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Research Article

The Use of Sterile Bovine Type 1 Hydrolyzed Collagen to Support Surgical Wound Management: A Case Series

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Abstract

Background: Patients undergoing spinal surgery are at risk of surgical site complications. Type 1 hydrolyzed collagen powder has been shown to aid in wound healing.

Purpose: The objective of this case series was to evaluate the effect of using type 1 hydrolyzed collagen on the incidence of surgical site complications (infection and dehiscence) following spinal surgeries.

Methods: Electronic medical records were queried for patients who had previously undergone spinal surgery to correct spinal deformity or to treat spinal fracture, received type 1 hydrolyzed collagen for wound application during surgery, and who had returned for at least one follow up visit between two and six weeks after surgery. All consecutive patients meeting these criteria were included for analysis. Pre-operative, operative, and post-operative data were collected on electronic case report forms. Surgical site infection was documented as per the Centers for Disease Control and Prevention definitions.

Results: Fifty-four (54) patients who met the inclusion criteria were included in the study. None of the patients that received type 1 hydrolyzed collagen powder at the time of wound closure experienced wound dehiscence or surgical site infection.

Conclusion: These results provide evidence that surgical site wound healing is safely supported by application of type 1 hydrolyzed collagen powder.

INTRODUCTION

Patients undergoing spinal surgery are at risk for numerous surgical site complications including surgical site infection and wound dehiscence. Surgical site infection and wound dehiscence following spinal surgery can be devastating and have been reported to be among the most common complications leading to hospital readmission [1-3]. Surgical site infections are reported to be some of the most expensive wound complications to treat due to additional inpatient hospital days [4]. Infection of the surgical site delays patient recovery and may require reoperation, leading to increased healthcare costs [4,5]. The Centers for Medicare and Medicaid Services has used hospital-acquired conditions, inclusive of surgical site infection and wound dehiscence, as a patient safety indicator with potential reimbursement implications. Wound care products to diminish or eliminate the burden of surgical site infections and wound dehiscence are a necessity.

In vitro laboratory data point to the possibility that type 1 hydrolyzed collagen for wound repair benefits wound healing at a biochemical level [6]. Type 1 hydrolyzed collagen powder is hypothesized to have an advantage over native collagen products by functioning as signaling molecules directly upon application without requiring further enzymatic breakdown [7]. Collagen also impacts the tensile strength of skin [8]. Type 1 collagen fibrils cross-link and aggregate into large fibers, improving the tensile strength of incisional wounds because the fibers bind to cell-membrane proteins across the wound interface. Type 1 hydrolyzed collagen has also been demonstrated to have tissue adhesive properties, further supporting wound closure and providing a mechanical barrier against bacterial insult [8,9].

Type I hydrolyzed collagen powder (CellerateRX® Surgical Powder) has been demonstrated to provide a favorable environment for wound healing [7,9]. The purpose of this retrospective case series is to evaluate the effect of using type I hydrolyzed collagen powder for surgical wounds during spinal surgeries on the incidence of surgical site complications, specifically surgical site infection and wound dehiscence.

METHODS AND MATERIALS

Fifty-four (54) patients who met the inclusion criteria and were included in the study. This retrospective study design was confirmed by the IRB to be exempt from IRB review per 21 CRF 46.104. Medical records were retrospectively reviewed for patients who underwent spinal surgery at one surgical center in Stamford, CT between April 2019 and March 2020. Eligible patients were those who were confirmed to have received type I hydrolyzed collagen powder for wound application during surgery, and who had returned for at least one follow up visit

between two and six weeks after surgery. All patients identified by the query and meeting the study criteria were included in the intent-to-treat data analysis. No personally identifying information was collected. For all patients included, surgical incisions were treated with type 1 hydrolyzed collagen powder, applied above the fascia to cover the entire wound bed and the edges of the wound, followed by application of an appropriate dressing to maintain the optimum moisture level of the wound bed.

Pre-operative, operative and post-operative data were collected on electronic case report forms maintained on a private server. Data were de-identified for each patient. Pre-operative data included patient demographics, medical history, and concomitant anti-inflammatory medications. Operative data included reason for spinal surgery, anatomical location of surgery, and whether fusion was performed. Post-operative data were specific to the surgical site complications of infection and wound dehiscence. The CDC definition of surgical site infection was used. A Data were analyzed using descriptive statistics (mean, standard deviation (SD), median, range, or percent of patients).

