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# Reconstructive REVIEW

OFFICIAL JOURNAL OF THE


**Joint Implant Surgery and Research Foundation**

Strategic Alliance with

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# Reconstructive REVIEW

OFFICIAL JOURNAL OF THE

JISRF

**Joint Implant Surgery and Research Foundation**

Strategic Alliance with

*An Announcement From:*

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President, Asia Pacific Arthroplasty Society & Associate Editor-in-Chief, Pacific Rim, Reconstructive Review

&

**Timothy McTighe, Dr. H.S. (hc)**

Executive Director, JISRF,

& Editor-in-Chief, Reconstructive Review

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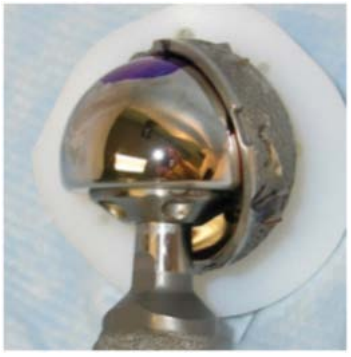
*Ian Clarke, PhD & Thomas K. Donaldson, MD*



*Metal on metal retrieval*

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**Timothy McTighe, Dr. HS (hc)**
Executive Director, JISRF
& Editor-in-Chief
Reconstructive Review

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CLINICAL/SURGICAL

# Subgroup Analysis of Topical Tranexamic Acid in Primary Total Hip Arthroplasty

*Walter A. Anazonwu, BS*; John R. Tuttle, MD*; Lee E. Rubin, MD**

## Introduction

Intraarticular or "topical" tranexamic acid (TXA) has increasingly received attention for reducing blood loss following total joint arthroplasty [1,3,6,8,14]. While our institution has seen transfusion rates drop from 17.5% to 5.5% after administration of topical TXA in total joint replacement, it is still not known which patients will benefit most from TXA administration [14]. Patients undergoing total hip arthroplasty (THA) at our institution continue to have a higher allogeneic transfusion rate compared to total knee arthroplasty (TKA). While THA patients respond to topical TXA, the question remains as to which specific subset of THA patients might benefit most from administration of topical TXA. To answer this question we performed a retrospective cohort study that involved 123 THA patients who received topical TXA, and compared them to 111 controls who did not receive TXA treatment. These patients were subdivided into groups based on gender, age, BMI, preoperative hemoglobin, and surgical approach.

Our goal in this investigation is to identify characteristics that will more accurately justify the use of topical TXA in THA; the ultimate goal is for a surgeon to correctly identify patients preoperatively (prospectively) who will most consistently benefit from topical TXA administration. Preoperative identification of patients who would most likely benefit from topical TXA administration would allow for more targeted use of the drug, ideally reducing cost and unnecessary exposure.

## Methods

Following IRB approval, we retrospectively reviewed 234 primary hip arthroplasties performed by 5 orthopedic surgeons at a single institution between March 2012 and March 2013. Treatment with topical TXA in all primary hip patients was initiated intraoperatively starting September 1st, 2012. The months of August and September of 2012 were excluded from the study in order to prevent any overlap of the experimental and control group. Bilateral and revision hips were excluded from this study.

All patients received spinal or general anesthesia as well as local anesthesia; 10cc of 0.5% Marcaine without epinephrine was used at the operative site after wound closure. Patients received preoperative antibiotics within 1 hour of surgical incision. Antibiotics used included: cefazolin, vancomycin (if MRSA history was present), or Clindamycin (if significant cephalosporin allergy was observed). Standard postoperative DVT prophylaxis was used by all of the surgeons that participated in the study (e.g. TEDS, SCDs, and chemical prophylaxis). One surgeon used postoperative aspirin for chemical DVT prophylaxis, while the other four used Coumadin. No intraoperative drains were placed. One gram of TXA was injected in the pericapsular and deep tissue spaces, or intra-articularly following iliotibial band closure, depending on the surgeon's preference. Otherwise, no changes were made to each surgeon's individual surgical and postoperative protocols between the control and experimental groups. No primary, unilateral total joint patients were excluded from TXA use.

Transfusion was triggered by hemoglobin of less than 8 g/dL or symptomatic anemia for all patients in both control and experimental groups. Each chart was reviewed via the electronic medical record and the following variables were

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recorded for analysis: age, gender, BMI, transfusions, preoperative hemoglobin, postoperative hemoglobin, days in hospital, disposition, 30 day readmission, and complications (including UTI, MI, DVT, stroke, and death). No routine screening for DVT/PE was performed. Symptomatic DVT was confirmed by ultrasound.

Statistical analysis was used to confirm the significance of the results. The chi square test was used for discrete variables (e.g. transfusion rate and hospital disposition). Independent t-tests were used for continuous variables (e.g. drop in Hgb, BMI, and age). Statistical significance was defined as $P < 0.05$ (Table 2).

*Table 1. Primary outcome*

| | Before TXA | After TXA | P-value |
|---|---|---|---|
| Readmission | 5 | 6 | 0.8928 |
| Complications | 0 | 1 | 0.3411 |
| Delta Hgb | 4.8 +/- 1.1 | 4.0 +/- 1.0 | < 0.0001 |
| Postoperative Hgb | 9.1 +/- 1.3 | 9.8 +/- 1.4 | 0.0001 |
| Patients Transfused | 24 | 9 | 0.0016 |
| Units Transfused | 39 | 13 | 0.0003 |
| Length of Stay | 3.2 +/- 1.0 | 3.1 +/- 1.0 | 0.4362 |

*Data reported as mean +/- SD or total sum. P values calculated using either independent T-test or chi square test.*

*Table 2. Demographic*

| | Before TXA (N = 111) | After TXA (N = 123) | P-value |
|---|---|---|---|
| Age | 63.3 +/- 13.5 | 64.9 +/- 12.1 | 0.3349 |
| Male | 54 | 52 | 0.3282 |
| Female | 57 | 71 | 0.3282 |
| BMI | 30.3 +/- 5.2 | 30.7 +/- 6.4 | 0.6766 |
| Preoperative Hgb | 13.9 +/- 1.4 | 13.9 +/- 1.5 | 0.8502 |

*Data reported as mean +/- SD or total sum. P values calculated using either independent T-test or chi square test.*

*Table 3. Subgroup Population*

| | Before TXA | After TXA |
|---|---|---|
| Age < 50 | 15 | 16 |
| Age 50 to 65 | 50 | 46 |
| Age > 65 | 46 | 61 |
| BMI < 30 | 49 | 60 |
| BMI > 30 | 50 | 63 |
| Female | 57 | 71 |
| Male | 54 | 52 |
| Hgb < 12 | 6 | 10 |
| Hgb > 12 | 92 | 94 |
| Anterior-lateral | 90 | 83 |
| Anterior | 20 | 35 |

*Table 4. Primary outcomes within subgroups*

| | Before TXA | After TXA | P-value |
|---|---|---|---|
| **Age <50** | | | |
| Transfusion | 2 (13.3%) | 0 (0.0%) | 0.13101 |
| Delta Hgb | 4.7 +/- 0.8 | 4.6 +/- 0.9 | 0.7018 |
| Postoperative Hgb | 9.4 +/- 1.2 | 9.9 +/- 1.7 | 0.3348 |
| **Age 50 to 65** | | | |
| Transfusion | 10 (20.0%) | 3 (6.5%) | 0.0538 |
| Delta Hgb | 4.8 +/- 1.3 | 4.2 +/- 1.0 | 0.0192 |
| Postoperative Hgb | 9.3 +/- 1.4 | 10.1 +/- 1.4 | 0.0105 |
| **Age > 65** | | | |
| Transfusion | 12 (26.1%) | 6 (9.8%) | 0.0261 |
| Delta Hgb | 4.8 +/- 0.9 | 3.7 +/- 0.9 | < 0.0001 |
| Postoperative Hgb | 8.9 +/- 1.3 | 9.6 +/- 1.3 | 0.0025 |
| **BMI < 30** | | | |
| Transfusion | 11 (22.4%) | 5 (8.3%) | 0.0383 |
| Delta Hgb | 4.6 +/- 1.1 | 3.9 +/- 1.0 | 0.0051 |
| Postoperative Hgb | 9.2 +/- 1.4 | 9.8 +/- 1.4 | 0.023 |
| **BMI > 30** | | | |
| Transfusion | 12 (24.0%) | 4 (6.3%) | 0.0075 |
| Delta Hgb | 4.8 +/- 1.1 | 4.0 +/- 1.0 | 0.0004 |
| Postoperative Hgb | 9.1 +/- 1.3 | 9.9 +/- 1.4 | 0.0042 |
| **Female** | | | |
| Transfusion | 22 (38.6%) | 8 (11.3%) | 0.0003 |
| Delta Hgb | 4.8 +/- 1.2 | 4.1 +/- 1.0 | 0.0005 |
| Postoperative Hgb | 8.4 +/- 1.1 | 9.3 +/- 1.1 | 0.0001 |
| **Male** | | | |
| Transfusion | 2 (3.7%) | 1 (1.9%) | 0.5805 |
| Delta Hgb | 4.7 +/- 1.1 | 3.9 +/- 1.0 | 0.0002 |
| Postoperative Hgb | 9.9 +/- 1.1 | 10.6 +/- 1.4 | 0.0034 |
| **Hgb < 12** | | | |
| Transfusion | 6 (100%) | 3 (30%) | 0.0063 |
| Delta Hgb | 3.4 +/- 1.2 | 3.0 +/- 0.7 | 0.4451 |
| Postoperative Hgb | 7.6 +/- 0.3 | 7.8 +/- 0.5 | 0.3126 |
| **Hgb > 12** | | | |
| Transfusion | 16 (17.4%) | 4 (4.3%) | 0.0038 |
| Delta Hgb | 4.9 +/- 1.1 | 4.1 +/- 1.0 | 0.0001 |
| Postoperative Hgb | 9.2 +/- 1.3 | 10.1 +/- 1.3 | 0.0001 |
| **Anterior-Lateral** | | | |
| Transfusion | 19 (21.1%) | 5 (6.0%) | 0.00413 |
| Delta Hgb | 4.4 +/- 1.9 | 3.9 +/- 1.0 | 0.0442 |
| Postoperative Hgb | 9.2 +/- 1.4 | 9.9 +/- 1.5 | 0.0015 |
| **Anterior** | | | |
| Transfusion | 5 (25.0%) | 2 (5.7%) | 0.039 |
| Delta Hgb | 5.5 +/- 1.1 | 4.1 +/- 1.0 | 0.0001 |
| Postoperative Hgb | 8.7 +/- 1.1 | 9.7 +/- 1.2 | 0.0098 |

