

Research Article

Preventogen: Shifting The Clinical Paradigm of Pin Site Care and Transosseous Wire Infections Associated with External Fixation in Limb Trauma & Reconstruction

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Abstract

External fixation is a versatile and indicated procedure for open/closed fractures, soft tissue and bone defects, significant infection including osteomyelitis, and limb deformity correction. Pin site infections associated with external fixation are a challenging problem caused by bacterial adhesion with biofilm formation. The current paradigm in treatment has been focused on patient selection, pin materials, operative technique, and oral antibiotic regimen and has been known to provide limited success often requiring complete removal of the pin. This larger case series and review aims to offer a paradigm

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shift and recommendation for future strategies for reducing pin site infections with utilization of external fixation, regardless of the type of pathology present.

Keywords: Limb deformity correction; Osteomyelitis; Minimally invasive surgery; Open surgery

Introduction

Utilization of external fixation in orthopedic and ortho-plastic surgery is often the treatment of choice in the face of elective and non-elective complicated and challenging pathology. External fixation versatility and ability to be used in multiple different pathologic situations stems from its ability to create both static and dynamic stability both at and away from the pathology site, while at the same time, offering acute and/or gradual correction of the deformity. The rapid construction of an external frame secured through the bone with pins or half pins away from the zone of injury allows minimal soft tissue dissection/damage and can be combined with definitive internal fixation acutely or at a later date when elective or semi-elective procedures are indicated [1]. External fixation has a wide array of uses including trauma and severe injury, infection cases often combining osseous procedures with large soft tissue defects requiring flap utilization, as well as bone shortening/lengthening and deformity correction procedures.

Often, in both acute traumatic cases or semi-elective or elective procedures, these external fixators remain in place for many weeks or months to allow for a delay period, followed by acute or gradual correction, followed by complete consolidation or healing of the osseous or soft tissue deformity. One of the biggest concerns and potential complications for the surgeon utilizing external fixation is pin site infections caused by increasing mechanical deterioration of the pin to bone or pin to skin interface [1,2]. Operative technique, host selection, pin site loosening, pin material/coating, diagnosis of pin site infection and extensive list of pathologies amenable to treatment with external fixation, are all factors associated with the wide range of pin site infection rates reported in the literature ranging from as low as 3% to as high as 80% [3-4]. Even the most commonly used pin site infection classification by Checketts and Otterburn lacks consensus among the surgical community leaving interpretation of the data variable [7,8].

External fixator pin site infections are caused by the formation of bacterial adhesion around the pin in combination with creation of biofilm at the pin-soft tissue and pin-bone interface. This biofilm is formed by a collection of bacteria that attaches itself to a foreign material and is surrounded by an extracellular matrix. Bacterial cellular proliferation forms clusters in the extracellular matrix releasing a protective exopolysaccharide layer giving protection against host defense systems by decreasing the release of host chemotactic signals preventing migration of polymorphonuclear cells into the biofilm there by reducing degradation [9-13].

Many different techniques have been discussed in the literature to attempt to lower pin site infections. Low energy application of the pins minimizing thermal necrosis and damage to the soft tissues remains paramount to decrease pin site complications. Optimal regimen and

time course are yet to be determined for prophylactic antibiotics which are often utilized with pin site infections [14]. Post operative pin site care has also been extensively studied, however, currently, there remains no clear consensus or guideline regarding best practice in pin care to reduce the incidence of pin site infections. The optimal method to prevent and treat pin site and half pin tract infections remains controversial [15]. There is no strong evidence to support a specific choice of dressing type, cleansing material or frequency of cleansing regimen [14]. Furthermore, there is no universally accepted definition of pin site infection making it difficult to quantify the current data [15].

In this case series of 58 patients, we offer a step-wise, repeatable, effective approach as a part of pin site care postoperatively after external fixation application utilizing preventogen, a biologic polymer aimed at significantly lowering the risk of pin site infections regardless of the type of pathology present.