RESULTS

Following review of patient medical records, fifty-four (54) patients met the inclusion criteria. This retrospective case series reflects the results obtained from these patients who underwent spinal surgery at Stamford Hospital between April 19, 2019 and March 20, 2020, and met the inclusion criteria. All patients had at least one follow-up visit between two and six weeks and twenty-one (21) of the fifty-four (54) patients had two follow-up visits. Data were available for all fifty-four patients. Pre-operative and operative data are presented in (Tables 1-4). Median age was 61.5 years (range 31 – 85) and over half of the treated patients were male (55.6 percent). Most patients were non-obese (83.3 percent), non-smokers (75.9 percent), and did not have diabetes mellitus (75.9 percent). The primary reason for spinal surgery was stenosis (35.2 percent - includes recurrent stenosis) or stenosis and spondylolisthesis (27.8 percent). For the vast majority of patients (94.4 percent), a posterior surgical approach was used. Duration of surgery was between 1 hour and 4 hours. Photographs of the surgical wound area were available for fifty-four patients, and none of the patients showed the presence of surgical site infection or wound dehiscence at follow-up.

Table 1: Patient pre-operative demographics.

Item	Calculation/Response	N=54
Age	Mean ± SD Median Range (min – max)	61.2 ± 12.8 61.5 (31 – 85)
BMI (calculated)	Mean ± SD Median Range (min – max)	30.4 ± 6.4 29.7 (18.4 -53.9)
BMI (calculated)	Non-obese (BMI ≤ 35) Obese (BMI > 35)	45 (83.3%) 9 (16.7%)
Gender	Male Female	30 (55.6%) 24 (44.4%)
Race	Black or African American White	11 (20.4%) 43 (79.6%)
Ethnicity	Hispanic or Latino Not Hispanic or Latino	9 (16.7%) 45 (83.3%)

Table 2: Medical/Operative History.

Item	Response	N=54
Smoking	No Yes	41 (75.9%) 13 (24.1%)
Diabetes Mellitus	No Yes	41 (75.9%) 13 (24.1%)
Hypertension	No Yes	32 (59.3%) 22 (40.7%)
Cardiovascular disease	No Yes	49 (90.7%) 5 (9.3%)
Hypercholesterolemia	No Yes	43 (79.6%) 11 (20.4%)
Other relevant medical history[a]	None Yes	36 (66.7%) 18 (33.3%)

[a]Other relevant medical history included: Anxiety, Asthma (2), Cancer (3), COPD, Factor 5 Leiden, Heart Murmur, Hepatitis B, Hepatitis C (2), Gout, Hyperparathyroid, Hypoparathyroid, Hypothyroid, Lupus, Obstructive Sleep Apnea (3), Psoriatic Arthritis, Pulmonary Embolism, Scleroderma, Seizures, and Waldenstrom's Macroglobulinemia

Table 3: Concomitant Medications.

Item	Response	N=54
Corticosteroids	No Yes	51 (94.4%) 3 (5.6%)
Methotrexate	No Yes	53 (98.1%) 1 (1.9%)
Hydroxyurea	No Yes	54 (100%) 0 (0%)

DISCUSSION

None of the patients treated with type 1 hydrolyzed collagen powder had surgical site infection or wound dehiscence, including high-risk patients with comorbidities such as diabetes mellitus, obesity, smoking, or history of prior spinal surgery, all of which are known to either compromise the healing process or are known risk factors associated with wound complications [10,11]. In the Stamford Hospital, type 1 hydrolyzed collagen powder has been used as part of the standard surgical closure protocol since 2019. Prior to 2019, surgical site infection and wound dehiscence rates were low (combined rate at approximately one percent). Historically, the rates of wound complications following spinal surgery are fairly low and have been demonstrated to be diminished by antiseptic surgical protocols, [12] with reported rates from 0.6 percent [13] for surgical site infection to 2.2 percent [12] for all wound complications inclusive of surgical site infection and wound dehiscence. Despite somewhat low rates of incisional wound complications, even one patient experiencing a surgical site adverse event can be devastating to the patient with the potential for reoperation, longer hospital stays or hospital readmission, or missed workdays, as well as the added cost to healthcare [1-4].

Similar to the present study, Dickerman et al. reported no surgical site infection or wound dehiscence in one hundred two (102) patients undergoing neurosurgery [7]. However, in the Dickerman et al. study, type 1 hydrolyzed collagen powder

Table 4: Spinal surgery procedure information.

