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Staples Equal Sutures for Skin Closure After Soft Tissue Tumor Resection

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Abstract

Background Wound closure accounts for a relatively constant portion of the time required to complete a surgical case. Both longer closure times and wound infections contribute to higher medical costs and patient morbidity.

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Questions/purposes We therefore determined whether (1) biologic and treatment factors greater influenced wound healing than the choice of sutures or staples; and (2) different times to closure affected cost when sutures or staples are used in patients with musculoskeletal tumors.

Methods We retrospectively reviewed 511 patients who had sarcoma resections of the buttock, thigh, and femur from 2003 to 2010; 376 had closure with sutures and 135 with staples. Data were abstracted on patient demographics, comorbidities, select procedural data, and wound complications. Wound complications were defined by hospitalization within 6 months postoperatively for a wound problem, irrigation and débridement, or infection treated with antibiotics. We determined the association between staples versus sutures and wound complications after controlling for confounding factors. The minimum followup was 2 weeks. A prospective, timed analysis of wounds closed with either sutures or staples was also performed.

Results We found an association between obesity and radiation and wound complications. Wounds were closed an average of 5.3 minutes faster with staples than with suture (0.29 minutes versus 5.6 minutes, respectively), saving a mean 2.1% of the total operating time although the total operating time was similar in the two groups.

Conclusions We found no difference in wound complications after closure with sutures or staples, although obesity and radiation treatment appear to affect wound outcomes. Data suggest that time saved in the operating room by closing with staples compensates for added material costs and does not compromise wound care in patients with lower extremity sarcomas.

Level of Evidence Level II, prognostic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

The selection of skin closure method for orthopaedic procedures is influenced by several factors, including the ease of closure, speed, cost, and potential complications such as wound infection and dehiscence [20]. During the past three decades, orthopaedic surgeons have had many choices for superficial wound closure, including metal staples or nylon sutures [8].

Initially this decision was guided solely by physician preference; however, as concerns about cost, poor wound outcomes, and patient satisfaction have become increasingly important, attention has been focused on demonstrating a clear benefit of one method over the other to guide practice [3, 7, 9, 18–21]. No clear advantage between sutures or staples has been demonstrated, and authors have attempted to show the advantages of each method. It has been argued that staples are more cost-effective, easier to use, and faster for closing wounds [6, 11]. Additionally, recent data have indicated that staples may be associated with higher risks of wound infection after orthopaedic procedures [20]. Other studies have shown that obesity, acute radiotherapy, and other comorbidities affect wound healing [10, 12, 17]. However, the combined influence of these patient characteristics and wound closure methods on wound outcome has not been adequately investigated.

We therefore determined whether (1) biologic and treatment factors would have a greater influence on wound healing than the choice of sutures or staples; and (2) the times to closure and cost differ when sutures or staples are used in patients surgically treated for musculoskeletal tumors.

Patients and Methods

With prior institutional review board approval, we retrospectively reviewed the records of 681 patients who had sarcoma resections of the buttock, thigh, and femur from 2003 to 2010. Patients were identified by searching a financial database for Current Procedural Terminology codes 27047, 27048, 27049, 27328, 27329, 27364, 27365, and 27059 and then identifying patients having undergone radical resections or excisions of the pelvis, thigh, or buttock. Excisions and resections were defined according to the MSTS-accepted Enneking definitions for these procedures [4]. Data were collected from the patients' electronic medical records and were managed using REDCap™ electronic data capture tools hosted at Vanderbilt University. Patients were excluded if (1) wounds were closed by nonorthopaedic teams (N = 14); (2) there was no 2-week followup visit (N = 17); (3) if death occurred within 1 month (N = 8); (4) amputation within 3 months of the

procedure (N = 3); or (5) the operation involved reconstruction with a wound flap, use of wound vacuum-assisted closure, or skin graft (N = 12). For patients with excisions followed by resection, only the final definitive procedure was included. Of 681 patients reviewed, 54 were excluded and 511 met inclusion criteria. Of those patients, 64% had operations involving the thigh (Table 1).