*Data reported as mean +/- SD or total sum. P values calculated using either independent T-test or chi square test.*

## Results

All 234 THA were analyzed based on gender, age, BMI, preoperative hemoglobin, and surgical approach. Age was divided into: younger than 50 years, between 50 and 65 years, and older than 65 years, BMI was divided by obesity (defined as > 30 by the World Health Organization). Preoperative hemoglobin (Hgb) status was delineated by 12 g/dL, and surgical approach was divided into direct anterior and anterolateral approach. There was no statistically significant difference in demographics between the pre and post TXA groups (Table 3). The total number of cases for each group is located in Table 1.

Topical TXA consistently reduced transfusion rate, increased postoperative Hgb, and decreased the change in Hgb (Table 2). However, further analysis of the subgroups revealed that these effects were not evenly distributed (Table 4).

### *GENDER*

Both males and females had a significant difference in their postoperative Hgb and delta Hgb. However, after administration of TXA, only females experienced a significant reduction in transfusion rate. The transfusion rate in females went from 38.6% to 11.3% after administration of TXA, p = 0.0003. Males experienced a transfusion rate reduction from 3.7% to 1.9% after TXA administration, which was not significant (p = 0.5805). One possible explanation for the difference in transfusion rates between men and women could be the increased risk for transfusion normally seen in women who undergo THA [2]. As seen in the control group of this study, women generally have a lower average Hgb than men (13.2 g/dL compared to 14.6 g/dL), which results in women having lower postoperative Hgb (8.4 g/dL compared to 9.9 g/dL). The female control group had 2 readmissions and no complications, while the TXA group had 3 readmissions and one UTI complication. The male control group had 3 readmissions and no complications, while the TXA group also had 3 readmissions and no complications.

### *BODY MASS INDEX*

All patients, regardless of their BMI, experienced significant differences in their delta Hgb, post-operative Hgb, and transfusion rate. In patients with a BMI of > 30, the control group had 3 readmissions and no complications, while the TXA group had 1 readmission and no complications. In patients with a BMI < 30, the control group showed 1 readmission and no complications, while the TXA group had 5 readmissions and 1 UTI complication.

### *AGE CATEGORY*

Patients younger than 50 years experienced no significant changes in delta Hgb, postoperative Hgb, and transfusion. In patients over 65 years and patients between 50 and 65 years, both groups had a significant difference in delta Hgb and postoperative Hgb. Patients over 65 years experienced a significant reduction in transfusion rate (26.1% to 9.8% after administration of TXA, p = 0.0261). Patients between 50 and 65 years experienced a transfusion reduction rate from 20% to 6.5% after administration of TXA, p = 0.0538. In patients over 65 years, the control group had 2 readmissions and no complications, while the TXA group had 3 readmissions and 1 UTI complication. The control group of patients between 50 and 65 years contained 1 readmission and no complications, while the TXA group had 3 readmissions and no complications. The control group of patients less than 50 years contained no readmissions or complications, and the TXA group also had no readmissions or complications.

### *PREOPERATIVE HEMOGLOBIN*

After TXA administration, patients with preoperative Hgb < 12 g/dL saw significant reductions in the rate of transfusion (100% to 30%, p = 0.0063). Also, after TXA administration, patients with a preoperative Hgb of > 12 g/dL experienced both a significant reduction in the rate of transfusion (17.4% to 4.3%, p =0.0038), and a significant change in delta Hgb (4.9 +/- 1.1 to 4.1 +/- 1.0, p = 0.0001). The control group in patients with a preoperative Hgb of < 12 g/dL had 1 readmission and no complications, and the TXA group also had 1 readmission and no complications. Additionally, in patients with a preoperative Hgb > 12 g/dL, the control group had 4 readmissions and no complications, while the TXA group had 3 readmissions and no complications.

## Surgical Approach to the Hip

After administration with TXA, patients who underwent either the direct anterior approach (DAA) or anterior-lateral approach (AL) both experienced significant differences in their postoperative Hgb, delta Hgb, and transfusion rates. The control group in patients who underwent DAA had 3 readmissions and no complications, while the TXA group had 2 readmissions and no complications. Furthermore, in patients who underwent AL, the control group had 3 readmissions and no complications, while the TXA group had 2 readmissions and no complications.

## Discussion

While the perioperative administration of TXA is being used more widely in total joint replacement surgery, both the method / route of TXA application and the exact patient population who stands to benefit the most from TXA utilization in THA have yet to be established in the literature. The goal of this study was to retrospectively determine which patients undergoing THA had a significant response to topical TXA.

The greatest weakness of this study was its retrospective design. Patients were followed for 30 days postoperatively in the electronic database, and therefore long-term complications or complications managed at a different healthcare facility were not recorded in this study. Some subgroups may be under powered to determine a significant difference in our outcome variables. For example, no significant differences were found in the <50 age group; this may be a false negative, or younger patients may truly not benefit from topical TXA in THA.

This study is consistent with the current literature by revealing significant differences in transfusion rate reduction, delta Hgb, and postoperative Hgb with topical TXA [7,12,13,15].

In concordance with Judge et al.'s paper, our study concludes that BMI has no bearing in primary hip replacement surgery despite TXA treatment [5]. The two BMI subgroups in our study showed no significant change in complication rates, and both subgroups experienced significant differences in their delta Hgb, postoperative Hgb, and transfusion rate after administration with TXA.

Surgical approach had no effect on the outcomes in THA despite TXA use. In both the direct anterior approach group and anterolateral approach group there was no significant change in complication rates. Also, both subgroups experienced significant differences in their delta Hgb, postoperative Hgb, and transfusion rate after administration with TXA.

Patients who are normally at risk for transfusions in THA appear to benefit the most with TXA treatment: women experienced a significant reduction in transfusion rate after TXA treatment. One explanation could be the increased risk for transfusion normally seen in women who undergo THA. According to Morrison et al.'s findings, the clinical significance of TXA is strongest in patients who have the highest anticipated blood loss [10]. Danninger et al. and Saleh et al. concluded that women are at an increased risk for transfusion in THA, our data is consistent with these findings showing a higher transfusion rate in women (38.6% compared to 3.7%) [2,11]. Also, women had a relatively greater clinical response to TXA (with transfusion rate reduction from 38.6% to 11.3% in women compared to transfusion rate reduction from 3.7% to 1.9% in men).

According to Saleh et al., a risk factor for transfusion after THA is increased age [11].Our study has shown that the rate of transfusion was highest in patients over 65 years old (26% compared to 20% in patients between 50 and 65 years old, and 13.3% in patients less than 50 years old). While the subgroup may be underpowered, patients less than 50 years of age do not appear to benefit from TXA use. This may be due to their ability to compensate for relative anemia compared to the older cohorts. Patients over the age of 65 consistently benefit from TXA use (Table 4).

