Microcurrent Dressing to Treat Infections, Before, During and After Surgery

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Evaluation of a Microcurrent Dressing for Prophylaxis Against Perioperative Prosthetic Joint Infection

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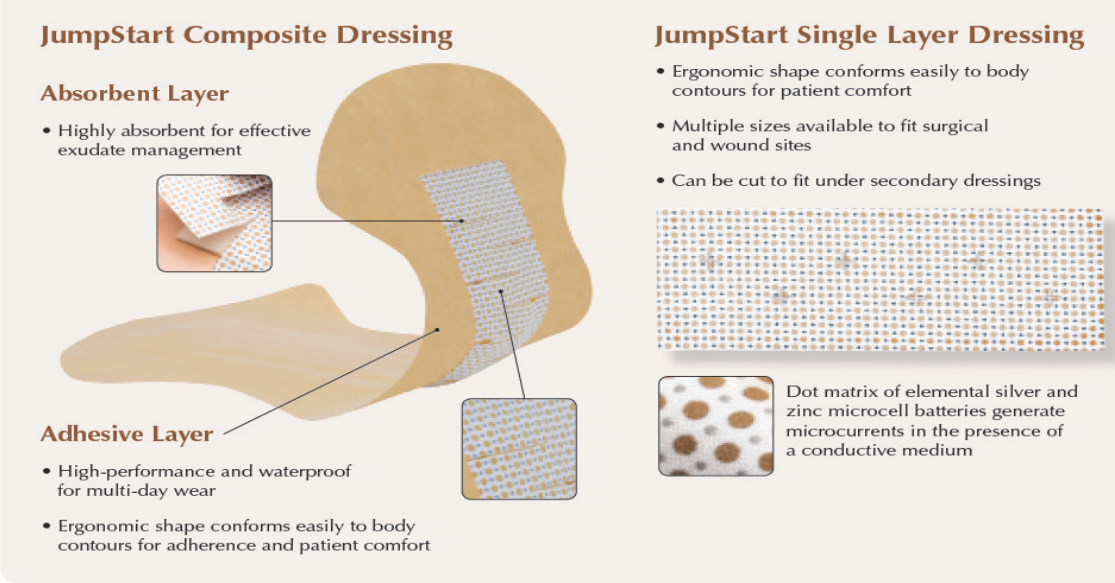
Lay Explanation

The purpose of the study is to evaluate the efficacy of a microcurrent dressing in eliminating certain bacteria that is found on our skin, thus it would reduce the risk of shoulder infections.

Deep periprosthetic infection following total joint arthroplasty is a major complication. Although it only occurs in a small percentage of patients (~1%), it results in substantial complications and a decline in functional outcome. A two stage revision and exchange is commonly required in order to clear the infection and provide the best opportunity for prosthetic replantation.

Propionibacterium Acnes is bacteria that are found in hair follicles, sebaceous glands, and moist areas of the shoulder and armpit. Because of its low virulence, infections caused by P. acnes typically have a low-grade, slow course, with shoulder pain often the only presenting symptoms after prosthetic replacement. P. acnes is particularly challenging to both diagnose and to eradicate, and is a substantial source of low quality and functional outcomes with shoulder arthroplasty.

JumpStart™ is a wireless, advanced microcurrent generating dressing used for the management of surgical incision sites. Microcell batteries made of silver and zinc, generate an electrical current when activated by conductive fluids, such as saline, hydrogel or bodily fluids from a wound. These microcells create low voltage electrical fields to stimulate the surrounding area and to provide antimicrobial protection to assist with wound healing. JumpStart has demonstrated superior broad spectrum bactericidal activity of a wound dressing against antibiotic-resistant strains of wound isolates within 24 hours.



The use of JumpStart as a prophylactic preoperative and post-operative dressing to alter the skin flora and thereby decrease the risk of prosthetic infection has not been investigated to-date. Given the morbidity of a prosthetic infection, this would be a remarkably valuable intervention for any joint replacement procedure.

