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Research Article

Comparing the Efficacy and Rates of Adverse Outcomes of Vashe to Standard Isotonic Saline for Irrigation in Orthopaedic Trauma Surgery

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Abstract

Objective: Surgical Site Infections (SSIs) are a serious complication in orthopedic surgery, While isotonic saline has long been considered the gold standard for wound irrigation, the current rate of SSIs and the recent saline shortage in 2024 have prompted consideration for using other types of wound irrigation. Vashe Wound Solution (Urgo Medical, Fort Worth, TX, USA) is a pure hypochlorous acid solution that kills bacteria and biofilms by disrupting cell membranes. However, Vashe, in its current commercial product, is not terminally sterilized and there is concern that there is an increased risk of infection. It was hypothesized that Vashe is not inferior to isotonic saline in orthopedic surgery.

Methods: With institutional review board approval, a retrospective chart review was performed to include patients treated by our orthopedic trauma service. The final cohort included 100 patients in the Vashe group and 201 patients in the isotonic saline group. Data collected included patient demographics, type of injury, surgical procedure, the type and amount of solution used for irrigation and postoperative complications.

Results: There were no statistically significant differences between the two groups regarding postoperative infection, adverse events or complications.

Conclusion: The results of this study demonstrate that the use of Vashe for irrigation in orthopedic surgery is safe and is not inferior to isotonic saline.

Level of Evidence: IV (Retrospective chart review)

Keywords: Orthopaedic Trauma Surgery; Surgical Site Infections; Wound Irrigation; Orthopedic Trauma Irrigation; Hypochlorous Acid; Vashe; Isotonic Saline

Introduction

Wound infection and wound complications are a major cause of morbidity and mortality for orthopaedic patients, especially in patients who sustain an open fracture [1,2]. While Prosthetic Joint Infections (PJIs) occur around a rate of between 1% to 3% and Fracture Related Infection (FRI) for closed fractures is between 0.5% to 2.5%, open fractures are associated with a much higher risk of infection, with rates ranging from 18% to 30% [1-3]. Treating PJIs and FRIs adds an additional cost of around $56,900 to $58,369 and $25,000 to $51,000 to the healthcare system, respectively and oftentimes results in an additional surgery and financial burden-including loss of income for the patient [4-7]. As bundled payments continue to become more common, these added costs create a larger financial burden on the hospital system. \

How can Surgical Site Infection (SSI) be decreased inside the Operating Room (OR)? While adequate preoperative patient optimization, intraoperative antibiotic prophylaxis, a thorough debridement, limited operative time, utilizing sterile technique,

conducting a biologically friendly surgical dissection and limiting OR traffic are considered by many orthopaedic surgeons to be keys in reducing the chances for an infection or re-infection, irrigation plays a role in removing debris, necrotic/damaged tissue and foreign organisms [1,8-11]. Normal isotonic saline has classically been considered the gold standard amongst many specialties, including orthopaedics [2,8,10]. Saline has the benefit of being safe, low cost and it can be used to improve visualization of the surgical site [1,10]. Isotonic saline has classically been used for improved visualization in arthroscopic procedures, although recent literature has supported the use of hypertonic saline due to decreased inflammatory and degradative responses as well as improved patient reported outcomes [10,12]. Isotonic saline has also been frequently cited in the literature as being readily available [1,10]. Some sources, however, argue that there has been a saline shortage in recent years that has caused many surgeons to seek alternative means of wound irrigation, especially after this shortage was exacerbated in October 2024 [13,14]. In an effort to decrease SSIs and mitigate periods of decreased saline availability, recent literature has begun to look at other options for irrigation in orthopaedic surgery including antiseptics, povidone-iodine, soap, chlorhexidine gluconate, hydrogen peroxide and hypochlorous acid [1,9,10].

Vashe Wound Solution is a wound cleansing solution that contains pure hypochlorous acid [15]. Hypochlorous acid is a naturally occurring molecule generated by white blood cells [4,10,16]. Its main mechanism of action is that the residual chloride ions in the wound bed act as oxidizers, disrupting the cell membranes of pathogens [1,10,16]. It has even been demonstrated to be efficacious at removing staph aureus biofilms *in-vitro* and in treating infected hardware [5,16]. An additional benefit of using Vashe is that a final saline rinse is unnecessary, as it has been demonstrated that the solution maintains its antimicrobial activity in the wound bed while remaining non-cytotoxic and biologically friendly [15-17]. There remains a paucity of evidence, however, that demonstrates the efficacy of using Vashe specifically in orthopaedic surgery and there is currently no literature to the authors' knowledge that directly compares the outcomes of patients who receive Vashe versus patients who receive normal saline for irrigation in orthopaedic surgery. One of the concerns during the saline shortage in 2024 was the fact that Vashe is not terminally sterilized, potentially leading to an increased infection rate if used for irrigation in the OR.