Our study is consistent with the conclusion that low preoperative Hgb is associated with an increased risk of transfusion during admission for THA [4, 11]. 100% of patients with Hgb < 12.0 g/dL received transfusion prior to TXA administration, while 17.4% of patients with Hgb >12.0 g/dL received transfusion prior to TXA administration. Only patients with Hgb > 12.0 g/dL experienced a significant change in delta and postoperative Hgb after TXA administration. There are two likely possibilities for this difference. The first is that patients with a low preoperative Hgb are more likely to receive an intraoperative transfusion which would alter both delta Hgb and postoperative Hgb. Second, the number of patients in the < 12 Hgb group may be too low to detect these differences. TXA appears to be effective despite preoperative Hgb status.

According to Mayr et al., when compared to the traditional AL approach, patients who undergo DAA experience a faster return to normal function [9]. Our results do not indicate a significant difference between the two approaches for THA regarding short term outcomes, and demonstrated similar blood product utilization in both groups. Patients undergoing either approach stand to benefit from TXA administration (Table 4).

## Conclusion

According to this study, there are no restrictions on the use of topical TXA in THA, however not all patients should be expected to benefit equally. A preoperative Hgb >12 is protective against perioperative transfusions especially in combination with TXA, however TXA significantly reduces transfusion rates regardless of preoperative Hgb status. Female patients and those over 65 years of age appear to have the most reliable and consistent response to topical TXA use in THA.

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ORIGINAL ARTICLE

# Mobile Versus Fixed Bearing Medial Unicompartmental Knee Arthroplasty: A Series of 375 Patients

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## Abstract

***Introduction:*** We sought to compare outcomes, complications and survival between mobile and fixed bearing medial unicompartmental knee arthroplasty (UKA) in a large multi-surgeon group.

***Methods:*** Medical records of patients who underwent a medial UKA were queried between March 2003 and August 2012. Variables investigated included final range of motion (ROM), type of complication, and overall survivorship.

***Results:*** 375 medial UKAs were analyzed (308 mobile bearing and 67 fixed bearing). Average time to follow-up was 47 months. Final ROM was comparable (mobile: 1-122°, fixed: 1-120°, p = 0.34). Complications occurred in 20/308 (6.6%) mobile bearing UKA and 5/67 (7.5%) fixed bearing UKA (p = 0.77). The most common complications in mobile bearing implants were progression of lateral compartment disease and component loosening. The complications in fixed bearing implants were arthrofibrosis and tibial plateau fracture. Overall survivorship differed, but not significantly (mobile: 94.8%, fixed: 96.9%, p = 0.44).

***Discussion:*** In this largest reported cohort series comparing mobile versus fixed bearing UKA, we found no significant difference in final clinical knee range of motion, rates of complications, and survivorship between the two bearing types.

***Level of Evidence:*** *Level IV, Type of Evidence: Therapeutic*

***Key Words:*** *Unicompartmental knee arthroplasty, mobile bearing, fixed bearing, survivorship*

## Introduction

The unicompartmental knee arthroplasty (UKA) is a reliable surgical option for patients suffering from unicompartmental arthritis of the knee. As implant design and surgical technique have improved, so have survivorship and outcomes. [1,2] Although lateral compartment [3,4] and patellofemoral compartment [5] arthroplasties have been investigated, the most common unicompartmental arthroplasty is medial.

In medial UKA designs, the bearing surfaces are either mobile or fixed. Proponents of mobile bearings argue that these devices provide superior conformity and improved tibiofemoral biomechanics, thus leading to natural joint motion and low wear rates. [6] Advocates of fixed bearing implants argue for technical ease in implantation, especially in regards to ligamentous balancing. [7,8]

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Several retrospective and prospective studies have been performed comparing mobile versus fixed bearing components in medial unicompartmental knee arthroplasty. [7,9,10,11] However, each component group was limited to approximately 20-50 participants. One meta-analysis has compared both designs, with pooled data from each bearing type, with no significant difference found in clinical outcome or complication rate between mobile and fixed bearing designs. [12]

The purpose of this study was to investigate the survivorship and complications between mobile and fixed bearing medial unicompartmental knee arthroplasties in a large multi-surgeon orthopaedic surgery group. Our hypothesis was that no significant differences would exist between the two component designs, in that both types of bearings would have similar survivorship and rates of complications.

## Methods

Following institutional board review approval, medical records of all patients who underwent unicompartmental knee arthroplasty (UKA) at our institution using CPT code 27446 from March of 2003 to August 2012 were queried. Inclusion criteria included adult patients who underwent either fixed or mobile bearing UKA for isolated medial compartment arthritis with complete medical records. Lateral and patellofemoral UKA were excluded.

Clinical variables abstracted from charts included sex, age at time of index surgery, and type of component implanted (mobile versus fixed bearing). Postoperative parameters queried included length of follow up and final knee range of motion at the most recent follow up visit. Complications were defined as return trip to the operative room for any reason. Complications were investigated for type of complication, management of complication, necessity of component revision, and time to any component revision from index operation.

Statistical analysis was performed with respect to both groups. Two-tailed Students' t-test and chi-square analysis was used to compare parametric data of patient demographics, knee range of motion, complications, and survivorship. A Kaplan-Meier curve was constructed to compare survivorship using SPSS version 20 (Armonk, NY). A p value of $<0.05$ was considered to be statistically significant.

## Results

From March 2003 to August 2012, 407 unicompartmental knee arthroplasties were performed at our institution by 12 surgeons. Of these, 4 were lateral compartment UKA, three were a patellofemoral UKA, and 25 had incomplete medical records. These patients were excluded from analysis. This left 375 medial UKAs with complete medical records who underwent full analysis.

Of the 375 medial UKAs that were performed, 308 were mobile bearing and 67 were fixed bearing. All mobile bearing components were Biomet Oxford (Biomet, Warsaw, IN), performed by 10 surgeons. The 67 fixed bearing designs were 37 Genesis (Smith and Nephew, Memphis, TN) performed by 2 surgeons, 22 Journey (Smith and Nephew, Memphis, TN) performed by 2 surgeons, 7 Stryker (Mahwah, NJ) performed by 2 surgeons, and 1 Aesculap (Center Valley, PA) performed by 1 surgeon. All surgeons exclusively utilized mobile or fixed bearing implants except for three. These three performed all mobile bearing except 1 fixed bearing implant case each.

Average age at implantation was similar between both groups (mobile: 62 years, fixed: 59 years, $p = 0.12$). Sex of patients between groups differed, as 58% of mobile bearing UKA patients were female, compared to 70% female fixed bearing patients ($p = 0.06$). Average time to follow up was 46.75 months (45.4 mobile [range 1-68], 48.1 fixed [range 1-75], $p = 0.15$). At final follow up, overall average knee range of motion was 1-122° (1-122° mobile, 1-120° fixed, $p = 0.34$) (Table 1).

*Table 1. Patient demographics, clinical outcomes, complications and survivorship between mobile and fixed bearing unicompartmental knee arthroplasty*

| | Mobile | Fixed | p-value |
|---|---|---|---|
| Age at implantation (years) | 62 | 59 | 0.12 |
| Female patients (%) | 58 | 70 | 0.06 |
| Time to follow-up (months) | 45.4 | 48.1 | 0.15 |
| Average knee range of motion (degrees) | 1-122 | 1-120 | 0.34 |
| Complications (%) | 6.5 | 7.6 | 0.77 |
| Overall survivorship (%) | 94.8 | 96.9 | 0.44 |

Complications occurred in 20/307 mobile bearing UKA (6.5%) and 5/66 (7.6%) fixed bearing UKA ($p = 0.77$). Complications in mobile bearing UKA included progression of lateral compartment disease (7), component loosening (4), bearing dislocation (3), tibial plateau fracture (2), infection (1), arthrofibrosis (1), implant subsidence without fracture (1), and inflammatory synovial disease progression (lipoma arborescens, 1). Complications in fixed bearing UKA included arthrofibrosis (3) and tibial plateau fracture (2).

Overall implant survivorship differed between the two

implants, but not statistically (mobile bearing 94.8% vs fixed bearing 96.9%, p = 0.44). Component revision occurred in 16 mobile bearing implants. Bearing dislocation resulted in simple polyethylene exchange in 2 cases. The other 14 UKAs required conversion to total knee arthroplasty for the following reasons: progression of lateral compartment disease (4), component loosening (4), tibial plateau fracture (2), infection (1), repeat bearing dislocation (1), component subsidence (1), and inflammatory synovial disease progression (lipoma arborescens, 1). The other four complications underwent return trips to the operating room for manipulation under anesthesia (1) and arthroscopic debridement of lateral meniscal tear and loose body removal (3). In the fixed bearing UKA, 2 cases returned to the operating room for conversion to total knee arthroplasty for tibial plateau fracture, and 3 underwent manipulation under anesthesia for arthrofibrosis. A Kaplan-Meier curve was constructed to portray survivorship (Figure 1).