Surgical protocols were standardized across the cohort; all patients received a chlorhexidine scrub in holding, Betadine (Purdue Pharma, Stamford, CT, USA) wash and DuraPrep (3M, St. Paul, MN, USA) in the operating room, and were treated with 24 hours of cephalexin. Patients for only two surgeons were used (GH, HS), who preferred closing with either sutures or staples. All cases were conducted in the same operating rooms with an experienced

Table 1. Descriptive characteristics of sutures and staples groups

Characteristics	Sutures (N = 376)	Staples (N = 135)	p value
Patient characteristics			
Age, mean years (SD)	49.5 (20.7)	52 (18.4)	0.30
Male	178 (47%)	58 (43%)	
Female	198 (53%)	77 (57%)	0.38
Diabetic	43 (11%)	27 (20%)	0.01
Smoker	130 (35%)	40 (30%)	0.30
Obese (body mass index > 30 kg/m ²)	109 (29%)	42 (31%)	0.64
Surgery characteristics			
Location: buttock	54 (14%)	14 (10%)	
Location: femur	80 (21%)	37 (27%)	
Location: thigh	242 (64%)	84 (62%)	0.24
Length of incision, mean (SD)	17.9 (10.6)	18.3 (13.5)	0.47
Incision: straight	243 (65%)	112 (83%)	
Incision: curvilinear	22 (6%)	8 (6%)	
Incision: other	111 (30%)	15 (11%)	< 0.001
Drain use	213 (57%)	84 (62%)	0.26
Tumor characteristics			
High-grade dysplasia	229 (61%)	87 (64%)	
Low-grade dysplasia	147 (39%)	48 (36%)	0.47
Tumor size, mean (SD)	11.7 (7.2)	10.3 (7.7)	0.01
Final pathology			
Primary sarcoma	189 (50%)	51 (38%)	
Benign tumor	155 (41%)	67 (50%)	
Metastatic disease	32 (9%)	17 (13%)	0.04
Treatment characteristics			
Chemo pre-/postoperative	70 (19%)	25 (19%)	0.98
Radiation pre-/postoperative	163 (43%)	43 (32%)	0.02
Complications			
Wound complication	41 (11%)	7 (5%)	0.08
Infection	23 (6%)	5 (4%)	0.40
Surgical débridement	6 (2%)	4 (3%)	0.53

surgical team dedicated to this division. In all patients, fascia was closed with 0 Vicryl (Ethicon, Somerville, NJ) sutures and subsequent layers deep to the dermis with 2-0 Vicryl sutures. Cutaneous wound closure with either staples or nylon sutures was identified in the operative note and recorded; 376 patients underwent surgical closure with sutures and 135 with staples. Wounds were closed by attendings, residents, or first assistants with either staples or 3-0 nylon sutures using a simple interrupted stitch.

Length of incision, antibiotics used, method of closure, and drain use were obtained from operative reports or discharge summaries. In < 5% of patients, length of incision was not recorded so tumor size was used as a surrogate. For patients with multiple incisions for more than one tumor, the largest incision and tumor were included. The average length of incision and tumor size was 18 ± 13 cm and 11 ± 7 cm, respectively. Tumor type and size were based on final pathology reports. The final diagnosis was primary sarcoma in 47% of patients with high-grade dysplasia being found in 38% of patients.

Comorbidities and patient demographics were determined through chart review. Radiation exposure was defined as therapeutic radiation to the operative site 1 month before or 1 month after surgical intervention. Patients with recurrent disease were only considered to have been irradiated if therapy occurred within 1 month of surgery. Patients with metastatic disease to bone with irradiation at the primary site were not considered radiation-exposed. Chemotherapy was defined as neoadjuvant or adjuvant chemotherapy either 1 month before or after surgical intervention. Pre- or postoperative radiation was documented in 40% of patients, wound complications (defined subsequently) in 9% of patients, and wound infection in 6% of patients. Patients closed with sutures tended to have less diabetes (11% versus 20%), larger tumors (12 cm versus 10 cm), more perioperative radiation (43% versus 32%), and more wound complications (11% versus 5%) (Table 1).

Wound complications were collected from followup clinic visit notes, hospitalizations, and operative reports. The minimum followup was 2 weeks (range, 2 weeks to 6 months). Patients were identified as having a wound complication if (1) they were hospitalized within 6 months postoperatively for a wound-related complication; (2) they ever received in-clinic or operative irrigation and débridement; or (3) they had infections described in clinic notes and were treated with antibiotics. Warmth, erythema, discharge, seromas, dehiscence, or postradiation changes without specific mention of infection or treatment were not considered wound complications.

To determine closure time, we prospectively observed 10 patients with 20- to 30-cm wounds in which the decision to close with sutures or staples had been predetermined by

the surgeon. Wounds were marked off into 10-cm segments, and the time to closure was measured in minutes. A total of 10 measurements were made for both sutures and staples. These were compared with total operating room time as outlined in the anesthetic record. Cost was determined for one package of 3-0 SH PO 18-inch nylon sutures and a 35-mm wide skin stapler (AutoSutureTM; Covidien, Mansfield, MA, USA). Hospital cost was determined per 30-minute block of operating room time for each Current Procedural Terminology code, converted to cost per minute, and then averaged across the data set.

