperscript{35,36}
- Helps improve perfusion\textsuperscript{37}
- Helps reduce oedema\textsuperscript{37}
- Reduces seroma and haematomas fluid collections\textsuperscript{28}

General surgery workstream: key points

- Evidence-based guidelines specify the use of NPWT in the management of the OA and provide clarity on its appropriate use.
- The combined use of NPWT and mesh-mediated traction is increasingly being considered by clinicians when the expectation is to keep the abdomen open for more than 1 week, because it maintains health of the fascia and allows a more rapid closure.
- SSC are heavily underestimated in colorectal surgery, due to a need for a clearer definition and for a follow-up of the patient after discharge, because many complications are actually seen in Community.
- In colorectal surgery, peri-operative strategies, like patient warming, antibiotic prophylaxis, method of incision and oxygenation, are important to prevent the insurgence of SSC, as is the use of incisional NPWT.
- PICO in colorectal surgery, has been shown to reduce the development of seroma and SSC and to facilitate faster wound closure, thereby reducing hospital stay.

Knowledge gaps centre on the relative lack of level I evidence, even if a lot of studies are actually ongoing.
Orthopaedic Surgery workstream  
Chair: James Stannard and Sudheer Karlakki

This stream covered the topic of surgical site complications across trauma, arthroplasty and spinal surgery.

James Stannard (US) presented an overview of the incidence and impact of incisional complications in trauma surgery. The aim of surgery is to get the soft tissue envelope to heal, particularly where fractures are in areas with minimal coverage over the bone and limited blood flow. Prof. Stannard presented his pioneering work undertaken in 249 patients to determine the effect of NPWT vs. standard care in high risk fracture repair sites. He also discussed other studies that have used NPWT in obese patients (excellent outcome), seroma/haematoma management (not conclusive), open fracture with immediate closure, fracture blisters (good healing) and soft tissue coverage. He concluded that prophylactic NPWT can be a useful adjunct in trauma surgery.

The management of complications following orthopaedic trauma surgery was outlined by Hans Goost (DE). Firstly, identify complications (e.g. SSI, dehiscence, implant infection) and patient/environmental risk factors. Within Dr. Goost’s organisation, iNPWT is used on clean trauma incisions and for temporary wound closure and debulking. He presented six case studies where iNPWT had been used and concluded that post-operative tissue management can be improved by NPWT and PICO, and that NPWT is essential in trauma care.

Mazen Ali (FR) after introducing the utility of NPWT in large traumatic wounds with a series of interesting clinical cases shared his clinical experience in using PICO for the management of high-risk incisions, such as tibial plafond fracture, ankle fracture, pilon-tibial fracture, mid-foot fractures and dislocation, calcaneus fractures. Dr. Ali also shared the results of a case series, where 37 patients with high energy trauma wounds were treated with PICO applied immediately after surgery and left in situ for five days. No complications were observed until day 30 after surgery, and the average length of treatment was 16 days.

While rarely seen in domestic theatres, war-zone trauma has facilitated the use of NPWT for the management of complex and traumatic wounds; in this session, Steven Jeffrey (UK) presented his experiences. Evacuation from the theatre of war to the operating theatre is much faster today, so patients survive extremely traumatic wounds. Management principles remain the same: debride, dress, and close at a later date (repeated debridement/dressings may be necessary before closure). Seemingly impossible trauma wounds have been healed with the use of NPWT. RENASYS is the system of choice in the British military in war-zone hospitals.

Sudheer Karlakki (UK) discussed the complications of total joint arthroplasty, a procedure which although ‘routine’, is challenging post-operatively; complications include SSI, wound dehiscence, and prosthesis infection. Pressure from patients to go home quickly (and safely) and from organisations to reduce costs requires risk assessment and prevention. Evidence is available for the use of NPWT prophylactically in orthopaedic surgical wounds. iNPWT can minimise wound complications, facilitate a more predictable wound healing and therefore reduce length of stay (LOS).