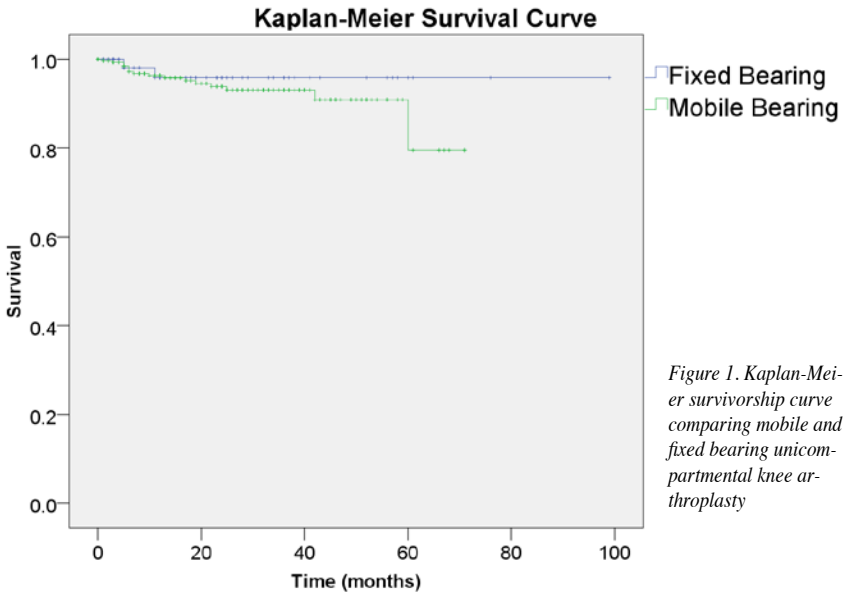


*Figure 1. Kaplan-Meier survivorship curve comparing mobile and fixed bearing unicompartmental knee arthroplasty*

## Discussion

With advances in implant design and surgical technique, unicompartmental knee arthroplasty has evolved as a safe and reliable intervention for patients suffering from unicompartmental knee arthritis. [1,2] Several previous series have examined outcomes and complications associated with these implants, but their cohort numbers have been relatively low in relation to other arthroplasty literature. [7,9,10,11]

Proponents of mobile bearing designs argue for a more normal restoration of knee kinematics, which may theoretically translate to better long term knee range of motion. Li et al found this to be false, as both mobile and fixed bearing patients undergoing kinematic anaylsis had similar ranges of motion. [11] In both of our groups as well, patients regained excellent range of motion, with no statistical significance between the two (1-122° mobile, 1-120° fixed, p= 0.34). This also confirms other reports that found no difference in clinical outcomes, [10] but we did not gather any validated functional scores.

Component loosening has been proposed to be one of the leading causes of conversion to TKA [13]. In mobile bearing implants, the motion and shear force transmission from the mobile bearing interface should theoretically lead to low rates of component loosening. In one of the largest comparative series, Emerson found a higher rate (16%) of loosening from tibial components in fixed bearing than in those with mobile implants (2%). [9] In our series, the rate of loosening of mobile components was similar (4/307 = 1.3%), however, none of our fixed bearing implants showed evidence of loosening at 4 year follow-up.

Some authors have argued that the mobile bearing implants may lead to earlier lateral compartment disease progression, [9] and we have found this to be the case in our series. Four patients with mobile bearing devices required conversion to total knee arthroplasty, while none in the fixed bearing group were revised for progression of lateral compartment disease.

Tibial plateau fracture is also another known complication of UKA, and can occur intraoperatively, or is detected in the postoperative period. [1] We detected four tibial plateau fractures, with 2 in each group, and all were discovered in the postoperative period.

Several studies have reported survivorship rates of both mobile and fixed bearing implants. In fixed bearing implants, survivorship at 10-13 year has consistently been reported as 91-96%. [1,13,14,15] Overall survivorship in mobile bearing implants has been reported at 85-98% at 10 year follow up. [9,16] Our survival rates of mobile bearing 94.8% and fixed bearing 96.9% are consistent with these literature reports.

Several limitations exist in this study. First, the retrospective design leads the study to incomplete data and inherent biases. Second, we did not collect any validated functional outcome measures on these patients, which may have helped to better differentiate patient satisfaction and clinical outcomes. Third, a large proportion of our data is from mobile bearing implants, which was due to surgeon

preference and outside the control of this retrospective review. A prospective matched data set may have more precisely defined differences between the two implant designs. Additionally, the groups are not matched in that a higher percentage of fixed bearing patients were female. Finally, the number of different surgeons and surgeon experience may play a confounding role in the heterogeneity of the data; however, this is representative of a multi-surgeon group and reflects modern practice.

In conclusion, we present the largest single series examining complications and survivorship between mobile and fixed bearing medial unicompartmental arthroplasties. No significant differences were found to exist between these two implants. Further studies which are prospective in nature and incorporate validated functional scores may be used corroborate these findings.

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ORIGINAL ARTICLE

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

*Jennifer A. Waterman, DO*; Jon E. Minter, DO**; Paul J. Ghattas, DO*; Brandon M. Green, DO**

## 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 methods 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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dure 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 Clorpactin trademark by Unite-Guardian Inc Hauppauge solution. Following the entire sequence of debridement and irrigation the wound is then packed with Clorpactin 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.

*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% | |

## 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. Sorili'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 statistically 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.

*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 | |

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.

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ORIGINAL ARTICLE

# Incision Length in Small Incision Total Knee Arthroplasty: How Long of an Incision Is Needed?

*Edward J. McPherson MD, FACS*; Brian Czarkowski, MS*; Matthew V. Dipane, BA*; Sherif M. Sherif, MD**

## Abstract

This prospective review studied incision length with a small incision TKA technique and compared measured incision lengths to various anatomic and clinical parameters. We prospectively reviewed 357 cases of primary total knee arthroplasty using a small paramedial incision and utilizing small incision instrumentation. By using linear regression analysis, we found that incision length was generally related to the width of the distal cut femur and the width of the proximal cut tibia. Incision length was not related to height, weight, BMI, or femoral implant width. Clinically based upon our data, a reasonable starting incision for small incision TKA (as measured in knee extension) is a length that is 1.6 times the measured width of the distal femur. The surgeon should always extend the incision if he/she encounters difficulty in exposure and/or placement of instrumentation.

***Keywords***: *Incision Length, Small Incision, Less Invasive, Total Knee Arthroplasty, Primary TKA, Surgical Technique*

***Level of Evidence***: *AAOS Therapeutic Study Level III*

## Introduction

Total knee arthroplasty (TKA) is a well accepted treatment for symptomatic end stage gonarthrosis. [12,19,30] Third generation designs have provided good functional results in the intermediate term. [32] Furthermore, polyethylene bearing technology continues to improve allowing longer term survival of implants before bearing changes are required. [13]

In the new millennium, the TKA procedure itself has been adapted to accommodate the shifting parameters in healthcare. Economic pressures on the healthcare system have prompted surgeons to seek methods to reduce hospital length of stay and lower the amount of post-operative visits for rehabilitation. [21] Along with better perioperative pain management techniques and coordinated "total joint care," surgeons have evolved the procedure utilizing "less invasive" surgical techniques. [6,7,8] The less invasive TKA procedure utilizes a smaller skin incision with a smaller arthrotomy. Additionally, instrumentation has been adapted to accommodate the smaller incision technique. [35,37]

Several variants of the small incision TKA technique have been described. [3,10] Interestingly, the starting incision length employed with the small incision technique has not been precisely described. Some surgeons report start-

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ing at an absolute length of 9-10cm and extending the incision as needed. Others report using landmarks starting adjacent to the tibial tubercle and extending just above the patella. There are no clear common guidelines dictating the starting length and the final working length needed for primary TKA.

This study was undertaken to examine our small incision primary total knee TKA technique. We believe that incision length at the knee is dictated by anatomic dimensions of the distal femur. Our focus of this study is to determine whether clinical landmarks can be utilized to provide a clinical guideline as to the proper starting incision length when utilizing a small incision technique for TKA.

## Materials and Methods

Between November 2007 and December 2013, 415 primary TKA procedures were performed at a single institution by the senior author (ejm). Patients who were excluded from the study group include the following:

1) Patients who had a prior medial or lateral incision that was used and modified for surgical approach (n=9)
2) Patients with post-traumatic arthritis who had retained hardware requiring an extended exposure for removal (n=7)
3) Patients with severe deformity requiring use of a revision constrained TKA or a salvage hinge TKA (n=42)

This left 357 TKA procedures for study review. The surgical technique remained consistent throughout the study period (see Surgical Technique). A small incision surgical technique was utilized for all procedures.

A small incision with a small paramedial arthrotomy (a.k.a., less invasive technique) was utilized for all procedures. Anthropometric parameters were measured and recorded for each case. This included height and weight. The width of the distal femur was measured after the distal femoral cut was made (Figure 1). The sizes of the femoral component and tibial component were recorded. Finally, after the closure the knee incision was measured with the knee in full extension with a flexible ruler (Figure 2) and the length was recorded.

