Vicner Medical LLC
Benzoyl Peroxide Jet Lavage Medical Device Project "*Cuticlens"*
August 31st, 2020.

The Overarching Issue:

In 2011, there were approximately 65,000 shoulder replacements performed in the United States,[1,2] and the volume was expected to grow. The overall estimated rate of deep infection after shoulder replacement is approximately 1%.[3]

Surgical site infection accounts for 22% of all health care related infection costs estimated from $1-10 billion annually. Cutibacterium acnes (C. acnes), formerly known as Propionibacterium acnes, causes more than 50% of infections after shoulder arthroplasty and that rate is higher in men.[5] C. acnes infections cause pain and stiffness and limited range of motion and function. Because the organism forms a biofilm,[8] it is protected from the body's immune defenses.[9] The only way to cure an infection caused by C. acnes is to remove the infected shoulder replacement and place a new one.

In North America, two stage reimplantation is the most common treatment strategy used for the infected shoulder replacement.[4] The mean overall hospital cost for a two stage treatment of a patient with an infected shoulder replacement is $35,824 which is more than double the cost of a primary shoulder replacement.[4] These patients are hospitalized twice, once to remove the infected shoulder replacement and then again to re-implant a new shoulder replacement 3-6 months in the future. The patients are treated with antibiotics which can be expensive and can cause side effects such as C. difficile necessitating further medical care. Unlike primary shoulder replacements, revision surgeries tend to be longer necessitating more anesthesia, have higher blood loss and increases in morbidity.

The Specific Problem:

In orthopaedic surgery, C. acnes has been linked primarily to spine and shoulder surgery because of the proximity of these surgical sites to the pilosebaceous glands and hair follicles in which these bacteria reside.[6] The skin knife must transverse the C. acnes containing sebaceous glands and hair follicles and can inoculate the deeper tissues.[6] Current skin surface surgical preparations cannot prevent the inoculation of bacteria from the dermal structures into the deep tissues at the time of skin incision.[7] C. acnes is not completely eliminated by chlorhexidine gluconate (CHG) or Betadine (povidone iodine) because topical surgical preparations cannot reach the bacteria in the sebaceous glands.[10] In fact, no current strategies have been proven to decrease the risk of postoperative C. acnes inection.[11]

The Solution:

Benzoyl peroxide (BPO) successfully treats acne vulgaris which is caused by C. acnes.[12] BPO is more effective than CHG in decreasing C. acnes skin burden.[11] Currently, Irrisept is frequently used in surgery as an irrigant. It is a combination of CHG and sterile water and is thought to work via three mechanisms.

These include a direct effect of CHG in killing Staphylococcus as well as a dilutional effect where the potential bacterial burden in the surgical incision is "watered down" by the irrigant. The final benefit of this intra-operative irrigant is a mechanical effect where potential bacterial are sprayed, loosened and washed out of the incision. Although CHG decreases the Staphylococcus aureus burden, it alone may not be the optimal choice for shoulder surgery considering the incidence of C. acnes infection.[11] We propose *Cuticlens* as a benzoyl peroxide (5% solution) surgical irrigant. BPO solutions (5%) are maximally effective without negative adverse effects.[14] *Cuticlens* is to be used in neck surgery and open and arthroscopic shoulder as it combines the benefit of reducing the C. acnes burden in these wounds with the mechanical benefits of an intra-operative irrigant. Not only has BPO been shown to be safe with rare cases of contact dermatitis (reported in 2.5% of patients)[13] but there is some evidence suggesting it has a benefit in wound healing.[15,16,17]

Market Size:

With over 60 thousand shoulder replacements per year conducted in the US that would benefit highly from the 5% Benzoyl Peroxide Jet Lavage, and over 500 thousand shoulder and spine arthroscopies every year in the United States, which can directly benefit from this product to prevent C. acnes. We would likely only be looking at the domestic market to start. We believe that this solution will reduce the risk for C. acnes not only in shoulder surgeries, but in many other upper body surgeries where C. acnes can pose a concern.

Market / More Information for Similar Products:

Irrisept, the manual single-use jet lavage system, retails for approximately $80-$120. It uses 0.05% CHG and 99.95% sterile water to prevent the spread of staphylococcus infections. It is used in hip, knee, and shoulder replacements. However, the most common form of postoperative infections in shoulder replacements is C. acnes, not staphylococcus infections. Irrisept uses Sterile Water for Injection, USP, a hemolytic agent, which can risk cellular hypoosmolarity. Irrisept is contraindicated for intravenous administration, without admixing to create a stable saline solution. (Essentially it can lead to cellular dilution as it is not saline based). We believe that Irrisept chose Sterile Water for Injection, USP, instead of a saline solution as a way to preserve shelf life and perhaps to prevent cellular deterioration caused from an unbuffered intraoperative saline solution, which would likely also marginally cut costs.

Legal and Regulatory Hurdles:

The end goal is to have full production and sales for this product. We have already filed a provisional patent with the basic idea, and will file an additional provisional patent once we have more chemical information. Irrimax Corp was granted this patent for CHG, and we are working with lawyers to try and follow their footsteps.[18] We are going to be going down the 510(k) FDA approval process, basing ourselves after the work done by Irrisept, which will allow for a speedier and more cost effective way of getting approved.

Technical Progress

We are currently working with an FDA consultant, Jose Cabrera, who has verified that not only is there a market for this, but there is research being done to combat C. acnes using alternative solutions. As of August 31st 2020, we are working with chemists to determine a stabile concentration of BPO so we can begin laboratory studies of the and longevity of the solution, to ensure long term stability and sterility, after that we will explore the efficacy and safety of the solution by working with either NAMSA or NELSON Labs for complete cell and tissue testing methodologies.

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