Preventogen: The Product

Preventogen is an FDA cleared Class I medical device. This organic polymer, when applied to the disrupted skin in liquid form, eradicates all organisms on contact, regardless of antibiotic sensitivity. It then quickly transforms into an elastomeric, transparent, biodegradable and occlusive dressing. Preventogen actively kills Fungi, bacteria and virus on contact by lysing the cell membrane leading to quick death. A list of the bacteria, fungi and is seen in Table 1 and Figure 1 below.

BACTERIA	FUNGI	VIRUS
Escherichia Coli	Aspergillus Niger (superbug)	Herpes Simplex (cold sore)
Pseudomonas Aeruginosa	T. Rubrum	Herpes Zoster (shingles)
Staphylococcus Aureus	Candida Albicans	
MRSA (superbug)	D Aspergillus Brasiliensis	
VRE (superbug)	Candida auris (superbug)	
Acinetobacter Baumanni(-superbug)		
Bacillus Subtilis		
Clostridium Sporogenes		
Streptococcus Pyogenes		

Table 1: List of Bacteria, Fungi, Viruses Susceptible to Preventogen Polymer.

Surgical Guidelines and Application Protocol

Application protocol is critical and should be performed by the orthopedic or orthoplastic surgeon. The product (Figure 2) is Ideal for infection prevention from “outside-in,” not starting with an infected case. Preventogen must be applied to a clean, dry surface. It is important to let the patient know it may sting upon application. Preventogen creates a barrier, not a seal like surgical glue and is a biodegradable, organic polymer and will break down naturally if exudate forms below the preventogen-skin interface. Preventogen does not replace the absolute necessity for stable wire insertion and fixation. secure application of the external fixator following sound biomechanical Ilizarov principles including placement of pins in the diaphysis of long bones and at an ideal 60 degree angle from one another in a manner that minimizes thermal necrosis with simultaneous tensioning [16].

Our guidelines for pin site management were based on the algorithm devised by Checketts and Otterburn [7] with a primary focus on the addition of utilizing Preventogen polymer postoperatively (Table 2).

Grade 1	Pin Tract Irritation	If wire is loose, re-tension Soft tissue involvement receives local treatment and/or soft tissue release
Grade 2	Pin tract irritation with drainage	Grade 1 interventions Oral antibiotics
Grade 3	Erythema >2 cm radius from pin w/ drainage and low grade constitutional symptoms	Grade 1 interventions IV antibiotics
Grade 4	Erythema >2 cm radius, w/ drainage and radiographic evidence of localized osteolysis	Pin removal
Grade 5	Radiographic osteolysis with soft tissue infection	Pin removal with surgical debridement
Grade 6	Suspected osteomyelitis	Radiologic and imaging confirmation with possible bone resection

Table 2: Checketts et al. 2000, pin site infection classification.

Following deformity correction with provisional external fixation surgery.

Step 1: Apply Preventogen polymer to a clean dry transosseous wire or half pin-skin interface extending one inch around the pin site approximately one week post operative (not at the time of surgery to allow decreased swelling and drainage).

Step 2: continue to apply once per week until external fixation device is scheduled for removal as part of a comprehensive pin care protocol.

*generally requires 1 tube per leg per external fixator per week.

Results

Data of 58 patients who underwent external fixation surgery to manage a wide range of different pathologies (Table 3), amputation, arthrodesis, arthrodiastasis, fasciocutaneous flap, muscular flap, angular deformity correction, osseous distraction, bone stabilization, pelvic support osteotomy, non vascularized fibular graft, free fibula vascularized graft, tumor resection, bone transport) including open long bone fractures, bone deficits, soft tissue and bone infections, was collected from 3 different hospitals and reviewed retrospectively. All patients underwent surgical debridement, soft tissue reconstruction, bone reconstruction techniques and external fixation. as shown in (Table 4) & (Figure 3).

