The Impact of use of Double Set-up on Infection Rates in Revision Total Knee Replacement and Limb Salvage Procedures

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Abstract

A retrospective analysis was performed to determine the impact of utilizing a double set-up procedure on reducing infection rates revision total knee and limb salvage procedures in patients with known joint infection. Eighteen cases fit selection criteria. The recurrence rate of infection was 5.5% which is less than reported recent literature review. This suggests the use of a double set-up in combination with other infection reducing protocols may help further reduce recurrent infection.

Keywords: double set-up, infection, revision total knee arthroplasty, limb-salvage

Introduction

Infection of an existing total knee arthroplasty (TKA) continues to be one of the most devastating complications associated with these procedures. Infection is costly [1] and has significant associated co-morbidities. Bannister et al estimated “that an infected hip replacement in modern practice cost the equivalent of five primary procedures [2]. Primary TKA infection rates are reported in recent literature ranging from 0.3%-3% cases [3]. A historic incidence of TKA infection is as high as 23% [4]. Unfortunately, deep infection rates increase in those undergoing revision surgeries to address previous infected TKA [1], and failure due to infection has been reported as high as 46% in some studies [5]. Infection is the most common cause of the revision implant failure [6]. There has been a focus on meth-

ods to reduce infection rates to include: mitigation of risk factors, use of operating room laminar flow, surgical team space suits, pre-operative workup prior to revision, staged procedures, use of antibiotic spacers and cement, antibiotic regimens, sonication [7], intra-operatives culture protocols among many other methods. As Cierny and Mader defined a staging system of the host based on medical conditions, systemic and local, that also impacts outcomes of surgical intervention to eradicate infection. In this staging system A-hosts are healthy, B-hosts are compromised by one or more local or systemic parameters, and C-hosts are not considered aggressive surgical candidates. In 2002 Cierny and DiPasquale also described the use of double set up for a total of 43 patients treated for total joint prosthetic infections with survival rate of 100% in type A hosts, 86% in B-hosts, and 0% of type C-hosts [8,9,10]. The use of a double set-up procedure in addition to existing accepted operative procedures and its impact on reducing revision infection reoccurrence has not been widely been investigated in the literature.

This series describes a novel technique that may be helpful in recalcitrant infection. The double set-up proce-

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ture was utilized for patients presenting for initial treatment and subsequent reimplantation. The Cierny system was utilized to label hosts to provide treatment specific to their disease process. This paper also provides details on the sequence of surgical steps required to successfully perform this technique.

The purpose of this study is to describe a novel technique that may help decrease recurrent infection in previously infected revision joint surgery and determine the impact of utilizing a double set-up procedure on reducing infection rate in revision total knee and limb salvage procedures performed for existing infected joints. I hypothesize that double set-up in combination with already accepted protocols to include preoperative infection screening (erythrocyte sedimentation rate, c-reactive protein, complete blood count, and joint aspiration) and intraoperative cultures (frozen section, aerobic, anaerobic, fungal, and acid fast bacilli cultures) will reduce incidence of infections in the revision setting. It is our hypothesis that the double set-up with aggressive surgical debridement an important factor in reduction of recurrent infection. In this case series, we show that the double set-up reduces infections rates in patients undergoing revision surgery for infection.

Methods

A retrospective analysis of medical records was performed. Inclusion criteria was any revision total knee arthroplasty or limb salvage procedures performed at our facility utilizing the double set-up procedure between the dates of July 1, 2008 through May 1, 2012. Pre-operative diagnoses of all 18 patients included infected total joint prosthesis. Cases using double set-up in joints other than the knee were excluded from the retrospective analysis.

A double set-up procedure involves the use of two separate sterile instrument sets, the first used for the initial debridement and resection and the second used for re-implantation or second portion of the procedure if re-implantation is not performed. This technique is utilized to address revision of previously infected joints. At no time are instruments from the initial debridement used in the second portion of the procedure. The procedure begins with extensive and thorough debridement; the incision is first carried down through the subcutaneous tissue to the level of the articular/capsular level. Devitalized and fibrous hypertrophic tissue is entirely debrided. The debridement is continued deeper and includes the previous antibiotic spacer (if present), cement or hardware remaining. Suspicious bone and surrounding tissues and bone canals are debrided. Bone