The number of study participants needed for this study was based on a sample size calculation for multiple logistic regression analysis using a method by Peduzzi et al. [13]. The estimate was based on the expected proportion of wound complications in the population (p), the number of expected covariates to include in the multivariable regression model (k), and a specified equation ($N = 10 \cdot k/p$). Using a conservative proportion of 0.13 and seven covariates, an alpha level of 0.05, and a power of 0.80, a sample size of 538 was needed to detect an association between closure type and wound complications, controlling for six covariates. A second a priori sample size calculation was performed to determine the sample size needed to detect a statistically significant difference in wound complications across closure type (sutures versus staples). We determined that a sample size of 494 was needed to detect a 9% difference in complications with an alpha level of 0.05 and power of 0.80. A failure to detect a difference across groups could represent a Type II error.

Descriptive statistics were used to summarize variables and to assess normality, identify outliers, determine appropriate summaries of location and spread, and assess the need for nonparametric analysis. Students' t -tests for continuous variables and chi-square or Fisher's exact tests for dichotomous variables were used to compare characteristics across closure groups. Bivariate logistic regression analyses were performed to assess associations between patient and clinical characteristics and wound complications. Type of closure and variables that were significant at $p < 0.05$ in bivariate analyses (Table 2) were entered into a multivariable logistic regression analysis. Stata statistical software (Version 11.0; Stata Corp, College Station, TX, USA) was used to analyze the data.

Results

Obesity and radiation were associated with ($p < 0.05$) wound complications after controlling for closure type, age, length of incision, drain use, tumor size, and pathology (Table 3). We found no association between closure type and wound complications.

Table 2. Bivariate logistic regression analyses for wound complication

Variable	Odds ratio (95% CI)	p value
Sutures versus staples	2.2 (0.98–5.1)	0.06
Age	1.02 (1.01–1.04)	0.01
Obese versus not obese	2.2 (1.2–4.0)	0.01
Diabetic versus nondiabetic	1.5 (0.70–3.3)	0.29
Smoker versus nonsmoker	1.2 (0.66–2.3)	0.51
Buttock versus thigh/femur	0.92 (0.38–2.3)	0.86
Length of incision	1.05 (1.03–1.08)	< 0.001
Drain versus no drain	4.0 (1.8–8.8)	< 0.001
Tumor size	1.1 (1.03–1.1)	0.001
Benign tumor versus others	0.13 (0.05–0.34)	< .001
Chemotherapy versus no chemotherapy	0.60 (0.25–1.5)	0.26
Radiation versus no radiation	7.7 (3.6–16.2)	< 0.001

Table 3. Multivariable logistic regression analysis for wound complication

Variable	Odds ratio (95% CI)	p value
Sutures versus staples	2.1 (0.89–5.1)	0.109
Age	1.0 (0.99–1.03)	0.47
Obese versus not obese	1.9 (1.1–3.7)	0.04
Length of incision	1.0 (0.98–1.1)	0.41
Drain versus no drain	2.3 (0.97–5.3)	0.06
Tumor size	1.0 (0.96–1.1)	0.82
Benign tumor versus others	0.45 (0.15–1.4)	0.17
Radiation versus no radiation	3.7 (1.5–9.0)	0.004

The mean time to close a 10-cm wound with staples was 0.29 ± 0.04 minutes (95% CI, 0.26–0.31) compared with 5.6 ± 0.39 minutes (95% CI, 5.3–5.9) with sutures. Closing with staples was 5.3 ± 0.12 minutes (95% CI, 5.0–5.6) faster ($p < 0.001$) than closing with sutures. In a series of 10 patients, closing with staples represented 0.1% of the average 258 ± 65 -minute (95% CI, 212–304) case, whereas closing with sutures represented 2.2% of the average 250 ± 72 -minute (95% CI, 198–301) case. The operating room time was similar ($p = 0.79$). With an average length of incision of 18.2 cm, an average of 9.6 minutes would have been saved closing with staples. The difference in material costs was \$12 per stapler versus \$1.85 per 3-0 nylon suture with an average of two sutures used per case. For the patients studied, the average cost for additional operating room time was \$9 per minute. Thus, on average, closing with sutures could result in an additional \$78 per case if costed on a per-minute basis. The mean cost for the entire hospitalization for all patients was $\$19,872 \pm \7213 .

Discussion

Although the wound complications after closure with sutures versus staples has been extensively researched [3, 5–9, 11, 14, 18–21], inconclusive results continue to fuel the debate. A series of prospective studies revealed inconsistent results, even among those comparing procedures at the hip [3, 7, 18, 19, 21]. A meta-analysis of several studies showed three times higher risk of infection with staples, but according to the authors, only “one study met acceptable methodologic criteria” [20]. Oncology patients are often the most debilitated patients seen by orthopaedic surgeons, and their cases represent a unique challenge to what is considered to be the highest level of evidence. Proposed theories to explain differences involved in closure method include penetration versus intersection of the surgical incision, differences in wound tension, blood perfusion characteristics, and the type of foreign body introduced into the wound (metallic versus nylon) [5, 14, 17]. Therefore, this retrospective study of 511 patients with pelvic, thigh, and buttock tumor resections and excisions aimed to determine whether identifiable patient and clinical characteristics might have more impact on wound complications than the method of closure and how the time required to close a wound with sutures or staples affected cost.