Item	Response	N=54
Reason for Spinal Surgery	Cervical stenosis	2 (3.7%)
	Lumbar stenosis with loose hardware	1 (1.9%)
	Recurrent stenosis	5 (9.3%)
	Recurrent stenosis, spondylolisthesis	1 (1.9%)
	Sacroiliitis	2 (3.7%)
	Schwannoma, stenosis	1 (1.9%)
	Scoliosis/spondylolisthesis	1 (1.9%)
	Spondylolisthesis	9 (16.7%)
	Spondylolysis	2 (3.7%)
	Stenosis	14 (25.9%)
	Stenosis, spondylolisthesis	15 (27.8%)
	Thoracic stenosis	1 (1.9%)
Surgical Location	Cervical	3 (5.6%)
	Lumbar	50 (92.6%)
	Thoracic	1 (1.9%)
Surgical Approach	Anterior	1 (1.9%)
	Lateral	1 (1.9%)
	Posterior	51 (94.4%)
	Posterolateral	1 (1.9%)
Revision Surgery	No	33 (61.1%)
	Yes	21 (38.9%)
Fusion	No	17 (31.5%)
	Yes	37 (68.5%)
Number of levels fused	0	17 (31.5%)
	1	17 (31.5%)
	2	7 (13.0%)
	3	8 (14.8%)
	4	2 (3.7%)
	5	2 (3.7%)
	6	1 (1.9%)

mixed with Vancomycin, which has been shown to protect against surgical site infections during spinal surgery [17,18], was applied during wound closure, while in the present study, only type 1 hydrolyzed collagen powder was applied to the surgical site. The addition of Vancomycin increases procedural costs and exacerbates risk of resistance to this drug of last resort [19], and in the absence of Vancomycin the present study found no wound complications.

Type 1 hydrolyzed collagen powder has been used in other surgeries with favorable results. In a study by Evans et al., patients with osteoarthritis undergoing total knee or total hip replacement were randomized into three groups: platelet-rich plasma (PRP), type 1 hydrolyzed collagen, or control [14]. There were no significant differences between these three groups pre-operatively. At follow-up, the PRP and type 1 hydrolyzed collagen powder groups had significantly greater healing at two weeks and significantly lower post-operative complication rates and blood loss values at forty-eight (48) hours post-surgery compared to the control group. In the thirty (30) patients receiving the type 1 hydrolyzed collagen powder, two patients presented with surgical site infection and one patient required re-operation for wound dehiscence. These authors stated type 1 hydrolyzed collagen powder was easy to apply [14]; which is consistent with the experience at the Stamford Hospital with no measurable increase in overall operative time. Of note, the reported rates of surgical site infection for patients undergoing knee or hip arthroplasty are a bit higher 2.1 percent to 15.6 percent [15,16] compared to reported rates for spinal surgery.

An important aspect of wound healing is time to complete healing. Acute wounds, such as surgical incisional wounds, normally heal in four to six weeks; however, healing has been shown to be compromised in some patient populations, including diabetic and/or obese patients [20]. Fei and colleagues demonstrated a two times higher rate of surgical site infection in diabetic and obese (Body Mass Index greater than thirty-five) patients undergoing spinal surgery [20]. Of the fifty-four patients treated in the present study, 24.1 percent had diabetes mellitus, 16.7 percent had a Body Mass Index greater than 35, and 7.4 percent presented with both diabetes mellitus and Body Mass Index greater than 35. Although the purpose of the present study was not to assess time to healing, anecdotally there was no noticeable difference in healing times for those patients with diabetes mellitus and/or obesity compared to non-diabetic, non-obese patients. Theoretically, type 1 hydrolyzed collagen powder supports the healing process. Type 1 hydrolyzed collagen has been shown to have antioxidant, antimicrobial, and chemotactic properties along with higher bioavailability, all of which are important in wound healing [8,21].

LIMITATIONS

The data from the present study provide initial evidence of safety and performance for the use of type I hydrolyzed collagen powder for surgical site healing; however, there are limitations to this study. This was a small case series using retrospective review of medical records rather than a prospectively designed study with designated endpoints and both treatment and control groups. Also, the data obtained were from one surgical group. Despite these limitations and lack of significant clinical data in the literature, the author believes that these data warranted publication. A prospective, multicenter clinical study may provide additional evidence for justification of the use of type 1 hydrolyzed collagen powder at the time of wound closure, including information on surgical site wound complications, time to complete healing, and cost benefit analysis.

CONCLUSIONS

Surgical site incisional wound healing is safely enhanced by use of type 1 hydrolyzed collagen powder, CellerateRX® Surgical Powder, applied above the fascia to the spinal surgical site with an appropriate dressing to maintain optimum wound bed moisture. In this case series, all treated patients were free from wound infection and dehiscence.

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