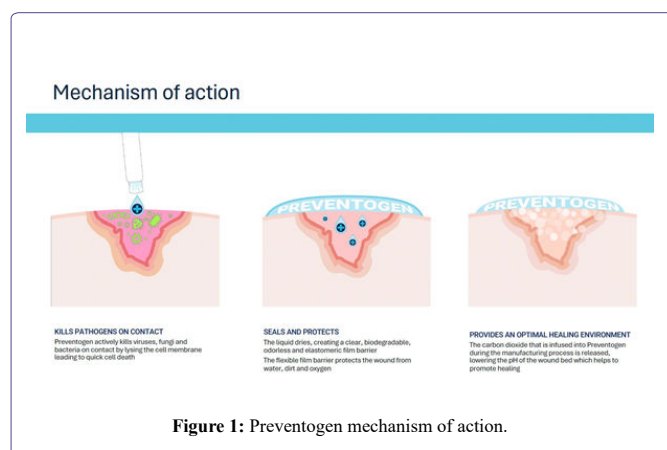


Figure 1: Preventogen mechanism of action.

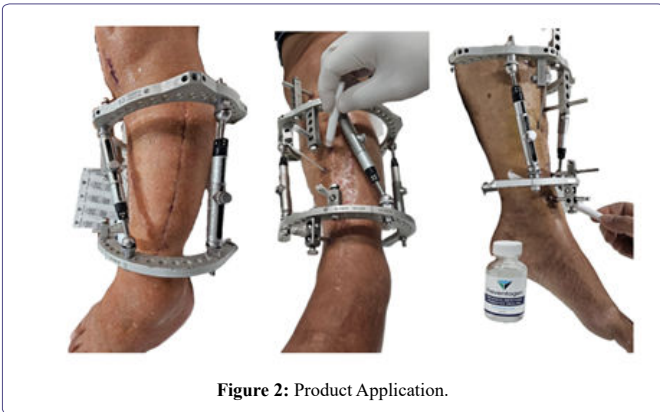


Figure 2: Product Application.



Figure 3: Product application.

Preventogen application was applied approximately 1 week from initial surgery and then on a weekly basis postoperatively as part of a comprehensive external fixator pin care protocol until the frame was removed, primary physician or trained orthopedic residents were in charge of applying Preventogen.

A total of patients N=29 different procedures in a variety of patients with different host type were performed by 3 different senior surgeons, (Table 5). All patients were treated with an external fixator, N=43 with a circular frame and N=15 with a uniplanar frame, a total of 329 pin wires and 139 schanz pins were used. A total of N=2 patients had pin tract infections, one patient with one pin insertion site and another patient with two pin insertion sites. Loosening of the pins was noted as a complication in two uniplanar frames, both of which

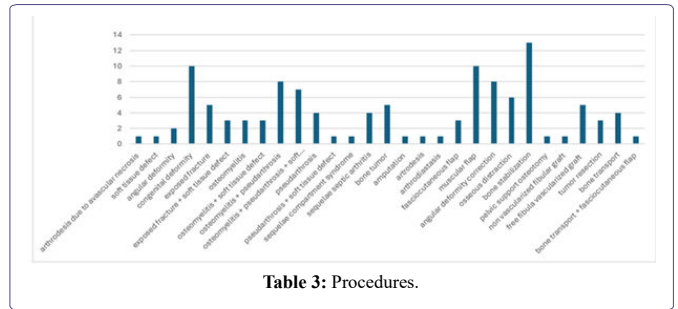


Table 3: Procedures.