The enhanced recovery after surgery (ERAS) approach to total joint arthroplasty (TJA) was discussed by Amerigo Balatri (IT). ERAS, driven by patient and cost reduction factors, aims to achieve discharge (within three days) by optimising peri-operative care. In relation to the prevention of SSI, interventions include addressing factors which may affect healing, through speedy surgery, less tourniquet time, use of barbed sutures, and use of advanced wound care dressings and/or, where wound drainage is high, NPWT.

Sudheer Karlakki (UK) presented the preliminary results of a randomized controlled trial evaluating the use of PICO in primary arthroplasty patients. After analysing the results, the authors concluded that iNPWT reduces the amount of wound exudate (statistically significant), may decrease length of stay (not statistically significant), reduces the number of dressing changes required (statistically significant), and minimises wound complications (statistically significant). Following on from this, Antonio Mazzotti (IT) presented preliminary results of a prospective randomised trial of PICO in total hip and total knee revision arthroplasty, which carries a higher risk of complications compared to the primary procedure. Results so far show a dry wound at day seven, with lower ASEPSIS and VAS pain scores compared to control, which also had a higher number of dressing changes and blister prevalence. The authors conclude that PICO is comfortable and well tolerated by the patients, and that rapid wound healing can facilitate earlier risk-free discharge.

Amerigo Balatri (IT) postulated that in order to ensure healing, the surgeon needs to balance the risk of bleeding against the risk of thrombo-embolism. A regimen of high dose anticoagulant is a risk factor for wound healing complications: guidelines for DVT prevention in primary joint arthroplasty allow low dose regimens for anticoagulants or pneumatic devices where an early mobilisation protocol is enforced. Finally, patients that require high dose prophylaxis for cardiac or increased DVT risk must be considered as patients at high risk of wound healing complications.
Matthias Brem (DE) closed the session with the results of a prospective, randomised study of NPWT on spinal surgery incision management (in press, International Wound Journal, June 2015). Twenty patients with spinal fracture, scheduled for an open surgical procedure, were randomised to receive either PICO™ or standard care. The wound was examined for seroma on the 5th and 10th day post surgery using ultrasound. Results showed less wound drainage in the study group after two days, and fewer dressing changes in the study group, making it more time-efficient and cost-effective. The study group were seroma-free at day five, thereby reducing SSI risk.

**Orthopedic Surgery workstream: key points**

- Wounds at risk of SSC can be determined by a careful analysis of individual patient risk factors. Surgeons should identify immediately the warning signs of potential surgical site complications (obesity, hypertension, heavy smoking, etc...).
- Early prospective randomised trials of iNPWT (particularly after arthroplasty procedures) are positive; less drainage, less seroma formation, and therefore predictable, safe and early discharge, and reduced risk of SSC.
- There seem to be indications that the application of iNPWT to the wider peri-wound area is beneficial. This can be achieved with the range of different sizes and shapes that PICO is available in.
- Thanks to its portability and canister-free design, the application of PICO is comfortable for the patient.
- Gaps in knowledge centre on knowing in which patients or procedures incisional NPWT is appropriate, in particular prophylactically, as one has to consider the financial implications of a wider use of the therapy, even if the availability of single-use devices like PICO are making the preventative use of NPWT more affordable.

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*Application of PICO in patients undergoing surgery for spinal fracture: note the size of the underlying defect and the application of PICO in the peri-wound area, in order to cover the whole defect (courtesy of Dr. M. Brem)*

Smith & Nephew recommends the PICO port should be positioned uppermost from the wound.
Discussion and Conclusion

There is an increasing number of authors, in various surgical disciplines, that are highlighting the fact that Surgical Site Complications or SSC (of which the most commonly defined is usually the Surgical Site Infection, or SSI) are highly underestimated. A recent commentary in Orthopedics Today Europe (March 2015) from Per Kjaersgaard-Andersen, Chief Medical Editor, highlights how the problem of postoperative surgical site infections still needs to be solved and how the problem itself is probably underestimated in the orthopaedic surgery area. In this meeting, Prof. Judith Tanner has clearly demonstrated how her post-colorectal surgery surveillance program has been able to identify a percentage of SSI much higher than what is reported in the literature (27% incidence, vs. an average of 19.4%), with most of these infections actually manifesting after discharge, in the Community. From her study, as also from comments of other experts, there is also a lack of consistency in what is reported as SSI, due to different interpretation of existing definitions. It was agreed that SSI tools need to be standardised in order to direct care more accurately, and allow like-for-like comparisons to be made of infection rates.