Background

Deep periprosthetic infection following total joint arthroplasty is a major complication. Although it only occurs in a small percentage of patients (~1%), it results in substantial morbidity and a decline in functional outcome. A two stage revision and exchange is commonly required in order to clear the infection and provide the best opportunity for prosthetic replantation. Following removal of the infected components, a minimum course of six weeks of parenteral antibiotics is given and resolution of the infection confirmed through the ESR, CRP, and repeated aspiration of the joint. In most instances a temporary spacer of antibiotic-loaded cement is inserted at the first stage and removed at the second operation.

Propionibacterium Acnes is a gram-positive, non-spore-forming, anaerobic bacillus found in lipid-rich areas, including hair follicles, sebaceous glands, and moist areas of the shoulder and axilla. Because of its low virulence, infections caused by P. acnes typically have a low-grade, indolent course, with shoulder pain often the only presenting symptoms after prosthetic replacement. P. acnes is particularly challenging to both diagnose and to eradicate, and is a substantial source of morbidity with shoulder arthroplasty.

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The use of JumpStart as a prophylactic preoperative dressing to alter the skin flora and thereby decrease the risk of prosthetic infection has not been investigated to-date. Given the morbidity of a prosthetic infection, this would be a remarkably valuable intervention for any joint replacement procedure.

Due to lower than expected accrual, the addition of arthroscopic shoulder surgery patients will still allow the study of the JumpStart dressing and the efficacy of eliminating P. acnes in a board patient population.

Objective: To evaluate the efficacy of a microcurrent dressing in eliminating P. acnes skin colonization and thereby reduce the risk of perioperative prosthetic shoulder infection.

Overall Study Design. This is a prospective cohort study of patients that are scheduled to have a total or reverse shoulder arthroplasty or arthroscopic shoulder surgery. There will be two groups for this study. Both groups will follow the same timeline below.

Group A: With the exception of the preoperative JumpStart dressing and cultures for assessment of P. acnes which will be paid for with department funds the study does not deviate from the standard of care typically provided to patients seeking treatment for a total or reverse shoulder arthroplasty or arthroscopic shoulder surgery within the University of Michigan Health System, and is in line with national and international standards of care.

Group B: With the exception of the preoperative and postoperative JumpStart dressing and cultures for assessment of P. acnes which will be paid for with department funds the study does not deviate from the standard of care typically provided to patients seeking treatment for a total or reverse shoulder or arthroscopic shoulder surgery arthroplasty within the University of Michigan Health System, and is in line with national and international standards of care.

An overview of the timeline of study visits is presented in Table 1.

Study Visit	Approx. Time from Initial Visit	Measures Performed
Study Enrollment Visit/ H&P Visit	-4wks to -1wks prior to surgery	Consent
Research Visit	-2d	Placement of JumpStart dressing, skin culture
Surgery	0	Skin culture and biopsy; Group B Postoperative JumpStart dressing applied
Post-op Research Visit	7 days	Removal of dressing for both groups, images of incision and reapplication of

		dressings for both groups that was applied at time of surgery
Post-op Visit	10-14d	Skin culture, images of incision

Table 1. Timeline of study visits and measures performed in study.

Subject Selection and Recruitment. The inclusion criteria will be strictly limited to total or reverse shoulder arthroplasty or arthroscopic shoulder surgery . Exclusion criteria- under the age of 18, revision shoulder arthroplasty patients, sensitivity or allergy to sliver or zinc or latex.

Patients will be recruited from clinic in Orthopaedic Surgery. Patients who seek treatment and who are deemed to be potential candidates for a total or reverse shoulder arthroplasty or arthroscopic shoulder surgery will be approached to participate in the research study.

JunpStart Dressing. Groups A and B will have the dressing applied 2 days prior to surgery by a member of the research team. Sterile saline will be used to moisten the dressing. Group B then will have the dressing again applied at the conclusion of surgery. This will be done using routine UM surgical OR protocols. Both groups will report for a research visit 7 days after surgery for a dressing check. Group B will have another JumpStart dressing reapplied until they report back for their first PO visit 10-14 days after surgery. Group A will have the same type of dressing reapplied that was placed on after surgery.