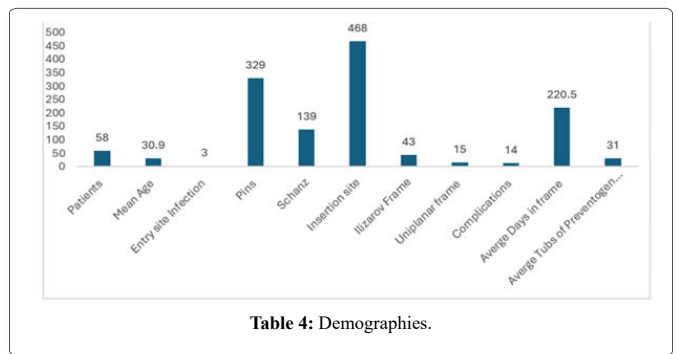


Table 4: Demographics.

required reapplication, but only one patient lost alignment. The overall pin site infection rate was 0.9 in 468 insertion sites, 14 patients presented with other complications apart from pin site infection as listed in (Table 6).

The goal of the research was to improve the overall protocol of postoperative pin site care leading to infection prevention in external fixation devices. The preventogen polymer, when utilized as part of the pin-care protocol, prevented infection at the source of the pin site-skin interface which is a notable shift in clinical practice paradigms.

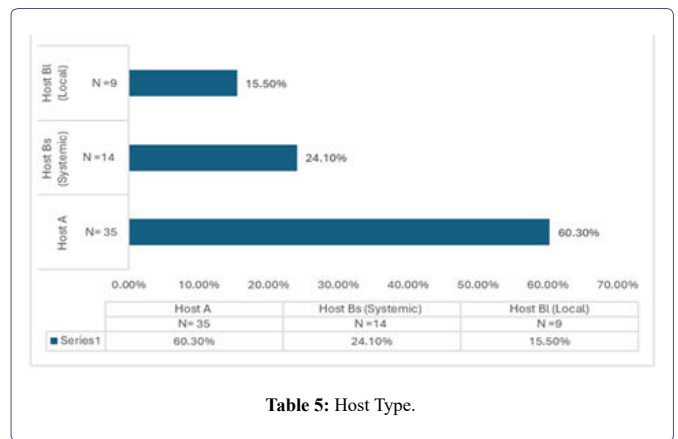


Table 5: Host Type.

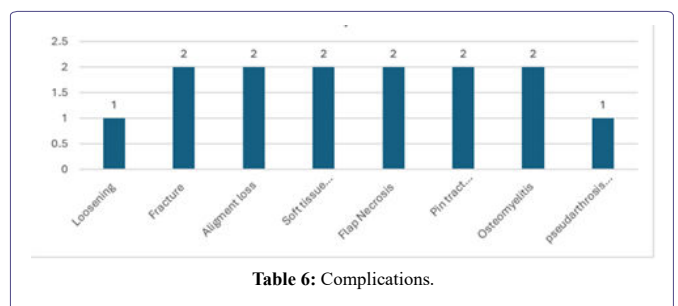


Table 6: Complications.

External fixation is routinely utilized in multiple different types of pathology including long bone and open fractures, soft tissue defects, and bone infections such as osteomyelitis, bone lengthening/shortening procedures and deformity correction. It has several benefits allowing orthoplastic surgeons the ability to address soft tissue and osseous defects simultaneously creating stability both at the pathology site and away from an infected area [17]. Despite its widespread use and benefits, there continue to be long-standing challenges and complications associated with external fixation.

Fracture-Related Infection (FRI), and Surgical Site Infections (SSIs) are serious and challenging complications in musculoskeletal trauma. Current studies have shown FRI rates to be as high as 27% with open fractures [18,19]. Musculoskeletal injury poses a significant global health challenge, particularly in low-and middle-income countries (LMICS), resulting in nearly 90% of trauma-related deaths worldwide [20]. Open tibial fractures are one of the most frequently reported traumatic injuries, and are associated with high rates of infection, nonunion and malunion. Furthermore, road traffic accidents have contributed to the rise in the incidence of open Tibia fractures, which has led to over 50,000 open fractures per year in some Latin American Countries. Complication rates in this very challenging pathology group have been documented reaching as high as 20% [20].