Incision length data was compiled and compared to anthropometric data using Microsoft Excel® spreadsheets (Microsoft Corporation, Redmond, WA). Statistical measurements were also calculated using Excel. We utilized linear regression analysis to determine the relationships between incision length and various measured parameters including height, weight, body mass index, femoral width, tibial implant size, and femoral implant size. The R-value coefficients were reviewed for significance. [34]

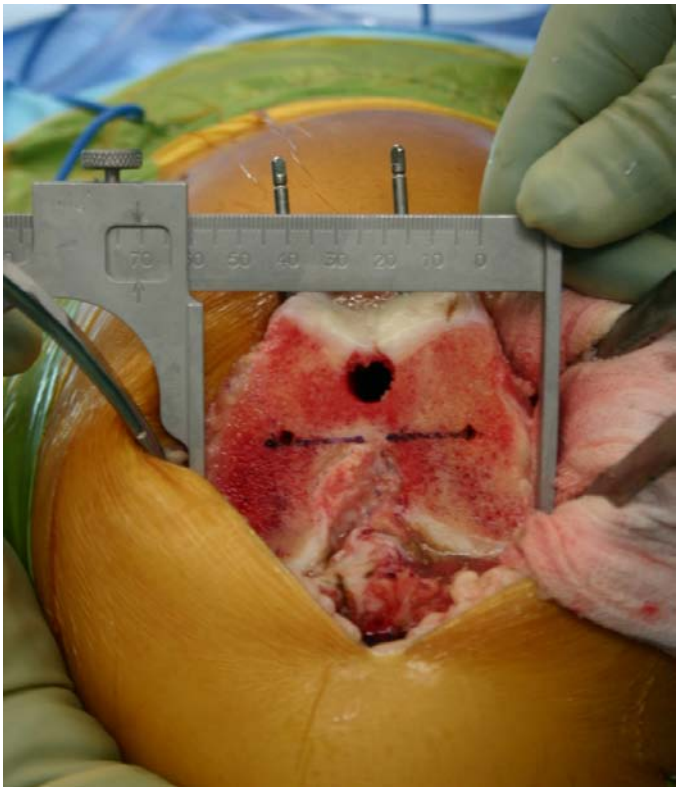

*Figure 1. Measurement of distal femur width. Photograph showing the end of the distal femur which has been cut at 5 degrees of valgus. The width is measured with a metallic caliper. For consistency, we measured the distal femur at the freshly cut edges, rather than the epicondyles.*

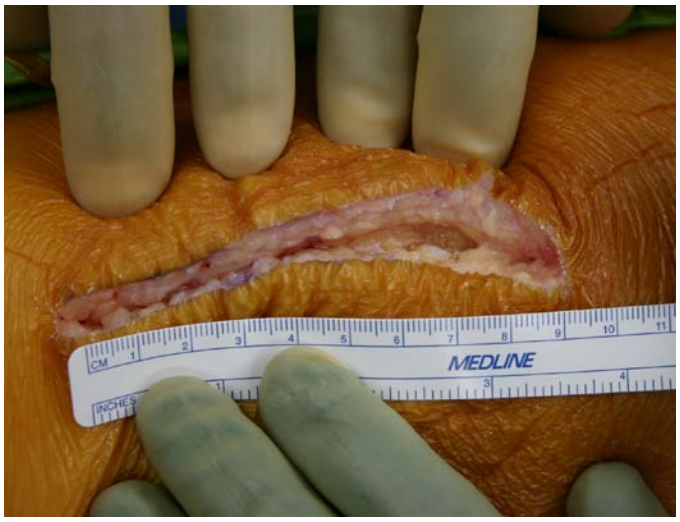


*Figure 2. Measurement of knee incision at closure. Photograph demonstrating the measurement of incision length which was measured at the completion of the TKA procedure using a flexible ruler. We used a flexible ruler as our incisions were curved around the patella. We measured skin incisions in full extension with the wound completely closed. Prior to starting our study, we determined that measurement of skin incision in extension with a completely closed wound reduced measurement variability compared to measurements in the flexed position and with the wound partially closed.*

All patients in this study were followed for a minimum of one year. Functional performance was graded using the Knee Society Score (KSS). [15,26] All charts were re-

viewed for complications and implant failures. Complications were defined as requiring re-operation for any reason. Failures were defined as requiring implant removal for any reason.

## Surgical Technique

All TKA's were preformed with a small skin incision and small arthrotomy employing a paramedial incision with a medial parapatellar arthrotomy. [8,22] The incision was made long enough to allow for comfortable access and exposure to the knee. The Vanguard Total Knee System™ (Biomet, Inc., Warsaw, IN) was used in all cases (Figures 3a & 3b). A cruciate retaining femur was inserted in all cases. Three polyethylene tibial bearing designs were used: a flat design, a dished posterior design, or an anterior stabilized (also known as "ultracongruent") bearing. [27] The anterior stabilized bearing had an extended anterior lip which was of a similar height to the Vanguard posterior stabilized post. Additionally, the posterior lip was extended 50% more than the dished tibial insert. The selection of each bearing design depended upon the flexion stability of the knee. An anterior stabilized bearing was used whenever the PCL was deficient or released significantly.

An intramedullary guide was used to cut the distal femur at a 5° valgus cut angle. Rotation of the femur was based upon the Anterior-Posterior axis as described by Whiteside. [9,38,39] Sizing of the femur was measured using a posterior reference technique. The proximal tibial bone cut was made using an extramedullary guide system. A bone block around the PCL was not used. A posterior slope was cut in all cases parallel to the medial compartment slope. [1,2,4,5,14,17,20] Coronal and sagittal plane balancing was performed utilizing a modified spacer block technique. Specifically, a trial femur was inserted along with a tibial trial sans a keel. Rotation of the tibia was set to provide congruent femoral-tibial mating in deep flexion. All patellae were resurfaced with a 3 peg polyethylene reduced thickness implant (Biomet, Inc., Warsaw, IN), a subset of implants that are 15% thinner than the standard patellar implant. All implants were cemented using Cobalt cement (Biomet, Inc., Warsaw, IN) without antibiotics. All surgeries were performed with body exhaust suits (Stryker Corporation, Kalamazoo, MI) in non-laminar flow rooms. Anesthesia consisted of a general anesthetic combined with spinal anesthesia with low-dose intrathecal preservative free morphine sulfate (0.1 mg).

*Figures 3a & 3b. Intraoperative photographs of small incision TKA procedure using the Vanguard Knee System.*

*Figure 3a. Demonstrates exposure of right knee using small incision technique. The arthrotomy was extended proximally just enough to allow the patella to fall into the lateral gutter without force. Retractors protect medial and lateral ligamentous structures.*

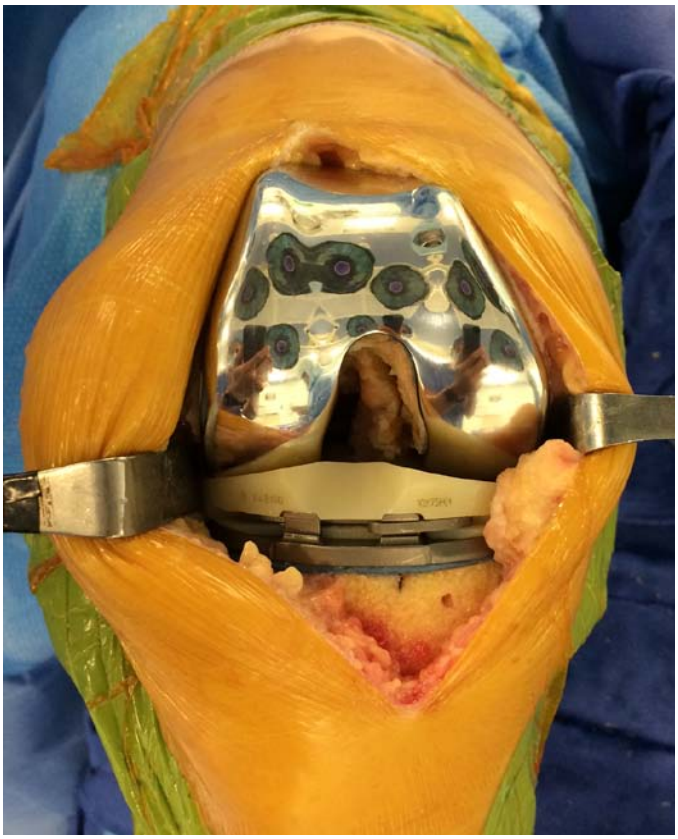

*Figure 3b. Taken after placement of TKA implants. In this case, a Vitamin E infused anterior stabilized polyethylene bearing was used. The femoral width of this patient measured 75mm. His incision length was 12cm. In this case, the incision length was 1.6x the femoral width.*

## Results

Between November 2007 and December 2013, we reviewed 415 consecutive primary TKA procedures. 58 were excluded from the study based on study criteria. 9 knees had prior medial or lateral incisions, 7 knees were excluded because a prior standard length arthrotomy was used to remove retained metallic hardware, and 42 knees required a revision or salvage hinge TKA implant system based on prior trauma and/or severe deformity.

