Wireless microcurrent-generating antimicrobial wound dressing in primary total knee arthroplasty: a single-center experience

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Abstract

The spread of multidrug-resistant bacteria and financial burden of periprosthetic joint infection (PJI) further the need for treatments to address pathogenic contamination and expedite healing. This retrospective study was a chart review of a series of 92 patients who underwent 100 total knee arthroplasties performed by the same surgeon and treated with a novel microcurrent-generating antimicrobial dressing (MCD). Mean hospital length of stay was 2.3±0.9 days, while the mean length of treatment with MCD was 8.3±1.2 days. No major complications, PJI or major infectious complications were reported, with two readmissions (2%) within 30 days of surgery. Knee Society Score function showed statistically significant improvements post-operatively, with a mean six-month score of 75.0±20.3 and mean change from baseline of 36.3±21.1 (P<0.0001). These results support previous findings that use of the MCD may result in improved outcomes as an element in post-operative wound management.

Introduction

The number of total knee arthroplasties (TKAs) is rising dramatically as a result of improved technology, expanding indications, and an active, aging population demographic. Although rare, periprosthetic joint infections (PJI) place a tremendous financial burden on the health care system and are associated with increased hospital length of stay (LOS), compromised function, reduced quality of living and increased likelihood of revision surgery. Compounding this problem is the alarming spread of multidrug-resistant bacteria following the widespread use of prolonged antimicrobial prophylaxis.

While the average length of stay for primary TKA has decreased from 7.9 days in 1991-1994 to 3.5 days in 2007-2010,[1] infection rates have not abated to a non-significant level. The literature reports infection rates for primary TKA to be 1-4%,[2,3] with readmission rates of 4% and 8% at 30 days and 90 days, respectively.[4] Associated costs in treating a single case of PJI are estimated to be between 50,000-100,000 US Dollars ($).[5,6] The current standard of care (SOC) for post-surgical incision dressing ranges from standard cotton gauze to silver impregnated dressings, and despite efforts to identify both intrinsic and extrinsic factors that contribute to microbial contamination, undesirable infection rates in orthopedic surgery persist. Despite emphasis on preoperative and intraoperative microbial prophylaxis in the literature, there is also growing concern of increasing multi-drug resistance in pathogens. Prolonged use of antimicrobials places the patient at an increased risk for developing resistant pathogens and consequent nosocomial infections,[7] contributing to increased medical costs.

Endogenous electrical fields are critical to the wound healing process.[8] In recent decades, energy-based systems have been employed to augment the wound healing process,[9] reduce infection,[10] and address edema and pain. The utilization of low-level microcurrents in surgical wounds is supported by a substantive and growing body of literature, and the efficacy of low-intensity electric fields as a bacterial growth inhibitor has been studied both *in vitro* and *in vivo*.[11] The effects of electrochemical currents on *Bacillus subtilis* has been reported to have significant influence on bacterial gene expression and viability in both planktonic and biofilm studies,[12] as DNA microarray results from this study showed that the genes associated with oxidative stress response, nutrient starvation, and membrane functions were induced by electrochemical currents.

A novel, wireless, low-level microcurrent-generating antimicrobial device (Procellera® Antimicrobial Wound Dressing, Vomaris Wound Care, Inc., Tempe, AZ, USA) has been employed in the treatment of partial- and full-thickness wounds, and its use has recently expanded into the orthopedic space. The device, applied as a primary contact layer, consists of a matrix of silver and zinc microcell batteries, which generate between 2 and 10 microamperes of current in the presence of moisture. Recent published findings have pointed to its efficacy in improving keratinocyte migration by generating hydrogen peroxide, phosphorylation of redox-sensitive IGF1R directly implicated in cell migration, reduction of protein thiols, and increase in Integrin$_{\alpha v}$ expression.[13] In *in vitro* testing, the MCD was observed to exhibit an electricidal effect in the presence of antibiotic and multi-drug resistant clinical wound isolates.[14] MCD demonstrated greater bactericidal activity versus silver and controls in *in vitro* testing, and effectively killed bacteria tested on *in vitro* biofilm models.[15,16] In *in vivo* porcine studies, evidence of reduced early wound inflammation was observed along with increased epithelial thickness.[17] In clinical settings, the MCD was observed to reduce healing times for both post-operative and open wounds by 34% and 45%, respectively.[18,19] Blount *et al.* evaluated the efficacy of the MCD in patients following skin grafting procedures in a prospective split-wound case series and reported a statistically significant 34% increase in healing rates, with improved scar formation outcomes. As a result of these findings, it has been hypothesized that application of the MCD in orthopedic applications would result in improved outcomes. The author herein describes his experience with a novel technique utilizing MCD for the management of post-surgical wounds in patients undergoing TKA.