External fixation is often indicated and utilized in open and closed fractures, bone and soft tissue defects, and severe infection, and these very challenging pathologies occur in multiple different patient populations. It has been documented that older patients with multiple comorbidities, prolonged treatment duration and those undergoing active correction with ex fix are at increased risk of complications [21] These patient populations often require high acuity acute care and long-standing hospitalization driving up the cost of healthcare. FRI cases generate as much as 6.5 times higher healthcare costs than non-infected cases, due to increased hospital stay. recurrence rates have been documented to be as high as 9% and reported successful treatment rates at 70%. Often, these cases require multiple surgeries and despite the surgeons' best efforts, amputation rates of 3% have also been documented in the literature [22]. Furthermore, Studies have estimated the average cost of a SSI to be more than \$25,000, increasing to more than \$90,000 if the SSI involves a prosthetic implant [23]. A growing concern globally is the potential associated rise in healthcare cost associated with SSIs and FRIs as surgical procedures for patient populations with increasingly more complex comorbidities combined with challenging pathology continue to increase.

The most common reported complication associated with external fixation is pin site infection [1,4]. This complication can result in delayed healing, permanent functional loss and even limb loss/ amputation leaving a long-lasting and be life altering impact on a patient's quality of life. Previous studies have shown Preventogen's effectiveness in dramatically reducing the rate of pin site infections related to external fixation [24,25]. Since reimbursement/cost is a limiting factor for both external and internal fixation, and external fixation is uniquely identified as a versatile and indicated procedure with these highly challenging patient populations, there is a goal to make a positive impact on the external fixation market through the reduction of the incidence of pin site infection associated with its use.

In our study of N=58 patients, we found that with the use of preventogen, there were no readmission rates, no major complications and the authors did not have to change treatment plan or remove wires or the external fixators earlier than planned throughout the course of treatment, despite the need for longer times in the external fixator due to the challenging pathology encountered. Furthermore, there was no radiographic or clinical evidence of osteomyelitis or infections of the pin sites of the external fixators.

Limitations of the study include a no incidence of type C [26] patients which have chronic metabolic diseases such as Diabetes in the patient population which may not be a good representation of the overall patient population that often undergoes utilization of external fixation particularly in other countries. The findings of this study noting very low incidence of pin site infections in both a large cohort of host Type A and a lesser cohort of host Type B patients is encouraging. It currently remains unclear as to whether or not diabetes and other chronic metabolic diseases will affect the success of Preventogen or other biologic polymers as part of the protocol for post operative external fixation pin site management or increase the likelihood for post operative pin site infections. Further research is needed to investigate the effect of chronic metabolic diseases as they relate to pin site management in a multitude of different types of pathology that lend to external fixation utilization.

Conclusion

Pin site infections associated with external fixation continue to be a challenging problem. Currently there are limited treatment options available and when these fail the results can be disastrous for the patient, often leading to increased risk for readmission and raising the cost of care. As per the latest literature, it is evident that modulating the pin-bone or pin-skin interface holds promise as a potential solution for reducing pin tract infections. Transitioning to utilizing a novel biodegradable and microbicidal polymer specifically at the pin-skin interface is a shift in the clinical paradigm.

Preventogen does not replace the absolute necessity for stable wire insertion and fixation. secure application of the external fixator following sound biomechanical Ilizarov principles including placement of pins in the diaphysis of long bones and at an ideal 60 degree angle from one another in a manner that minimizes thermal necrosis with simultaneous tensioning Preventogen is applied early, within the first week of pin application where there is the highest risk for bacterial adhesion and formation of biofilm due to weakened host defense mechanisms. The product is easy to use and provides a repeatable result with a multitude of different skill sets for those applying it. It is tolerated well by patients. Preventogen has demonstrated its effectiveness as a bioorganic polymer occlusive dressing, that when utilized as part of the pin site care protocol with external fixation, can reduce the incidence of pin site infections.

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