Measurement of P.Acnes. Twenty patients scheduled for total or reverse shoulder arthroplasty or arthroscopic shoulder surgery will have a topical skin culture in duplicate at the site of the deltopectoral incision 48 hours before the surgical procedure. Then a Jumpstart dressing will be applied to the deltopectoral incision site and left in place until intraoperative preparation and draping for the surgical procedure. Prior to preparation with chlorhexidine, a topical skin culture will be taken in duplicate. The skin will then be prepared for surgery in the standard fashion, and the deltopectoral incision will be made. A small biopsy from the edge will be taken for deep tissue culture and evaluation.

All topical and deep tissue specimens will be cultured for aerobic and anaerobic cultures, including specific culture for Propionibacterium Acnes. The type and number of colony forming units (CFU) will be recorded.

Chart Review. Patients' chart will be monitored for clinical outcomes related to shoulder surgery and any cases of acute, subacute, or chronic prosthetic infection and will be recorded for a minimum of a year postoperatively.

Images. At 7 and then again 10-14 day postoperatively, the wound will be inspected and images will be obtained to evaluate cosmesis and apposition. Care will be taken to protect subject's privacy.

Group Assignment. Subjects will be randomly assigned to either group A or B. There will be a 50% chance of being assigned to either group.

Risks
The risks associated with the research study include:

Skin Cultures and Biopsy: There are no risks related to the skin cultures. These are taken topically. The skin biopsy will be taken prior to incision closure and should not cause extra scaring as it will be taken form the margin of the incision.

JumpStart Dressing: Should not be use on individuals with sensitivity or allergy to silver, zinc, latex. MRI Non Compatible: Neither MRI Safe nor MRI Compatible and should not be used in conjunction with MRI systems. Frequent or prolonged use of this product may result in permanent discoloration of the skin (i.e. argyria). The use of adhesive dressings on fragile or sensitive skin may pose a risk of skin damage upon removal of the dressing. The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration or any irregular skin discoloration occurs.

Confidentiality:
There is a small risk of breach of confidentiality. Your research data will not leave the University of Michigan medical campus (Ann Arbor, MI).Data and images will be retained until data related to the research is published at which time all the materials will be destroyed.

As with any research study, there may be additional risks that are unknown or unexpected.

Data Safety Monitoring Plan

The risk level indicated for this study is no more than minimal risk. All study team members including PI, Co-Is, study coordinators, and research assistants will obtain informed consent, and will provide study information and instructions to the subjects beyond what is included in the informed consent document, and will collect and record study data.

Adverse events will be reported to the IRB using the standard IRBMED AE reporting timetable, utilizing the generalized AE grading scale:

0 - No adverse event
1 - Mild AE: No treatment needed
2 - Moderate AE: Resolved with treatment
3 - Severe AE: Inability to carry on normal activities, required professional medical attention
4 - Life-threatening or disabling AE
5 - Fatal AE

Serious Adverse Events (SAEs) will be categorized according to the following FDA definition:
- Death
- A life-threatening adverse drug experience
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity

- A congenital anomaly/birth defect
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

The PI and/or Co-I will determine the attribution/relatedness for each AE in the following manner:
- Definitely related
- Probably related
- Possibly related
- Unlikely to be related
- Definitely not related

The expectedness will be assigned for each AE according to the following definitions:
Unexpected adverse events (i.e., has NOT been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, protocol or procedures for this study, published literature, other documentation)

Expected adverse events (i.e., has been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, protocol or procedures for this study, published literature, other documentation, or characteristics of the study population)

The frequency with which the study team will conduct scheduled assessments of study recruitment, data integrity and quality, adverse events, withdrawals, and compliance with protocol plan will be on a quarterly basis because this is a minimal risk study. No additional monitoring is required – the nature, size, and complexity of this study does not require additional safety monitoring to that provided by the IRB. Monitoring reports will be provided to the IRB.

Related Literature:

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