saucerization and resection are also performed based on findings. Tissue specimens are collected and sent to pathology for evaluation for signs of acute inflammation (ie. Frozen section) Della Valle et al in their retrospective review of 64 two-stage arthroplasties reported that intraoperative analysis of frozen sections at time of reimplantation had sensitivity of 25%, a specificity of 98%, a negative predictive values of 95%, and accuracy rate of 94. % They used a mean of >10 polymorphonuclear leukocytes (PMN) per high-power field in the five most cellular sites examined as a positive test for acute inflammation [11]. Bori et al utilized the Feldman Criterion (more than five PMN per high-power field in the five most cellular fields and the presence of at least one PMN per high-power field identified in 10 cellular fields) and found that frozen sections have a sensitivity of 28.5%, specificity 100%, positive predictive value 100%, and negative predictive value of 73.6% [12]. The high specificity and positive predictive value of this makes this criterion a strong predictor the presence of persistent infection. Periprosthetic tissue specimen of the soft tissue, bone-cement interface or the pseudocapsule, were considered positive for active infection if there were more than five polymorphonuclear leukocytes per high-power field. The wound is then copiously irrigated with pulsatile lavage using a Clorpackin trademark by Unite-Guardian Inc Hauppauge solution. Following the entire sequence of debridement and irrigation the wound is then packed with Clorpackin soaked sponges prior to wound capsule and skin closure. If no signs of acute inflammation are detected reimplantation can be performed. All members of the operative team perform complete change of gloves, gowns and sterile preparation. The patient is draped again in the standard sterile fashion and all new sterile instrumentation is used for the second portion of the case. Approximate turnaround time was 17 minutes between cases.

Statistical analysis was performed and 95% confidence intervals were calculated using the Clopper-Pearson intervals formula assuming binomial distribution. CP-confidences intervals were calculated for other studies that reported on 2-stage revision techniques aimed to prevent infection. (See Table 1)

Results

The patients were first identified by reviewing records and pulling charts on all patients with current procedural terminology (CPT) code 27599 which is associated with double set-up procedure in time period of October 2008 through April 2012. A total of 79 patients were identified and then this was narrowed to include on those pro-

Table 1. Patient Data

Patient	Age at last Sx	Sex	Host Classification	Number of Revision Surgeries	Final Surgery	Time from final surgery as 7/1/13
1	55	F	B systemic	2	Hinged total knee Depuy limb salvage system	27months 2weeks
2	80	F	B systemic	2	Depuy TC3	27months 1week
3	62	F	A	2	Limb salvage system	15months 1week
4	64	M	B	2	Depuy TC3	14months 2weeks
5	67	M	A	2	Depuy TC3	42months 2weeks
6	78	F	C	4	Above knee amputation	13months 1week
7	73	M	B systemic	1	Arthrodesis	30months 2weeks
8	72	F	B systemic	3	Hinged total knee Depuy limb salvage system	15months 1week
9	59	F	A	2	Depuy TC3	40months 2weeks
10	67	F	A	3	Depuy Limb salvage system	23months
11	63	F	B systemic	1	Polyethylene exchange	20months 2 weeks
12	54	F	B systemic	2	Depuy TC3	49months 3weeks
13	63	M	B systemic	3	Depuy limb salvage system	31months 2weeks
14	66	F	B systemic	2	Depuy TC3	15months
15	78	M	B systemic	2	Depuy TC3	51months 2weeks
16	66	F	A	2	Depuy TC3	25months 3weeks
17	54	M	B systemic	1	Polyethylene exchange	49months 3weeks
18	41	M	B systemic	1	Polyethylene exchange	33months 3weeks

Table 2. Antibiotic Regimen

PT	Antibiotic treatment prior to final surgery	Peri-op antibiotic final surgery	Infectious Disease Consult
1	doxycycline/trimethoprim-sulfamethoxazole	cefazolin/cefipime	Yes
2	ceftriaxone/flagyl	vancomycin	Yes
3	daptomycin	vancomycin	Yes
4	none	cefazolin	No
5	minocycline	vancomycin	Yes
6	vancomycin	vancomycin	Yes
7	vancomycin	daptomycin	Yes
8	daptomycin	vancomycin	Yes
9	piperacillin/tazobactam	cefazolin	Yes
10	daptomycin	vancomycin	Yes
11	vancomycin	cefepime	Yes
12	vancomycin	vancomycin	Yes
13	None	cefazolin	No
14	rifampin	vancomycin	Yes
15	None	cefazolin	No
16	vancomycin piperacillin/tazobactam	vancomycin	Yes
17	vancomycin/rifampin/piperacillin/tazobactam	piperacillin/tazobactam	Yes
18	piperacillin/tazobactam vancomycin	piperacillin/tazobactam / vancomycin	Yes

cedures involving the knee and excluding hip procedures. The charts of the remaining knee patients then were carefully reviewed to confirm a double set-up procedure was performed to address infection. In this retrospective analysis a total of 18 cases were identified that fit selection criteria. All patients belonged to a single fellowship trained total joint surgeon. The breakdown of women to men was 11 to 7 respectively. Ages at final surgery ranged from 41 to 80 years with a mean of 61 years. Using the Cierny/Mader host classification five were A-hosts, 12 patients were B-host, one patient was a C-host. Perioperative antibiotics were utilized in every case (Table 2). Fifteen patients completed an antibiotic course prior to their definitive surgical intervention as prescribed by infectious disease specialist. Four cases were single revision procedures using a double set-up. Ten patients underwent two-stage revisions utilizing the double set-up. Three patients had a total of three revision surgeries to address their initial infection prior to definitive reimplantation or final surgery. One patient required a total of four surgeries, the third surgery a result of failed hardware in arthrodesis and the most recent surgery was an amputation with recurrent infection. The patient who required amputation was the only C-host in our study. This is consistent with Cierny's work in which no C-host's had successful resolution of infection in C-host patients. At the time of this publication only one patient of 18 (5.5%) had developed recurrent infection and no patients had expired. Eight patients had revision components