The purpose of this study was to demonstrate the efficacy and safety of Vashe through a head-to-head analysis with normal, isotonic saline and it was hypothesized that the use of Vashe would not lead to inferior outcomes when compared to saline, particularly not a higher rate of infection.

Methodology

With institutional review board approval, we performed a retrospective cohort study through medical record chart review of patients who received wound irrigation for an orthopaedic procedure performed by our orthopaedic trauma service. A data pull was performed to include procedures performed by our orthopaedic trauma service from Jan 1, 2019 to March 1, 2025. Patients treated with either Vashe (Urgo Medical, Fort Worth, TX, USA) or normal saline were included. Based on a priori power analysis using preliminary data to determine a minimum sample size of 87 per group (difference in proportions of infections = 11%, confidence level = 95%, power = 80%), patients treated within the study period were screened until reaching a minimum of 100 patients in each cohort that met inclusion criteria, which were as follows:

- Patients undergoing an orthopaedic procedure by one of our orthopaedic trauma attendings who underwent irrigation using either Vashe or isotonic saline.
- Exclusion criteria included:
- Patients undergoing an orthopaedic procedure where a type of irrigation other than Vashe or isotonic saline was used.
- Patients undergoing an orthopaedic procedure where no irrigation was used.

Data points collected included patient cohort (Vashe or saline), patient demographics such as age, sex and body mass index, a history of smoking or current smoking, comorbidities such as diabetes, peripheral arterial disease, autoimmune disease, a history or current diagnosis of cancer, rheumatoid arthritis and a diagnosis of human immunodeficiency virus or acquired immunodeficiency syndrome. We also collected information on medications that could potentially affect the host's ability to fight infection such as corticosteroids, disease-modifying antirheumatic drugs and other immunosuppressants. Orthopaedic-related information collected included the diagnosis, the procedure performed, surgery duration, all types of irrigation used, the volume of irrigation for each solution, contamination of the wound according to the Center for Disease Control and Prevention (CDC) classification and any use of intraoperative antibiotics [18]. The amount of irrigation used was based on surgeon preference and all surgeons used a simple lavage for surgical irrigation. Vashe was started to be used during the saline shortage

of 2024. The surgeons started questioning their overall irrigation volumes. Therefore, moving forward, only one bottle of Vashe was used unless more volume was specifically needed for the particular surgery.

Descriptive statistics were calculated to report means, standard deviations and percentages. Treatment cohorts were compared for statistically significant differences using unpaired t-Tests for continuous variables and chi square or Fisher's Exact tests for proportions. Differences were considered statistically significant when $p < 0.05$.

Results

The study design and data collection time period resulted in inclusion of 201 patients in the saline group and 100 patients in the Vashe group (Table 1). Regarding demographics, the average age for the saline patients was 56.4 years while the average age for the Vashe group was 51.5 years, which was a statistically significant difference (p=0.029). The saline group also had a significantly lower proportion of males (43.8%) compared to the Vashe group (58%) (p=0.027). There were no other statistically significant differences regarding patient demographics or medical history. Regarding surgical variables, only irrigation volume was significantly different between treatment groups, with saline patients receiving an average irrigation volume of 1.6 liters while Vashe patients received an average of 0.8 liters of irrigation (p<0.0001).

	Saline (n=201)	Vashe (n=100)	p-value
Age (y)	56.4 ± 18.5	51.5 ± 17.7	***0.029***
Sex (Male: Female)	88:113	58:42	***0.027***
BMI (kg/m²)	31.3 ± 7.7	30.6 ± 8.2	0.51
Comorbidities	68 (33.8%)	35 (35%)	0.89
Nicotine	42 (20.9%)	16 (16%)	0.35
Drug Use	45 (22.4%)	33 (33%)	0.052
Surgery Duration (m)	126.5 ± 78.7	113.9 ± 76.2	0.19
Irrigation Volume (L)	1.6 ± 1.3	0.8 ± 1.1	***<0.0001***
Class I	157	72	0.31
Class III	16	6	0.71
Class IV	28	22	0.13
Antibiotics	200 (99.5%)	100 (100%)	1
Postop Infection	18 (9.0%)	4 (4%)	0.16
Adverse Event	9 (4.5%)	3 (3%)	0.76
Reoperation	36 (17.9%)	16 (16%)	0.75

Key: Y=years; BMI= Body Mass Index. Kg/m²=kilogram per meters to the second power; M=minutes; L=liters; Class=Center for Disease Control and Prevention (CDC) Wound Classification; Comorbidities include diabetes, peripheral arterial disease, autoimmune disease, history of cancer or current cancer diagnosis, rheumatoid arthritis, human immunodeficiency virus or acquired immunodeficiency syndrome

Table 1: Comparison of patient demographics, irrigation volume and postoperative complications.

