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Original Research

Retrospective Study to Evaluate the Use of Type 1 Bovine Hydrolyzed Collagen to Support Surgical Wound Healing After Spinal Surgery

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Abstract

Surgical site infection (SSI) and wound dehiscence are among the most common postoperative spinal surgery complications. Treatment can be complex, costly, and may require hospital readmission. Type 1 Hydrolyzed Collagen (T1HC) powder can be used during surgery to support the healing environment of the surgical wound. This study is a retrospective review of 154 patients who underwent spinal surgery using CellerateRX ® Surgical powder. A total of three (1.9%) high-risk patients developed postoperative wound complications (SSI or dehiscence). All complications resolved with local wound care and oral antibiotics; no hospital readmissions were required. This low incidence of surgical complications further supports the use of TIHC as an effective wound therapy agent in spinal surgery.

ABBREVIATIONS

SSI: Surgical Site Infection, **T1HC**: Type 1 Hydrolyzed Collagen, **EMR**: Electronic Medical Records, **ECRF**: Electronic Case Report Forms

INTRODUCTION

The volume and complexity of spinal surgery cases in the US continues to grow as the aging population increases and healthcare technology continually improves. While wound dehiscence and surgical site infection (SSI) are important concerns after any surgical procedure, following spinal surgery these complications carry considerable morbidity and are associated with long term disability, increased length of stay, and mortality [1]. Treatment of these complications can be challenging, with patients often requiring prolonged antibiotic therapy, multiple revision surgeries, or advanced soft tissue reconstruction [2]. SSI and wound dehiscence are among the most common postoperative spinal surgery complications, and leading causes of 30-day hospital readmissions [2-3]. Incidence rates of SSI have been reported between 0.2% and 16.1%, and vary by type of spinal surgery [4] and patient risk factors including age, diabetes and obesity [2]. Hospital readmission rates are a key quality indicator and many quality improvement measures aim to reduce unnecessary readmissions within 30 days. Effective measures to prevent SSI and wound dehiscence have the potential to improve patient outcomes and prevent unnecessary costs. Supporting the wound healing process is key in preventing infection and complications at the wound site. As early as 1881, exogenous collagen has been used as an adjuvant to enhance surgical wound healing [5]. During the normal wound healing process, proteases degrade and hydrolyze native collagen. The resulting collagen fragments in the wound bed help create a favorable environment to recruit macrophages and fibroblasts, supporting the production of granulation tissue. Collagen-based dressings and powders have shown to be effective wound therapy agents by enhancing the wound healing process. More recently, the use of type 1 hydrolyzed collagen (T1HC) has been used to support the healing environment of surgical wounds. T1HC can be extracted from a variety of animal sources and tissue types, and has demonstrated human biocompatibility in culture [6]. When used for wound therapy, these low molecular weight peptides (3-6 KDa) bypass the need for breakdown by endogenous enzymes, allowing for immediate signaling [7]. CellerateRX ® Surgical (CellerateRX ® Surgical Powder; Sanara MedTech, Fort Worth, TX) is T1HC, FDA cleared for use in the management of acute and chronic wounds including surgical wounds, traumatic wounds, full thickness wounds, venous stasis ulcers, arterial ulcers, diabetic ulcers, first and second degree burns, and superficial wounds. CellerateRX ® Surgical is not indicated for third degree burns. Hospitals have incorporated T1HC in the care of surgical wounds to support an environment conducive for wound healing and potentially reduce complications associated with surgically-induced wounds. This study is a retrospective review of patients who underwent spinal surgery using CellerateRX ® Surgical powder (T1HC) at one orthopedic center in the Southwest. Incidence of surgical site complications (wound dehiscence and SSI) was evaluated.