The number of knees measured in this study was 357, consisting of 291 patients. There were 214 female cases and 143 male cases. The average age of the study group was 65.5 years (33-91). In the female group the average age was 65.8 years (33-91) and in the male group the average age was 65.2 years (33-85). The average body mass index for the study group was 31.9 (18-57). In females, the average BMI measured 32.3 (18-57). In males, the average BMI measured 31.4 (23-56).

The results of our study are summarized in Tables 1 and 2. In the study group, average incision length measured 11.1cm (7-19). In females, the average incision length measured 10.5cm (7-19). In males, the average incision length measured 11.8cm (8.5-18). The femoral width measured varied considerably. The average width for the study group was 71.1mm (57-88). In females, the average width measured 67.1mm (57-87). In males, the average width measured 76.8mm (58-88).

*Table 1 – Summary of Anthropometric Data*

| | Incision Length Average | Incision Length Range | Age Average | Age Range | BMI Average | BMI Range |
|---|---|---|---|---|---|---|
| Study | 11.1cm | 7 - 19 | 65.5 | 33 - 91 | 31.9 | 18 - 57 |
| Females | 10.5cm | 7 - 19 | 65.8 | 33 - 91 | 32.3 | 18 - 57 |
| Males | 11.8cm | 8.5 - 18 | 65.1 | 33 - 85 | 31.4 | 23 - 56 |

*Table 2 – Summary of Intra-Operative Knee Measurements*

| | Femoral Bone Width Average | Femoral Bone Width Range | Femoral Implant Size Median | Femoral Implant Size Range | Tibial Implant Size Median | Tibial Implant Size Range |
|---|---|---|---|---|---|---|
| Study | 71.1mm | 57 - 88 | 62.5mm | 55 - 75 | 71mm | 59 - 83 |
| Females | 67.1mm | 57 - 87 | 60mm | 55 – 72.5 | 67mm | 59 - 83 |
| Males | 76.8mm | 58 - 88 | 67.5mm | 57.5 - 75 | 75mm | 63 - 83 |

*Table 3 – Linear Regression Analysis of Incision Length versus Measured Parmaters*

| Factor | Correlation (0-1) | P-value | 2-Tailed Probability (<.05 is considered statistically significant) |
|---|---|---|---|
| Tibial Implant Size | 0.23023 | 0.00001 | p < .05 |
| Femoral Bone Width | 0.16937 | 0.00065 | p < .05 |
| Femoral Implant Size | 0.12754 | 0.015933 | p < .05 |
| BMI | 0.03484 | 0.255856 | p > .05 |

*Note: The R-value is a measure of how closely the data fit onto the regression line. It is a percentage of all response variable variation that is explained by the linear model. Having a low R-value that is statistically significant is still important as one can use this information to draw conclusions about how the fluctuations in the values of these variables are associated with changes in the outcome variable. Statistically significant predictors, regardless of the value of R, still reflect the mean change in the outcome variable for one unit of change in the predictor variable, while holding other variables constant that are in the model.*

Femoral implant size in the Vanguard Knee System was labeled based upon the width of the femoral component. The size options for the femoral implant ranged from 55mm to 80mm, increasing in 2.5mm increments. The median femoral implant size for the study group was 62.5mm (55-75). In females, the median femoral implant measured 60mm (55-72.5). In males, the median femoral implant measured 67.5mm (57.5-75). Tibial implant size in the Vanguard Knee System was labeled based upon the width of the tibia. The size options for the tibial implant ranged from 59mm to 91mm, increasing in 4mm increments. The median tibial implant size for the whole group was 71mm (59-83). In females, the median tibial implant measured 67mm (59-83). In males, the median tibial implant measured 75mm (63-83).

We compared incision length to several measured parameters. These parameters were analyzed using linear regression analysis and are summarized in Table 3. The scatter plot graphs are shown in Figures 4a – 4d. Linear regression analysis showed a correlating trend of incision length and femoral width (R2=0.17, p=0.00065) as well as tibial implant size (R2=0.23, p=0.00001). There was a lesser correlation with femoral implant size, but the p-value was still significant (R2=0.12, p=0.015933). There was no correlation with body mass index (R2=0.03, p=0.255856).

Using the regression equation for the parameter femoral width, we calculated a ratio of incision length to femoral width in order to determine a typical starting incision length. Beginning with the smallest femoral width measurement (55mm), we calculated the predicted incision length for each 5mm increment (55, 60…) up to 90mm. For each predicted incision length, we then calculated the ratio of predicted incision length to femoral width and then averaged the produced ratios to find one ratio for the study group. The calculated ratio for the entire study group was 1.55 times the width of the distal femur. By 5mm increments, the ratios ranged from 1.65 for the narrowest femoral width to 1.5 for the widest femoral width. From a practical standpoint, we determined that the starting incision length should be 1.6 times the width of the distal femur, measured just above the joint line. From a clinical standpoint, the best way to measure this value is to place the knee at 90° of flexion, palpate the distal end of the femur, and measure this width with a ruler.

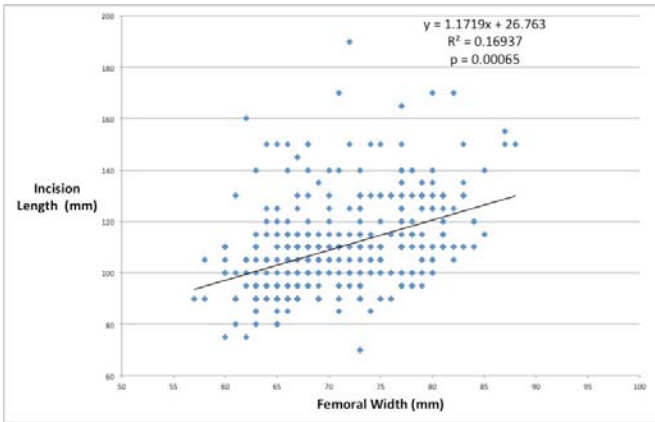


*Figure 4a.*

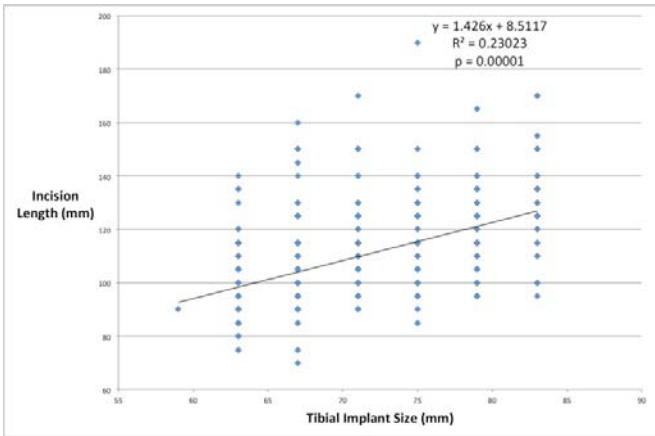


*Figure 4b.*

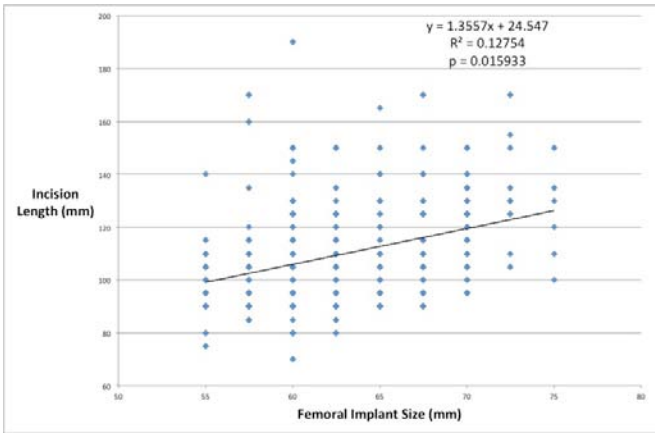


*Figure 4c.*

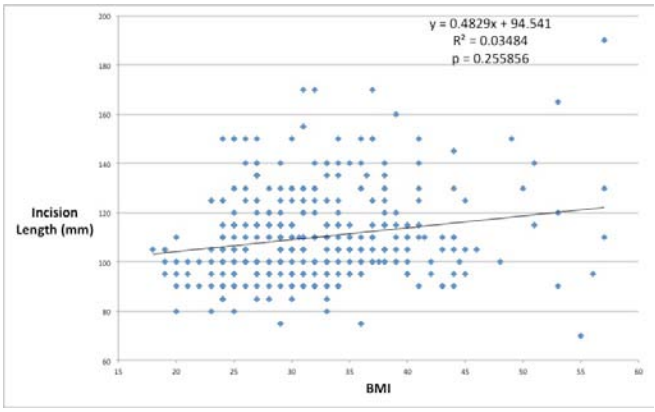


*Figure 4d.*

Pre-operatively, the average KSS score for the study group was 32.5 (0-80). Average flexion measured 114° (70-140). At a minimum of one-year follow-up (range 1-7 years), the average KSS score was 93.7 (55-100). Average flexion measured 128° (95-145). There were 17 cases which required manipulation (4.8%). All manipulations were performed between 5 to 7 weeks. There were 7 complications as a result of mild hyperextension that required a modular bearing exchange in all instances. We attribute the hyperextension deformity to cutting too much posterior slope which allowed these knees to develop hyperextension over a period of 1 to 3 years. We have since reduced the extent of our posterior slope cut. There were 6 cases of infection (1.7%) in this series. All infected patients were treated successfully with a 2-stage revision protocol utilizing an interim articulating PROSTALAC arthroplasty (prosthesis with antibiotic-loaded cement).

