Role of Biofilm-Disrupting Technology in Management of Surgical Infection Risk: A Case Study of Bactisure Wound Lavage Solution

Next Science Limited
Study Completed October 2020

Introduction

Deep tissue and surgical site infections (SSIs) often lead to serious complications, such as failure of wound healing, additional procedures and hospitalisations, and even death. Bacterial resistance and other bacterial defence mechanisms, such as biofilm production, combine to limit the effectiveness of chemical and mechanical interventions. Bactisure™ Wound Lavage (BWL) solution is a biofilm-disrupting technology that removes planktonic and biofilm bacteria from wounds. BWL consists of a mix of surfactants, chelating agents, salts, and 10% alcohol that deconstruct biofilm, exposing bacteria to antibiotics, host immune defences, and physical removal. In clinical studies, BWL reduced bioburden and bacterial count by >99% and 99.98%, respectively, in patients with prosthetic joint or surgical site infections. Herein, we present a case study from Dr Altay Altuntas (St. Vincent's Private Hospital; Melbourne, Australia) whereby operative use of BWL along with application of SurgX™ Sterile Wound Gel (Next Science Ltd, Jacksonville, FL) helped prevent infection and allowed tibial union after the patient had experienced a series of complications over the past year.

Methods

The case of a 52-year-old man who experienced multiple traumatic leg injury is summarised (timeline).

- **Traumatic injury** (Type IIIA open tibial fracture) was sustained by patient during a motorcycle accident (see Figure 1A)
- **1st internal fixation surgery (July 2019)**—Intramedullary tibial nail with proximal and distal cross screw fixation augmented with plate fixation
    - 3 months post surgery, patient experienced tibial non-union with progressive pain (see timeline and Figure 1B)
- **2nd internal fixation surgery (October 2019)**—Removed proximal and distal cross screw fixation and also removed the additional plate and screw fixation.

Timeline

July 2019

Multitrauma motorcycle accident

Intramedullary tibial nail with proximal and distal cross screw fixation

Tibial non-union (Oct)

October 2019

Removed proximal and distal cross screw fixation and additional plate and screw fixation; performed autologous tibial bone graft at tibial fracture

Postoperative infection *(pseudomonas)*

Tibial non-union

May 2020

Referred to Dr Altay Altuntas

Tibial nail was removed, the intramedullary canal was reamed, debrided and lavaged with BWL. Exchanged tibial nail with proximal and distal screw fixation; performed autologous bone graft from iliac crest; applied wound care with SurgX as clinically indicated