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Materials and Methods

Study design

A single-institution chart review was conducted on 92 patients who underwent 100 total knee arthroplasties performed by the same surgeon and treated with the MCD between 2010 and 2013. Criteria for inclusion in the chart review included patients ≥18 years and ≤99 years undergoing primary total knee arthroplasty who had received the MCD as a postoperative treatment. Exclusion criteria

included individuals with silver or zinc sensitivity, active cancer, participation in another clinical trial, revision surgeries, connective tissue disease, and traumatic injury at the site of TKA. Prior IRB approval (WIRB#20071089) and informed consent was obtained from patients by way of the senior author's personally funded and maintained TKA research registry: Epidemiology and Outcomes of Primary and Revision TKA at the Hedley Orthopaedic Institute for outcomes monitoring. All surgeries were performed at a single inpatient hospital, Phoenix St. Luke's Medical Center. Demographics and comorbidities were collected at time of the TKA; outcomes included LOS, acute infection within six months, 30-day readmission rate, complications, and function as measured by Knee Society Score.

Procedure

Within 1 hour of the procedure, 1-2 mg of intravenous cefazolin was given (or clindamycin for patients allergic to cefazolin) as per the hospital's routine for TKA prophylaxis. Chlorhexidine gluconate was used alongside standard institutional protocol for preoperative skin preparation. All patients received a cemented Legion™ Oxinum® Cruciate Retaining TKA, with a High Flex XPLE insert and an onlay tri-peg patellar button (Smith & Nephew, Hull, UK). Following implantation, deflation of tourniquet and maintenance of hemostasis, patients received final tibial spacer and intrarticular drains (ConstaVac™ CBCII Blood Conservation System, Stryker, Kalamazoo, MI, USA). Multiple layer reapproximation was performed using knotless absorbable sutures (Quill™ Knotless Tissue-Closure device, Angiotech Pharmaceuticals, Inc., Vancouver, British Columbia, Canada). The incision was secured with adhesive skin closure strips (Steri-Strip™, 3M, St. Paul, MN, USA). All patients received a sterile MCD, applied intraoperatively according to the manufacturer's guidelines using aseptic technique, directly on top of the adhesive skin closure strips. The device was electrically activated and maintained moist by saturating with sterile hydrogel upon application, covered with a semi-occlusive dressing to secure the dressing in place and to maintain a moist healing environment (Figure 1). Dressings were scheduled to be removed at their one-week clinic appointment post-procedure. Patients received physical therapy and occupational therapy during their inpatient stay per TKA post-operative protocols and standing orders.

Statistical analysis

Data were evaluated on a TKA procedure level for procedure-specific data such as infection and re-admission, and on a patient level for data such as gender and demographics, counting patients who underwent multiple TKAs only once. As the study was not powered to detect significant differences in the incidence of clinical events, rates of infection and hospital readmissions were compared qualitatively to results obtained from the clinical literature. Paired t-tests were used to assess post-operative change in Knee Society Score function, evaluated by TKA procedure.

Results

None of the 100 TKA procedures experienced intraoperative complications. Demographics, primary diagnoses and comorbidities for all 92 patients enrolled are shown in Table 1. The mean age of patients enrolled was 63.5 and 65% were female; primary osteoarthritis was the primary diagnosis in the vast majority of patients. Hypertension, which was present in 59% of all subjects, was the most common comorbidity.

Postoperative patient statistics are described in Table 2. LOS was 2.3±0.9 days, with mean length of treatment with MCD of 8.3±1.2 days. Mean follow-up time was 341±177 days. No major complications or PJI were reported. No infection was observed, which was favorable in comparison to the rate reported in the literature (1.6%), while the 30-day post-operative readmission rate of 2% was half of the published lower bound (4%). Over three-fourths of patients were discharged home post-operatively, while the remaining

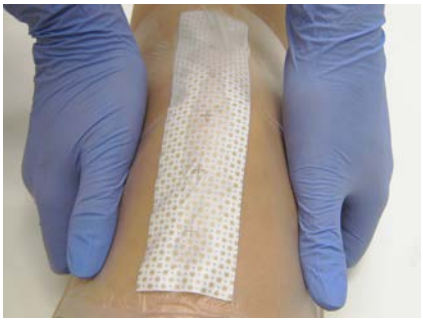

Figure 1. Application of semi-occlusive dressing to keep dressing electrically active and maintain dressing in place.

Table 1. Preoperative patient demographics and comorbidities.