SSC are a massive economic burden: just considering infections, each SSI will prolong the patient hospital stay of up to 10 days and will generate additional costs, for treatment, re-hospitalization, etc., to the European Health services for up to 19 billion of Euro per year. Considering the increasing pressure on maintaining the sustainability of healthcare, already strained by the ageing of the population and the increased demand for better care, it seems clear that SSC prevention strategies need to be implemented. In US there is already a high level of attention, mainly driven by the National Surgical Quality Improvement Program (NSQIP) implemented by the American College of Surgeons, and which has a specific indicator in the number of hospital readmissions caused by avoidable post-surgical complications.

Prevention of SSC demands stakeholders look at the various stages of surgery, and to how each step is performed: there is no easy solution which is going to work for every source of potential breakdown or contamination. Each workstream of this conference has looked in detail to the major sources of complications, and to the specific tactics which can be put in place to prevent them, from frequent glove changes to gentamicin-impregnated collagen sponges, from careful surgical planning to specific post-operative product bundles including NPWT devices like PICO®. It’s unsustainable to propose SSC prevention at 360°. We can’t expect that every surgical patient will receive the same intensity of postoperative care, regardless of the risk, therefore the identification of high-risk patients, through some sort of risk assessment tool has the highest priority. There is no lack of risk tools, which have been discussed, in the Cardiothoracic Surgery workstream by Prof. Johan Nilsson, but there is still a need for a simple and reliable system which could be adopted by a wider base of surgeons, possibly across specialties. A possible solution is to focus specifically on the surgical wound, trying to define a “risk score”, which could describe the level of risk that a specific wound has of breaking down, due to existing comorbidities or confounding factors.

The definition of this “surgical wound risk score” would be a great step forward in the implementation of a rational approach to prevent surgical site complications, because it would allow the definition of a “risk threshold”, above which it would be recommended to use advanced devices for the prevention of SSC.

Incisional NPWT, with devices like PICO, is becoming a more accepted strategy to prevent SSC in high-risk patients. There is a growing base of evidence, ranging from breast surgery, where PICO has been shown to reduce the incidence of dehiscence of 36% and to provide a better cosmetic result, compared to the standard care, to orthopaedic surgery, with studies both in primary and revision total joint arthroplasty and in spinal surgery, which have demonstrated a significant reduction of wound complications, wound exudate and seroma formation. A significant base of data has been collected in colorectal surgery, with the studies on Crohn’s disease and in cardiovascular surgery, with the studies on sternotomy and groin incisions.

The 6th International Negative Pressure Wound Therapy (NPWT) Expert Meeting has clearly demonstrated, that while further high-level studies are required to add to the body of knowledge using incisional (iNPWT) prophylactically in different surgical specialties, there is now a consistent series of data which support the fact that a peri-operative approach in high-risk patients done with an iNPWT device like PICO, can prevent SSC and facilitate faster discharge, thus reducing costs and improving patient outcomes.

Closing Plenary session. From left to right: Michael Sugrue (IE), Richard Ingemansson (SE), Rene van der Hulst (NL), Maurizio Nava (IT), Sudheer Karlakki (UK), James Stannard (US)
References


3. Birke-Sorenson H, Malmigjo M, Rome P, Hudson D, et al. Evidence-based recommendations for negative pressure wound therapy: Treatment variables (pressure levels, wound filler and contact layer)! Steps towards an international consensus. JPRAS 64, s1-s16.