Our retrospective study has several limitations. First, these data were collected from a critically ill patient population with tumors at a single, large referral center and may not be generalizable to other surgical fields or types of patients. Although our results reflect only this unique subset of patients, similar trends are likely to be found in other debilitated patient populations. Second, the strict identification criteria used to define wound complications in this study may not have captured every adverse outcome seen by practitioners. Given the limitations of retrospective chart review, all efforts were made to standardize identification of wound complications. By using conservative definitions for wound complications, our study ensured that only clinically important complications were included. Third, patients with severe wound complications may have presented to outside hospitals, been lost to followup, or were otherwise not accounted for. As a major tertiary care center in the region, patients were unlikely to have sought care elsewhere for wound complications requiring additional therapy. Additionally, less than 4% of patients identified were lost to followup, and these patients were appropriately excluded from the analysis. Fourth, our study was underpowered to detect the 6% difference in wound complications between sutures and staples (11% versus 5%). However, this difference is clinically important and a sample size of 706 would be needed to assess statistical significance. Fifth, not all incisions from the study

population were included, because only the largest was included when multiple incisions were placed. It is possible that multiple, smaller incisions are an unaccounted for contributor to adverse outcomes. Nonetheless, because the largest incision served as a marker for the site of excision or resection of the primary tumor, using these criteria allowed us to investigate the role of radiation and other tumor characteristics on wound outcomes. Sixth, although other studies have evaluated the impact of closure with staples on pain and cosmesis [3, 7], we did not use patient surveys or other methods to document subjective results. Capturing these metrics was not among the goals of this study but does reflect a necessary consideration when making clinical decisions.

Of the potential cofactors included in multivariate analysis, the only patient and clinical factors associated with wound complications were obesity and radiation. Although we found a trend toward a lower complication rate among wounds closed with staples (5%) versus sutures (11%), this was not significant. The impact of radiation and disease burden is a hitherto uninvestigated factor in wound closure type after orthopaedic procedures. In a meta-analysis of six prospective studies of wound closure after orthopaedic procedures, Smith et al. [20] identified wound infection after 20 of 683 procedures (2.9%). This is lower than the incidence of wound infection in our study population (5.5%), highlighting the inherent risk for wound complication among these patients regardless of closure method. Possible explanations for the higher rate of infections in this study include impaired barrier defenses from radiation, locally invasive disease, decreased patient motivation, and more anatomically disruptive operations. Patients with oncologic problems represent a more complex class of patients with multiple factors contributing to wound healing. Prospective, randomized controlled trials comparing wound outcomes during hip arthroplasty are not sufficient to recommend closure with sutures for every surgical procedure at the hip, particularly in the oncologic patient population.

Prospective, timed analysis revealed closing with staples could save an average 9.6 minutes and a maximum \$78 per case for a similar hospital charging on a per-minute basis. Because this study shows similar wound outcomes after closure with sutures and staples, time and cost can be considered important factors. Prior studies of cost-effectiveness have focused largely on the material cost of sutures or staples rather than the cost burden incurred by their systemic use [18, 19, 21]. Although it is generally agreed that closing with staples saves time [6, 7, 19], no studies have investigated the effect of reduced operating room time on cost. Our study reports only the effect of the operating expenses of longer procedures and does not consider the potential cost savings for anesthesiologists and

surgeons. More important than cost-effectiveness is the possibility of reducing patient morbidity and mortality with decreased operating room time. Several investigations of nonorthopaedic surgical procedures have found patient mortality and morbidity, including surgical site infections, venous thromboembolism, and other negative surgical outcomes, to be inversely correlated with time under anesthesia [1, 2, 15, 16]. Although this study did not evaluate outcomes other than wound complications, other improved patient outcomes might result from reduced operating room time, particularly with lengthy incisions.

This study shows that, at minimum, surgeons are not compromising care by closing with staples and, in fact, may be improving patient care. There now exists a demonstrated need for a prospective investigation of wound closure specific to orthopaedic oncology. Future research may focus on developing an algorithm or wound complexity scale that considers the size of the incision, disease burden, and other patient factors to determine the best method of closure. These results suggest patient and clinical factors greatly outweigh the biomechanical factors in wound healing after musculoskeletal tumor resections and excisions. We suggest placing more emphasis on preoperative clinical evaluation of patients before determining the most effective method of closure.

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