Parameters	Results
No. patients	92
No. knees	100
Age (years)	63.5±11.9
Female gender	65%
Weight (lbs.)	205.3±54.3
Body mass index (kg/m^2)	32.5±7.7
Side of total knee arthroplasties	
Right	54%
Left	46%
Primary diagnosis	
Primary osteoarthritis	94%
Rheumatoid arthritis	3%
Post-traumatic arthritis	2%
Comorbidities	
Avascular necrosis	1%
Hypertension	59
Dyslipidemia	30
Asthma	17
Hypothyroidism	17
Gastroesophageal reflux disease	17
Type 2 Diabetes	14
Anemia	7
Coronary artery disease	6
Morbid obesity	5
Renal insufficiency	5

Table 2. Postoperative patient values.

Parameter	Results
Duration of procedure (min)	104±21
Hospital stay (days)	2.3±0.9
Days of treatment with microcurrent-generating antimicrobial dressing	8.3±1.2
Dressing changes required prior to discharge	1%
Discharge status	
Home	77%
Acute rehabilitation	13%
Skilled nursing facility	10%
Infection	0%
Follow-up (days)	341±177
Readmission within 30 days	2%
Medical	1%
Surgical	1%
Knee Function Score, pre-op *vs.* post-op	38.0±14.3 *vs.* 75.0±20.3
Change in Knee Function Score, pre *vs.* post-op	36.3±21.1, t-test (15.03,75df) P<0.0001

patients were referred for acute rehabilitation or to a skilled nursing facility.

Of the two readmissions within 30 days of surgery, one was for pneumonia three days post-operatively and the other was for aseptic prepatellar bursitis at 27 days, which required separate treatment. Nine cases returned for revision surgery, five for elective manipulation under anesthesia and four for elective tibial insert exchange. One case suffered a mechanical dehiscence following an accidental fall. In addition, one case returned for excision of stitch abscess due to a suture fragment. Knee Society Score function showed statistically significant improvements post-operatively, with a mean six-month score of 75.0±20.3 and mean improvement of 36.3±21.1 ($P<0.0001$).

Discussion and Conclusions

There is currently an unmet need for non-antibiotic interventions to optimize the healing environment and minimize risk for developing infectious complications after TKA. Changes in the healthcare environment, including reimbursement and stringent penalties on hospital-acquired surgical site infections, are driving a shift in focus to quality measures including reducing length of stay and infection prevention. The associated economic implications have heightened the need for clinically significant, cost-effective post-operative treatment alternatives. This manuscript details the author's early experience utilizing a MCD for incision site healing following TKA. The use of MCD as an adjunct to standard surgical closure methods, including suturing for wound closure following TKA, appears to be safe and effective.

Hospital nursing staff also noted improved incision site appearance. However, without the ability to quantify this measure, this is anecdotal information alone. Additionally, this may have been influenced by observer convenience bias. Since there was a reduced need for dressing changes and nursing time, use of the MCD reduced the burden on clinical personnel. Nonetheless, these improved logistics can potentially improve associated treatment costs. Additional work is needed to quantify these observations and is beyond the scope of this paper. This study has several limitations including a relatively small sample size and a retrospective design lacking a control arm for comparison. A two-armed, prospective design would better capture comparative outcomes with standard of care treatment protocols, although it should be noted that MCD is used as the standard of care on all patients under the care of the author. Additionally, revision TKAs, which are associated with significantly higher complication rates, were excluded.

The series of patients reported presented with a diverse mixture of comorbidities, and yet no PJI and a low rate of hospital re-admission were observed. Follow-up duration was moderate, with a mean terminal follow-up of just under one year. Longer follow-up times (*e.g.*, two to three years) may provide more useful data in assessing long-term outcomes as they relate to TKA, but might not represent the effect of MCD once the incision has closed and is fully healed. Despite the aforementioned limitations, the length of stay, incidence of infection and hospital readmission rate appear favorable given MCD treatment when compared with published data on SOC outcomes. Infection rates at any level adversely impact healthcare costs, quality outcomes and patient satisfaction, and as such, efficacious and cost-effective antimicrobial solutions must be sought out as a means to help stabilize healthcare spending. Considering the nominal cost of postoperative treatment with the MCD (~$50) *versus* the cost of a single PJI ($50,000-$100,000), the number needed to treat (NNT) to prevent one PJI is far less costly than the lowest estimated cost of treating one patient with an infection. Findings from this single-center study correlate with previous studies and support the notion that use of a wireless microcurrent-generating antimicrobial device for post-surgical wound dressing shows low infection and PJI rates and a relatively short length of stay. No disadvantages were observed compared to conventional wound treatment. Comparison to historical controls based on a review of the recent literature indicates that the MCD has potential to be an efficacious and economical approach for TKA post-operative wound management. Larger prospective, randomized studies focusing on healing and complication rates in other orthopedic applications deserve consideration to further establish efficacy and value with the MCD as part of the treatment protocol or SOC algorithm.

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