MATERIALS AND METHODS

This study was a retrospective review of medical records from one orthopedic operative center to evaluate surgical site complications in adult patients who underwent spinal surgery with confirmed use of CellerateRX ® Surgical Powder between July 1, 2017 and June 26, 2019. During surgery, CellerateRX ® Surgical powder was used according to the FDA-approved package insert, with one to five grams used depending on would size and depth per surgeon judgement along with vancomycin powder. The study was Seemed exempt by Advarra Institutional Review Board and a waiver of informed consent was granted. Study procedures were limited to the review of existing electronic medical records (EMR). A query of the Investigator's EMR database for patients aged > 18 years who underwent spinal surgery to correct spinal deformity, or to treat spinal fracture or a degenerative condition with confirmed use of CellerateRX ® Surgical powder during the study timeframe was conducted. Patients who returned for at least one post-surgical follow up visit & gt; 2 weeks and < 6 weeks following surgery were eligible for inclusion in the study. Surgical site complications of wound dehiscence and SSI were evaluated post-surgery through the 6-week post-surgical visit. Details including whether the infection was superficial or deep (using CDC definitions), and any treatments required were obtained. Patient demographics, operative history, medical history, progress notes, and medication logs were reviewed. Data was de-identified and collected on electronic case report forms (eCRF) housed on a private server. Statistical Analysis Rates of surgical site complications (wound dehiscence and SSI) and time to wound resolution data were calculated for all subjects. Patient demographics, baseline characteristics, and surgery characteristics data were summarized. For continuous data, the descriptive summary statistics of n, mean, median, standard deviation, min, and max were calculated. For categorical data, frequency counts and percentages were presented.

RESULTS AND DISCUSSION

One hundred fifty-four (154) patients met study criteria and were included in the analysis. Patient demographics are listed in [Table 1]. The age of patients enrolled ranged from 18 to 82 years; half of the patients were female and half were male. Surgical characteristics are included in [Table 2]. The majority of surgeries were lumbar surgeries (77.9%), due to degenerative condition (72.7%), and used a posterior surgical approach (94.8%). Nearly half of surgeries were revisions of previous surgeries. The majority of patients underwent spinal fusions (92.9%), ranging from 1 to 14 levels fused, with a median of 3 levels. All patients included in the analysis were treated with CellerateRX ® Surgical powder. Overall, SSI occurred in 1 patient (0.6%), and wound dehiscence occurred in 3 patients (1.9%) (Figure 1). The case of SSI was preceded by wound dehiscence, so overall 3 patients experienced postsurgical complications. To aid in assessing individual risk factors, details of these 3 patients are described below: A 66 year-old female with a history of diabetes, osteoporosis and scleroderma, with current use of corticosteroids and BMI of 35 kg/mm 2 underwent spinal fusion (2 levels) in the lumbar region using a posterior approach for a degenerative condition. Twenty-eight (28) days after surgery, mild wound dehiscence was noted and resolved with local wound

Table 1: Patient Demographics and Baseline Risk Factors.

		N=154
Age (years)		58.6
Body Mass Index (BMI) (kg/m^2)		30.1
Gender		
	Male	76 (49.4%)
	Female	78 (50.6%)
Race		
	White	145 (94.2%)
	Black	7 (4.5%)
	Asian	2 (1.3%)
Ethnicity		
	Hispanic or Latino	7 (4.5%)
	Not Hispanic or Latino	147 (95.5%)
Positive history of diabetes		30 (19.5%)
Current smoker or history of smoking		15 (9.7%)
Concomitant medication use		
	Corticosteroids	13 (8.4%)
	Methotrexate	3 (1.9%)
	Hydroxyurea	0

Mean or N (%)
Abbreviations: BMI=Body Mass Index

Table 2: Spinal Surgery Characteristics.

		N (%)
		N=154
Reason for surgery		
	Deformity	35 (22.7%)
	Degenerative	112 (72.7%)
	Trauma	6 (3.9%)
	Tumor	1 (0.6%)
Location of surgery		
	Cervical	20 (13.0%)
	Lumbar	120 (77.9%)
	Thoracic	14 (9.1%)
Surgical approach		
	Anterior	8 (5.2%)
	Posterior	146 (94.8%)
Revision Surgery		
	Yes	71 (46.1%)
Spinal Fusion		
	Yes	143 (92.9%)
If fusion, number of levels fused		
	1	34 (23.8%)
	2	37 (25.9%)
	3	20 (14.0%)
	4	12 (8.4%)
	5	5 (3.5%)
	6	7 (4.9%)
	7	9 (6.3%)
	8	8 (5.6%)
	9-14	11 (7.7%)

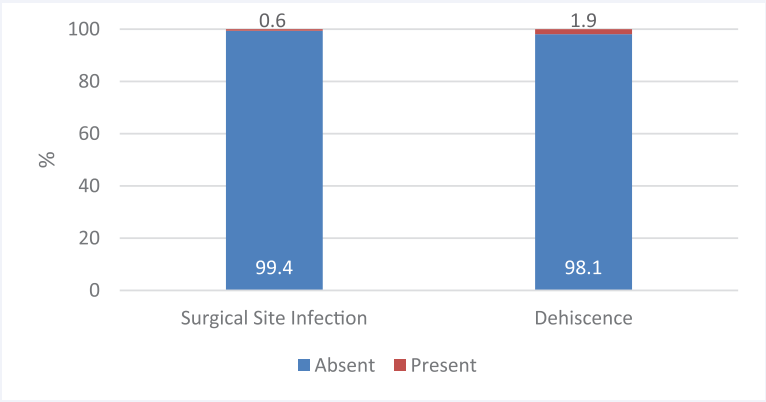

Figure 1 Incidence of postsurgical complications of surgical site infection and wound dehiscence.