August 2020

Patient has resumed running and is training to run a marathon in November

October 2020

Tibial union achieved

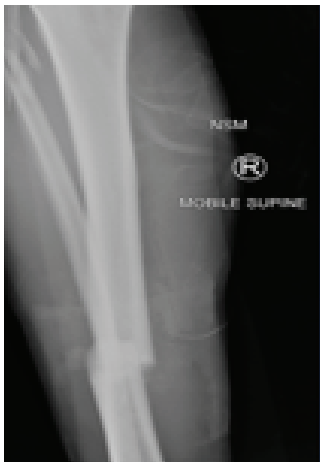

Figure 1A

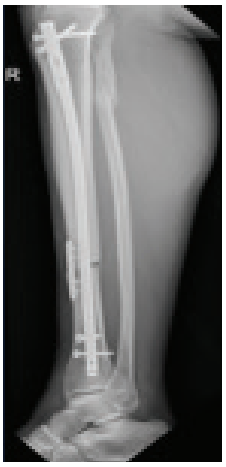

Figure 1B

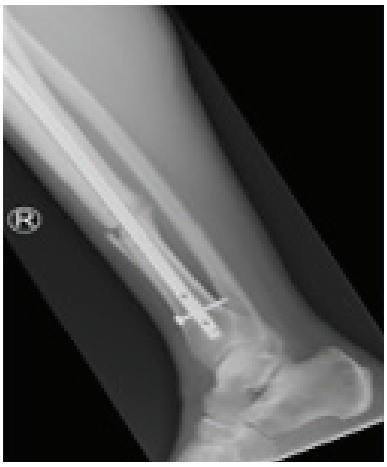

Figure 1C

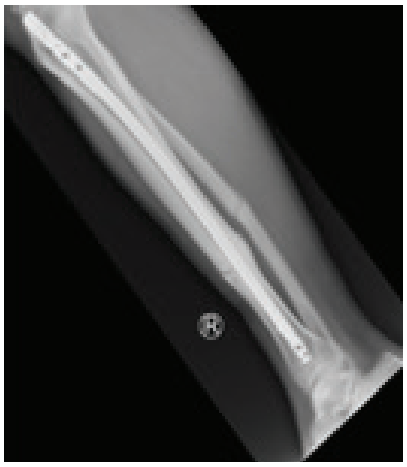

Figure 1D

Radiographs depicting primary tibial injury (Figure 1A), later tibial non-union 3 months post surgery (Figure 1B), non-union after removal of cross screw and bone graft (Figure 1C), and eventual tibial union (Figure 1D)

Autologous proximal tibial bone graft was used at tibial fracture site

- Attempt to fill the gap, which remained between the bones
- Patient developed a temperature 6 days post-discharge (*pseudomonas*) and IV antibiotics were started in the hospital
- Infection, antibiotics, or a combination of the infection + antibiotics delayed wound healing and the wound reopened at 3 months
- Combination of above factors impaired the union of the bone
- Postoperative infection; wound dehiscence, due to the infection
- Tibial non-union (see Figure 1C)

"I was in and out of the hospital receiving some heavy-duty intravenous antibiotics. I was terrified of the infections because many people in similar situations had amputations. I wanted to get out of hospital and home to my children and dog. They are the highlight of my life."

- **Patient was motivated to find a solution**
  - During his research, found Next Science and BWL contacted Next Science
  - Referred to Dr Altay Altuntas in May 2020
  - Surgeon and patient discussed the use of BWL and SurgX, and Dr Altuntas agreed to use the products

"I was terrified I would lose my life or leg to infection and was determined to impact my outcome. I did my own research and discovered Next Science and Bactisure. I was introduced to Dr Altuntas who agreed to use it in the next procedure.

- Product was not approved in Australia, so patient
- **3rd surgery (May 2020)**—The tibial nail was removed; the intramedullary canal was reamed, debrided, and lavaged with BWL. An exchange tibial nail with proximal and distal screw fixation was inserted. Autologous iliac crest bone graft was applied to the non-union site via a separate incision to minimise pre-tibial wound dehiscence and infection that were encountered after the index procedure
  - BWL was applied by pulsed lavage into the intramedullary canal with a canal brush nozzle, and the wound was irrigated with saline after Bactisure immediately prior to application of bone graft and on closure
  - No operative/postoperative infection occurred, and complete tibial union was verified 7 months post-surgery (see Figure 1D)
  - SurgX was applied as clinically indicated and covered with a dressing after the wound was sutured (see Figures 2A – 2C)
  - SurgX was applied at each dressing change

Discussion

Surgical site infections (SSIs) are the most common

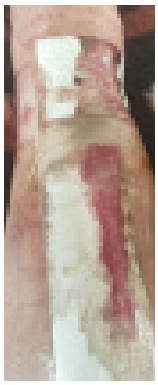

Figure 2A

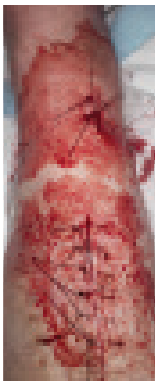

Figure 2B

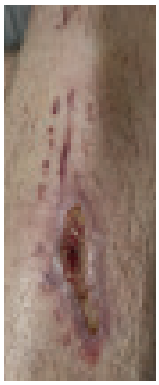

Figure 2C

Wound closure time lapse after 3rd surgery following application of SurgX: Day of surgery (Figure 2A), day 1 post-surgery (Figure 2B), and 1-month post-surgery (Figure 2C)

"After my first surgery, the wound was oozing and bleeding for 2 months, and after my second surgery, the wound reopened for approximately 3 months. When Dr Altuntas used SurgX after my third surgery, the wound completely healed in less than a month."