Discussion

In this retrospective cohort study, we compared Vashe hypochlorous acid to isotonic saline solution as surgical irrigants to determine if significant differences in the rates of infection and adverse outcomes were noted. Our results demonstrated no significant differences in surgical duration, antibiotic use, postoperative infection, adverse events or reoperation rates. These results demonstrate that using Vashe in orthopaedic surgery is not inferior to using isotonic saline. Importantly, patients in the Vashe cohort required significantly less irrigation volume compared to the saline cohort while maintaining similar rates of postoperative infection, adverse outcomes and reoperation rates. This further supports the use of Vashe by having a potentially added benefit of decreased operative times and it helps to offset the added cost of using Vashe compared to saline. Future studies should look at the minimum necessary amount of Vashe required to maintain its effectiveness and to establish a more standardized irrigation volume based on fracture type, procedure performed and injury severity.

The major concern during the saline shortage in 2024 was that Vashe is not terminally sterilized and there may be a higher risk for SSI. Our retrospective cohort study showed that there was not a higher risk of infection when Vashe was used compared to saline. While *in-vitro* studies and case reports have been published, this is the first cohort study that compared Vashe to another form of irrigation in orthopaedic surgery to the authors' knowledge.

Previous studies have looked at using hypochlorous acid as a means of irradicating infection [4,16,19]. Kubacki and Gilbert looked at how hypochlorous acid can cause corrosive damage to prosthetic joint implants, specifically against cobalt chromium [19]. Their results demonstrated that hypochlorous acid does not lead to an increase in the corrosion current at lower concentrations (5 mM), but it can lead to an increased corrosion current at higher magnitudes (15 mM and 30 mM). Importantly, this study created hypochlorous acid in a laboratory by combining hydrochloric acid with sodium hypochlorite until a pH of 7.4 was reached and the hypochlorous acid solution was applied to the cobalt chromium alloy *in-vitro*. A case report published by Clayman, et al., demonstrated that hypochlorous acid solution can effectively be used to treat chronic hardware infections [4]. Two orthopaedic trauma patients had a postoperative course complicated by hardware infection. Patient A had a draining sinus from an intramedullary nail and patient B had both a bone forearm fracture with a serious soft tissue injury that required coverage with a flap. Both patients' clinical situation made hardware removal not feasible without serious repercussions. Hypochlorous acid was used to soak the hardware intraoperatively for 5 minutes and the same solution was again used to wash the wounds via a closed suction drain system for 5 minutes for 4 days in patient A and 7 days in patient B. Both patients had complete eradication of their infection with no evidence of recurrence on follow-up at 10 months. Being able to cleanse these hardware infections could be due in part to the ability of hypochlorous acid to disrupt bacterial biofilms. A study performed by Robson demonstrated that hypochlorous acid is effective at reducing *staphylococcus aureus* numbers and at disrupting the biofilm formed by *S. aureus in-vitro* [16]. While they only looked at the effect of hypochlorous acid on *S. aureus* biofilms, it can be reasonably assumed that hypochlorous acid can reduce the total cell and biofilm count of other species. Further studies would be needed to confirm this theory.

Other systematic reviews and meta-analysis have looked at the efficacy of various irrigation solutions. Groenen, et al., performed a systematic review and meta-analysis of randomized controlled trials that compared the use of irrigation versus no irrigation and trials that compared two different types of irrigation [2]. Their results demonstrated that the use of antibiotic solutions and antiseptic solutions were superior to using no irrigation regarding the incidence of SSIs. They also demonstrated that saline irrigation showed no significant difference compared to using no irrigation. Importantly, these SSIs were not specific to orthopaedic procedures like our study was; they did exclude studies that included irrigation for intracavity lavage, however.

The effectiveness of Vashe can be explained by its physiological properties. Vashe has a pH of around 5.5, which has been demonstrated in previous studies to provide an improved wound healing environment due to an increase in protease and oxygen release, reduced toxicity of bacterial end products, epithelization and angiogenesis and increased macrophage and fibroblast activity [15,17,20-24]. Vashe is also a pure hypochlorous acid solution. Hypochlorous acid is naturally produced by neutrophils in the human body. This hypochlorous acid then attacks critical components of the bacteria's cell membrane, leading to rupture and disintegration of the cell [10,16,25]. Hypochlorous acid has been shown to be effective against gram-positive bacteria, even methicillin resistant staph aureus, gram-negative bacteria like pseudomonas aeruginosa and even fungi [16,25].