care. An 81 year-old female with a history of coronary artery disease, hypertension, and Parkinson's disease with BMI of 23.0 kg/mm 2 underwent spinal fusion (2 levels) in the cervical region using a posterior approach due to trauma. Fourteen (14) days after surgery, mild wound dehiscence was noted and treated with local wound care. Forty-one (41) days after surgery, a superficial SSI infection was noted and treated with local wound care. The wound dehiscence and superficial SSI resolved with local wound care. A 73 year-old female with a history of diabetes, scleroderma and osteoporosis with BMI of 44 kg/mm 2 underwent spinal fusion (2 levels) in the lumbar region using a posterior approach as revision surgery for a degenerative condition. Eighteen (18) days after surgery, mild wound dehiscence was noted and resolved following treatment with oral antibiotics and local wound care. This retrospective analysis of spinal surgery patients supports the effectiveness of CellerateRX ® Surgical powder for surgical wound management in high-risk patients. Only three study patients total (1.9%) in this medically complex surgical population experienced SSI or wound dehiscence, with only 1 patient (0.6%) experiencing an SSI. Zhou et al found a pooled SSI incidence rate of 3.1% in 22,475 patients across 27 studies [4]. A case review of 99,152 spine surgery cases found that 2.2% patients experienced at least one wound complication (SSI or dehiscence) with over half of the complications (1.2%) either a deep or organ space SSI [1]. This review also showed that 46% of the patients who experienced wound dehiscence also had a concomitant SSI. The overall complication rate in the current study using CellerateRX ® Surgical powder was lower than rates reported in the literature, and the events were of lower severity with no deep or organ space SSI. Additionally, only one of the three patients with dehiscence experienced a concomitant SSI. Results of the current study are consistent with results shown by Dickerman et al, who followed 102 consecutive neurosurgery cases for at least 16 weeks [8]. CellerateRX ® Surgical powder and vancomycin power were used during the surgical procedure, and study results showed no cases of wound dehiscence or infection. The authors stated that previous studies using only topical antibiotic powder lowered SSI rates but did not eradicate them [9-10]. and that the unique biochemical design of CellerateRX ® Surgical powder supported wound healing and contributed to prevention of post-surgical complications. Preoperative characteristics associated with wound complications include BMI & gt; 30, female, smoker, chronic steroid use, emergency surgery and operation time >3 hours [1]. Corticosteroids have anti-inflammatory properties and therefore chronic use can be common in the population undergoing spinal surgery. However, they also have immunosuppressive properties, and have been associated with increased risk of infection and delayed wound healing [11]. The population enrolled in the current study had a mean BMI of 30.1 kg/mm 2 , half were female, and a third were complex surgeries involving fusion of more than more than 3 levels. Even with these risk factors, the rate of postsurgical complications was extremely low in this complex surgical population. The study results support previously identified risk factors for postoperative complications; the three patients who experienced SSI or wound dehiscence were female, two were obese and had diabetes, one was currently using corticosteroids, and one was 82 years old and required surgery due to trauma. Wound complications in the study were managed by outpatient wound care and oral antibiotics, and none of the patients required readmission for further treatment. Readmission rates after spinal surgery reported in the literature vary from 7.3-21.3% and increase with age, comorbidities, and surgical complexity [3]. A retrospective review of 14,939 patients showed a readmission rate of 5.5% after instrumented spine surgery, with SSI identified as a leading cause for readmission [3]. SSIs in neurosurgery patients have been reported as the highest costs of all specialty-based SSIs, on average contributing excess costs of $23,755 per case [1]. In the current study, no patients with SSI or dehiscence required readmission, which could provide a cost-savings in addition to benefit to patients.

CONCLUSION

In the present study, patients who underwent spinal surgery using CellerateRX ® Surgical powder had a low incidence of post-surgical wound complications including SSI and dehiscence supporting its use as an effective wound therapy agent. All three patients who developed SSI or wound dehiscence were high risk and treatment included oral antibiotics and outpatient wound care only; no patients required readmission. Limitations of this study include that it was performed at a single site and there was no control group for comparison.

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