## Discussion

Society in general, including the United States, does place some value on the physical appearance of a surgical incision. Psychologically, a person who has a small incision perceives oneself as less "defective" or "broken." Actually, a small incision has more importance psychologically than many physicians believe. It is the arrogant surgeon who believes that a large incision does not affect the patient. In our personal reflections of patients who have undergone TKA, we not infrequently encounter patients comparing knee incisions and lamenting that they could also have a smaller incision. In regards to primary TKA, if the surgeon can perform the procedure in a technically proficient fashion and obtain similar clinical results to a larger, more extensive exposure, then it is fair to discuss the application of a small incision approach. We therefore believe there is inherent value in researching small incision technique.

In essence, this study demonstrates that incision length is most directly related to the bone width of the knee. With a wider knee, a longer incision is required to pull the soft tissues medially and laterally to expose the distal femur and proximal tibia. There was considerable variability in the scatter plot of incision lengths for a fixed femoral bone width. In fact the R-values for femoral bone width and tibial width (i.e., tibial implant size) were not strong. However, we feel that there is a correlation with the width of the knee and incision length. The R-values for femoral width and tibial implant size are 0.17 and 0.23, respectively. Although the R-values obtained were low (≥0.7 would be preferred), the p-values were highly significant and the

study group as a whole was large. This means that the R-value calculations are still useful, but there is going to be significant variability for each point value measured. This is obvious upon viewing the scatter plot data. To us, this makes sense clinically. Whenever we could not retract the arthrotomy to see the entire width of the distal femur, the incision and arthrotomy were extended to provide effective exposure of the knee.

There are several factors we observed that contributed to the wide variability seen in the incision length measurements. One main subjective factor is pliability of the soft tissue envelope. Some patients have remarkably "stretchable" soft tissues compared to others. In those cases with pliable soft tissues, the soft tissue envelope could accommodate additional retraction without risking tearing of adjacent tissues. In contrast, patients with thin, attenuated skin (for example, patients with advanced age, prednisone use, or smoking habituation) were easy to tear. Thus skin incisions were increased in such cases. Another important factor was soft tissue thickness over the patella. Some obese patients with a gynecoid body habitus carry their adipose tissue in their extremities. [11,16,40] A patient who has 5-6cm of adipose tissue overlying the patella certainly requires a longer incision compared to a patient who has 0.5cm of subcutaneous fat above his/her patella. This was definitely a drawback to this study. In retrospect, we should have measured the distance of skin to patella as one of our measured parameters. Even with this deficiency, we still found a generally linear correlation with boney knee width and incision length.

In this study we chose to measure incision length in extension rather than flexion. In a prior study we discovered that at 90° of flexion, incision length increases by approximately 22%, but there was significant variability for multiple factors including soft tissue pliability and subcutaneous thickness. [29] We felt that incision measurements in extension were reasonably consistent and permitted a more accurate comparison to measured anthropometric data.

We also found that there was a correlation with tibial implant width and skin incision. For purposes of this study we chose to not measure the width of the cut tibia. Instead, we recorded tibial implant size out of convenience. In the Vanguard Knee System, the size of the tibial implant is measured in millimeters at its maximal width. Since our surgical technique was employed to maximize coronal rim coverage, we felt that the recorded tibial implant size was a close approximation of tibial width. This is not the case with the width of the femur. The Vanguard femur is considered a universal femur, by which we mean that the implant accommodates both narrow and wide distal femurs. In wide femurs, the implant will have residual underhang. Therefore, for this study, the width of the distal femur is the more accurate parameter predicting the ultimate incision length. Since tibial implant size increased in 4mm increments, there is probably less accuracy in predicting incision length with this parameter.

There are several potential advantages of utilizing small incision technique for primary TKA. The first is a reduced exposure risk for bacterial inoculation as a small incision reduces the exposed soft tissue area. It is well known that bacteria are present in the air in an operating room. With vortex air currents, these bacteria can land into the wound and potentially cause infection. [24] In this series, our infection rate was 1.7%. We did not use antibiotic-loaded cement. We utilized IV antibiotics pre-operatively for 24 hours adhering to SCIP guidelines. [33] We attribute our reasonably low infection rate to careful technique, but we also feel that a less invasive incision was a helpful factor in keeping the infection rate low. The only way to prove a smaller incision as a factor in reducing infection rates would be to perform a randomized study comparing long and small incision techniques. This, however, would require a large number of patients and would be an arduous study to conduct.

A second advantage of utilizing a less invasive incision is that the arthrotomy length into the suprapatellar pouch is shorter. A limited disruption of the quadriceps mechanism translates to a potentially improved rehabilitation experience. [23,25,28] With the initiation of the Affordable Care Act (ACA), all surgeons have witnessed a significant reduction in the approved number of out-patient visits allowed by Medicare for physiotherapy sessions. [21,31] Those patients who cannot participate in an "accelerated rehabilitation program" will have difficulty obtaining good ultimate knee function. [18,36] In our series, our manipulation rate was reasonable, despite patients having very limited post-operative physiotherapy. Our manipulation rate was 4.8%. Furthermore, 95% of our patients went directly home. We attribute our successful functional outcomes in part to a good perioperative pain management protocol and a small incision technique. Our KSS scores and range of motion after follow-up support this claim. Our KSS scores averaged 93.7 across the study group with a minimum of one-year follow-up.

In summary, when performing a primary TKA, the surgeon should always utilize an incision length that provides him/her comfort and allows him/herself to execute the procedure correctly and efficiently. In our study, the lower limits of incision length were tested. We found that an incision length (measured in extension) that is approximately 1.6 times the width of the distal femur is a reasonable measurement to use for a small incision TKA technique. This

rule would provide a uniform starting point for the surgeon and create consistency in surgical technique. If the surgeon encounters difficulty with exposure (especially with a stiff knee with a thick subcutaneous layer) the incision should always be extended to address the exposure needs of the procedure.

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BASIC SCIENCE

# In Vitro Characterization of Lavage Splash and Effectiveness of Lavage Shield

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## Abstract

BACKGROUND: Utilization of fluid to remove debris from surgical wounds has been a standard of medical care for centuries. Electrically powered pulse lavage systems are now regularly used to flush wounds in the operating room. This study aims to characterize splash patterns and contamination generated by different irrigation techniques commonly used in the treatment of surgical wounds.

METHODS: 4 different irrigation scenarios: gravity flow (GF), asepto bulb syringe (ABS), high pressure pulsatile lavage without splash shield (HPPL), and high pressure pulsatile lavage with splash shielding (HPPL-S) were conducted on a Sawbone® knee model anchored to a standard operating table in a fully operational operating room of a community hospital. Normal saline supplemented with Fluorescein dye was utilized as the fluid. The OR was divided into 4 quadrants and surveyed with a UV light source to characterize the presence of fluorescent fluid/droplets and radius of droplet displacement.

RESULTS: The HPPL trials contaminated the entire room with droplets that were too numerous to count. The HPPL-S trials reduced the number of droplets in quadrants outside of the "head right" quadrants, to a range of 0-12 droplets. In addition, the HPPL-S trial reduced the droplet distance to levels comparable to or below the GF and ABS droplet distance.

DISCUSSION: This is the first study to characterize splash patterns seen with different irrigation systems. The addition of an inexpensive splashguard during high-pressure irrigation drastically reduced splash displacement. Decreased splash displacement theoretically reduces OR contamination and the resultant risk of nosocomial contamination.

## Introduction

The use of fluid to remove debris from surgical and/or traumatic wounds has been the standard of care for centuries. Historically, gravity-based fluid delivery systems were utilized to pour fluid from a holding vessel into an open wound to flush contamination from the operative field. Bulb syringes, pressurized by the surgeon's hand squeeze force have also been used for this purpose. More recently the use of small electrically powered mechanical pumps have become a common place method of delivering pressurized intermittent flow of liquid in order to wash contamination and debris from wounds, so called "pulse lavage" systems.