There are some important limitations to consider when interpreting the results of this study. Since this was a retrospective cohort study, there was no randomization to either the saline or Vashe group. It is possible that the treating surgeon may have had a bias to use one solution over the other based on the type of injury, presence of infection or patient comorbidities. leading to a selection bias. However, as most patients in this study were selected during the period of the saline shortage, it can be reasonably assumed that the Vashe solution was being used less selectively due to the surgeon's choice being more limited than under normal circumstances. Another important limitation to consider is that a broad range of diagnosis were included, as the list of patients received from the data pull included all patients who were treated by one of our orthopaedic surgeons from the previously listed period. All patients were selected from the same list of data, however, so many similar procedures performed by the same surgeon were treated with a different type of irrigation.

The results of our study demonstrated that the use of Vashe as an irrigation solution in orthopaedic surgery is not inferior to the use of the current gold standard: isotonic saline. Vashe did not prove to be any more cytotoxic or any less effective at preventing

infection or increasing the reoperation rate. As this was a retrospective cohort study, selection bias is bound to occur. Future studies should look at the use of Vashe in specific orthopaedic procedures to improve the cohort comparison. To compare these two forms of irrigation more effectively, a randomized control trial is warranted.

Conclusion

Vashe appears to be non-inferior to normal saline when used as a surgical irrigant in orthopaedic procedures.

Conflict of Interest

The author group also reports the following disclosures:
Brent A. Prenger has no conflicts to report.

James L. Cook reports the following:

- AANA: Research support
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- AAOS: Board or committee member
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- Arthrex, Inc: Paid presenter or speaker; Research support
- CarboFix: Stock or stock Options
- Johnson and Johnson: Paid consultant; Paid presenter or speaker
- ODi: IP royalties
- Orthopaedic Trauma Association: Board or committee member

Mauricio Kfuri has no conflicts to report.

James P. Stannard reports the following:

- Arthrex, Inc: Paid consultant; Research support,
- DePuy, A Johnson and Johnson Company: Paid consultant
- Journal of Knee Surgery: Editorial or governing board
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- Smith and Nephew: Paid consultant
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Gregory J. Della Rocca reports the following:
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- Invibio: Other Professional Activities
- Missouri State Orthopaedic Association - president-elect
- American Orthopaedic Association - membership committee, North American Traveling Fellowship taskforce (chair)
- Orthopaedic Trauma Association - diversity committee, traveling fellowships committee
- American Academy of Orthopaedic Surgeons - diversity advisory board, Board of Councilors
- Journal of Orthopaedic Trauma - editorial board
- Geriatric Orthopaedic Surgery and Rehabilitation - editorial board
- Clinical Orthopaedics and Related Research - board of trustees

Brett D. Crist reports the following:
- AO Trauma North America: Board or committee member
- Arthrex, Inc: Other financial or material support
- Curvafix: Paid consultant; Paid presenter or speaker
- DePuy, A Johnson and Johnson Company: Paid presenter or speaker
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- Globus Medical: IP royalties
- International Geriatric Fracture Society: Board or committee member
- Journal of Hip Preservation: Editorial or governing board
- Journal of Orthopaedic Trauma: Editorial or governing board
- KCI: Paid consultant; Paid presenter or speaker
- Orthopaedic Trauma Association: Board or committee member
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Data Availability Statement
Data will be available through a genuine email request to the corresponding author.

Ethical Statement
The University of Missouri Institutional Review Board approved this study (IRB #2125010).

Informed Consent Statement
No informed consent was obtained from subjects as this study is based on all retrospective data.

Authors' Contributions
Conceptualization: J.L.C. and B.D.C.; Formal analysis: B.A.P., J.L.C., D.R.H., K.M.S., M.K., J.P.S., G.J.D.R. and B.D.C.; Investigation: P.R, B.W.R., C.W.N., J.P.S., S.F.D. and J.L.C.; Surgical expertise: D.R.H., K.M.S., M.K., J.P.S., G.J.D.R. and B.D.C. Resources: J.P.S., J.L.C. and B.D.C.; Supervision: J.L.C. and B.D.C.; Writing - original draft: B.A.P., J.L.C. and B.D.C.; Writing - review and editing: B.A.P., J.L.C., D.R.H., K.M.S., M.K., J.P.S., G.J.D.R. and B.D.C.

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