using the Depuy TC3, three patients underwent polyethylene swap only, one patient kept an arthrodesis as final treatment, and five had Depuy limb salvage systems implanted. Time out from final surgery ranged from 13 months to 51 months 2 weeks with mean time out 28 months and a median 27 months. In the cases of two stage treatment time range from initial temporary arthrodesis to reimplantation was a mean of six months.

Discussion

The recurrence rate of infection in this study was 5.5% which is less than that expected in the management of the infected TKA, and as discussed previously recurrence rate after revision has been quoted much higher than this. Therefore, patients in our case series have lower infection rates than those quoted in recent publications. Within our literature review our case series most closely mirrors Cierny's studies. The Cierny study used a double set up procedure but had higher infection rates than found in our retrospective following revision surgery. In Cierny's work infection reoccurrence occurred in all C patients and in some B patients [8]. Our results showed no infection reoccurrence in B patients and our only failure was in our single C-host. This would suggest that the double set-up procedure with aggressive surgical debridement used in combination with other infection reducing protocols such as intraoperative cultures and postoperative antibiotic regimens may help further reduce recurrent infection in recalcitrant infectious revision cases. Sorli's work showed that explanted antibacterial spacers were colonized at the second stage, which implies the sterile field is no longer sterile after removal; this provides further evidence and motivation to utilize a double set-up. [13]. Table 3 demonstrates confidence intervals between our study and multiple studies examining reinfection rates in revision surgery. In Mortazavi's work infection in revision surgery was tenfold higher than in primary TKA, after retrospective review of 499 TKA revisions 102 (18%) required re-revision with infection being the most common cause (445). [14] Further comparing our study to Sorli and Mortazavi with Fisher's exact test we can show a Fisher's exact test of 0.020 which is statisti-

Table 3.

	No Infection	Total		% No Infection	Low 95% CI	High 95% CI	
Waterman	17	18	95%	94.4%	72.7%	99.9%	
Gooding	101	115	95%	87.8%	80.4%	93.2%	Antibiotic Implant
	12	14	95%	85.7%	57.2%	98.2%	Triple Revision
Kubista	310	368	95%	84.2%	80.1%	87.8%	Simple two-stage revision
Macheras	31	34	95%	91.2%	76.3%	98.1%	Two-stage revision
McPherson	59	70	95%	84.3%	73.6%	91.9%	Staging System/Two-stage revision
Mortazavi	68	91	95%	74.7%	64.5%	83.3%	Two-stage revision
Mortazavi (B	69	95	95%	72.6%	62.5%	81.3%	
Sorli	37	55	95%	67.3%	53.3%	79.3%	Overall Failure
	4	11	95%	36.4%	10.9%	69.2%	Failure in subclinical infections
Suarez							
Cierny	30	43	95%	69.8%	53.9%	82.8%	Double Change
Theoretical	94	100	95%	94.0%	87.4%	97.8%	

cally significant and 0.0676 respectively which is nearly statistically significant (Table 4) this also supports that the use of a double set up may significantly impact infection in revision TKA surgery.

Limitations of this study are related to being a retrospective analysis which by default can cause data bias. This is a small case series, with only 18 cases. An increased power 100 patients with a 4% infection rate would indicate clinically significant improvement in infection rates. There are confounding variables as the patients in the series underwent different surgeries; polyexchange, Depuy TC3, limb salvage, arthrodesis, and amputation. Another limitation is not having a control group without a double-set up for comparison. A potential weakness is that our study did not include total hip arthroplasty, however, limiting this study to total knees did allow us control variables between these types of surgeries.

A future direction would be to consider a prospective review of infection rate/recurrence in revision TKA performed using a double set up procedure and compare that to our present results to determine significance and further plausibility of this technique which the senior author has utilized for years.

Author's Note:

This paper is dedicated to the memory and legacy of George Cierny, M.D.

Table 4.

Double Change vs. No Double Change		
	Infection	No Infection
Waterman	1	17
Sorli	18	37
Fisher's Exact Test: 0.0290		
	Infection	No Infection
Waterman	1	17
Mortazavi	23	68
Fisher's Exact Test: 0.12		
	Infection	No Infection
Waterman	1	17
Mortazavi B	26	69
Fisher's Exact Test: 0.0676		
	Infection	No Infection
Waterman	1	17
Cierny	13	30
Fisher's Exact Test: 0.0469		

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