complication associated with surgical procedures requiring an incision. In Australia, SSIs occur in approximately 3% of those cases.[1] The infection is caused by the colonisation of bacteria at the site of the surgical incision. Approximately 90% of bacteria naturally exist within biofilm, which are implanted in an extracellular polymeric substance (EPS) matrix that protects from mechanical and chemical interventions.[2] Biofilm-producing bacteria also proliferate slowly, rendering antibiotics that target replication machinery less effective.[3] In aggregate, biofilms are more tolerant to antimicrobial agents, disinfectants, and host immune defences. Bacteria in biofilms can be up to 1000-fold more resistant to antimicrobial agents than planktonic bacteria.[3]

There is a growing appreciation for the need to prevent and control biofilms in the medical setting. *Pseudomonas* plays a role in biofilm formation, and the patient, in this case, experienced a post-operative infection (*pseudomonas*) that affected wound healing and tibial fracture union.[4]

Bactisure™ Wound Lavage (BWL) solution (Next Science Ltd, Jacksonville, FL; distributed by Zimmer Biomet) is a biofilm-disrupting technology that removes planktonic and biofilm bacteria from the articular joint space via pulsed (jet) lavage. BWL consists of a mix of surfactants, chelating agents, salts, and 10% alcohol. BWL deconstructs biofilm (breaks EPS crosslinks), exposing bacteria to antibiotics, host immune defences, and physical removal.[2] When used as labeled, BWL does not harm human tissue. When used as adjunct wound lavage, BWL enhances wound irrigation and debridement processes to promote effective removal of common bacteria and to create an environment for normal healing.

In a clinical study of 40 patients with prosthetic joint or SSIs undergoing primary or Stage 1 revision total knee arthroplasty, Bactisure reduced the bioburden and bacterial count within the surgical site after surgical lavage. There was a 2.3 log reduction (>99%) in white blood cells and a 3.8 log reduction (99.98%) in bioburden in patients with countable bacteria. The 90-day infection rate was 12.9%.[2]

SurgX™ Sterile Wound Gel (Next Science Ltd, Jacksonville, FL) was also used in this patient at the point of incision. SurgX Sterile Wound Gel deconstructs the EPS matrix, destroys bacteria within the gel, and prevents recolonisation while maintaining a moist wound environment. In a randomised controlled clinical study, SurgX applied directly to the wound bed on a Monday–Wednesday–Friday interval reduced wound volume by 80% compared with 53% with standard of care.[5] Use of SurgX plus standard of care reduced wound volume by 93%. The use of BWL and SurgX may offer novel benefits for prevention and/or treatment of deep tissue and SSIs.

References

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2. Hunter C, Duncan S. Clinical effectiveness of a biofilm disrupting surgical lavage in reducing bacterial contamination in total knee arthroplasty revision surgery in known cases of prosthetic joint infection. 2019:1-10.
3. Malone M, Bjarnsholt T, McBain AJ, et al. The prevalence of biofilms in chronic wounds: a systematic review and meta-analysis of published data. *J Wound Care.* 2017;26(1):20-25.
4. Petrova OE, Sauer K. Sticky situations: key components that control bacterial surface attachment. *J Bacteriol.* 2012;194(10):2413-2425.
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About Bactisure

Instructions for Use

Bactisure is available in a sterile 1000-mL polypropylene plastic bag with an integrated single spike port and is indicated for use on all wound types

- Apply Bactisure just prior to wound closure using Zimmer Biomet Pulsavac® Plus or similar pulsed lavage system
- Immediately rinse with an equal amount of normal saline using pulsed lavage
- Not intended for repeated use
- Not indicated for use during dressing changes or for use by soaking the product into dressings
- Do not use if there is a history of allergy to any of the ingredients

Tips for Success With Bactisure

- Be aware that Bactisure changes colour when it mixes with iron from red blood cells (Bactisure does not harm human tissue when used as labeled)
- Be prepared to pulse (jet) lavage before closing the wound: have the proper lavage systems, irrigation solutions, and trained personnel in place
- Plan for the time required for each stage of the application

About SurgX™

Indications

SurgX is indicated for the management of post-surgical wounds, stage I-IV pressure ulcers, partial and full-thickness wounds, diabetic foot and leg ulcers, first and second-degree burns, and grafted and donor sites.

Contraindications

SurgX™ should not be used if there is a history of allergy to any of the ingredients.

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