In the 1960's, the United States Department of Defense medical staff recognized wound contamination as a major cause of delayed healing in casualties injured during the Vietnam conflict [20]. The clinical application of

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pulse lavage systems in the treatment of contaminated battle wounds was the subject of several published studies [9,11,21]. Numerous studies have since reported on the application of pulse lavage systems in the civilian wound management setting. Both positive and negative reports on the merits of the civilian application of mechanical pulse lavage fluid for wound washing can be found in the medical literature since that time [5,7,10,16,18,19,24,27,30,31, 33]. These electric powered pumps have now been collectively referred to as High-Pressure Pulse Lavage (HPPL) systems. Many manufactures currently market HPPL devices [1-4].

Several reports have demonstrated the risk of nosocomial infection due to residual contamination on surfaces in hospitals [12,14,28,29]. Known high-risk nosocomial infection pathogens including methicillin resistant Staphylococcus aurous (MRSA), vancomycin resistant Enterococcus species (VRE), Clostridium difficile spores, Pseudomonas species, Actinobacter species and Norovirus have been shown to survive on dry surfaces for up to 5 months [26,34]. Guidelines have been published on the proper cleaning of hospitals and their contents [32]. In spite of these measures, nosocomial infections continue to have a major impact on morbidity, mortality and increased medical related costs [23].

To date no study has evaluated the contamination caused to the surrounding physical space, equipment/furniture and surfaces of the operating room through the use of any irrigation system. Our goal is to compare the spread of fluid from the surgical field into the surrounding room when various irrigation systems are employed. Additionally, we will demonstrate a simple method to reduce splash back and subsequent contamination through the use of an inexpensive disposable physical splash barrier.

## Materials and Methods

To characterize splash patterns of various irrigation methods we measured splash distance, volume of irrigation fluid "lost" during the procedure, and the patterns of contamination. To do so, we have chosen four common methods of intraoperative irrigation systems including: gravity flow (GF), asepto bulb syringe (ABS), high-pressure pulsatile lavage (HPPV), and high-pressure pulsatile lavage with splash shielding (HPPV-S). Six experimental iterations were preformed.

Trial #1: Gravity Flow (GF): Simulation of gravity-based irrigation for wound cleansing. A 1L stainless steel pitcher was used to pour irrigation fluid over the knee model from a distance of 15cm. Force of the irrigation was gravity based. The simulation surgeon was instructed to irrigate the knee model through a gentle wrist turning maneuver with the pitcher positioned directly above the model.

Trial #2: Asepto Bulb Syringe (ABS): A bulb syringe irrigation simulation was evaluated. The bulb syringe is generally considered a low-pressure method of cleansing a wound. This experiment used a 50ml Davol® plastic and rubber surgical bulb syringe. The simulation surgeon was instructed to irrigate the knee model with the bulb syringe from a distance of 15cm directly over the knee model.

Trial #3 and Trial #4: High-pressure pulse lavage without splash shield (HPPL): To investigate the splash generated by high-pressure irrigation systems, two different commercial systems were utilized, the Stryker® InterPulse (Stryker) and the Davol® Simpulse SOLO High Flow Tip (Davol). Irrigation of the knee model with each respective HPPL system was conducted from a distance of 15cm above the knee model.

Trial #5 and Trial #6: High-pressure pulse lavage with splash shield (HPPL-S): A simple splash shield device was utilized with both of the HPPL systems in separate trials. A radiographic plastic cassette cover 60cm by 120cm was fashioned into a splash barrier by cutting away one of the sealed corners, creating an opening through which the HPPL system could then be inserted. The shield was tented about the knee model and the HPPL systems were again used to simulate irrigation 15cm above the knee model.

A Sawbone® right knee model with elastic cording as the knee joint served as the experimental model in an operational operating room (OR) of a community hospital actively engaged surgical management of patients in all surgical subspecialties. The contents of the OR were removed with the exception of the anesthesia equipment, the surgical table and the fixed overhead lighting system. The OR had been terminally cleaned per standard protocol and had been out of service for 18 hours prior to this experiment. The walls were then covered with Husky® 2 mm clear plastic sheeting from ceiling to ground, using adhesive tape at the ceiling to hold the sheeting up. The anesthesia equipment, at the head of the surgical table was draped in a similar fashion. The surgical table padding was removed and the table was then covered with Husky® 2 mm plastic sheeting that reached the floor. The OR floor was covered with standard white fabric sheeting, obtained from the facility central supply. After initial OR preparation and between each trial iteration, the area was surveyed with the UV light source and confirmed that no visible contamination was present. The floor sheeting was changed following each trial in order to ensure the area was free of residual fluorescent splatter contamination. The plastic

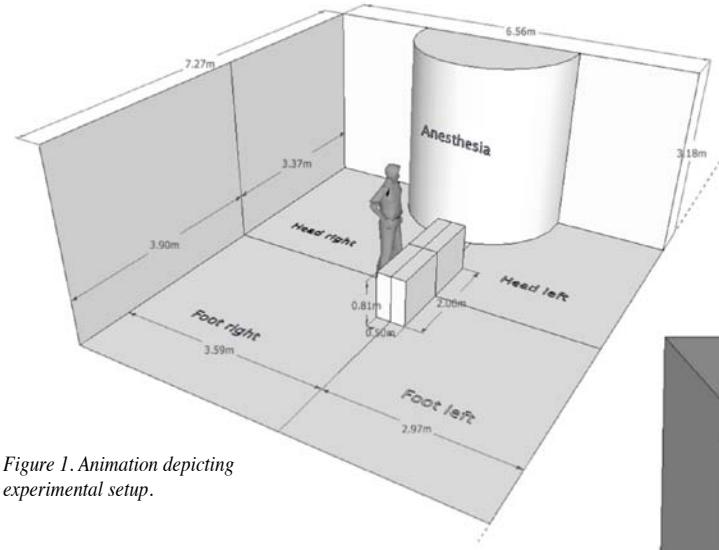


*Figure 1. Animation depicting experimental setup.*

wall coverings were wiped clean under UV inspection to ensure the walls were also free of residual fluorescent splatter contamination between each trial.

The dimensions of the room were measured as noted in Figure 1. Each experimental trial was performed in the same operating room. The surgical table used was an Amsco® 3085 SP with a length of 200cm and width

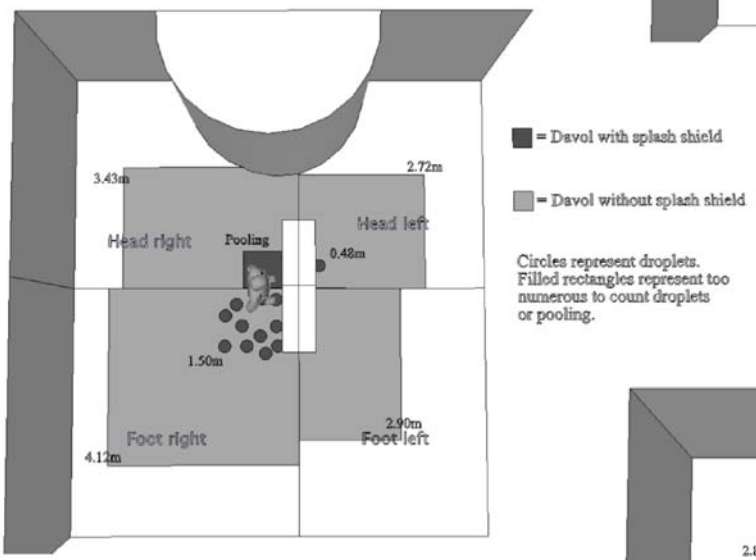


*Figure 2. Animation characterizing droplet pattern and maximum droplet displacement in four experimental quadrants for Gravity flow trial and Asepto Bulb Syringe trial.*

of 50cm and set at a height of 81cm which was constant throughout all trial iterations. The experimental quadrants of the room divided into patient's head left (HL), patient's head right (HR), patient's Foot Right (FR), and patient's Foot Left (FL) (Figure 1). The surgeon was positioned on the table's right side at mid table during all trials. The knee model was attached to the surgical table with the use of a clamp and flexed to 100 degrees. The knee model was positioned on to mimic the left knee of a supine patient. The two over-head surgical lights with a diameter of 58.4 cm were positioned directly over the head of the bed and at the foot of the bed, angled 45 degrees directed towards the knee model. Each light was positioned 90 cm above the table at its lowest point.

Study participants consisted of a simulation surgeon and an observation team of 6 persons. The simulation surgeon wore a standard surgical hood, Stryker® T5 "Personal Protection System" and a Kimberly Clark Standard surgical gown, latex surgical gloves and fluid impervious protective boots. Clean disposable surgical shoe covers were worn and changed by observation team upon entering/exiting OR.

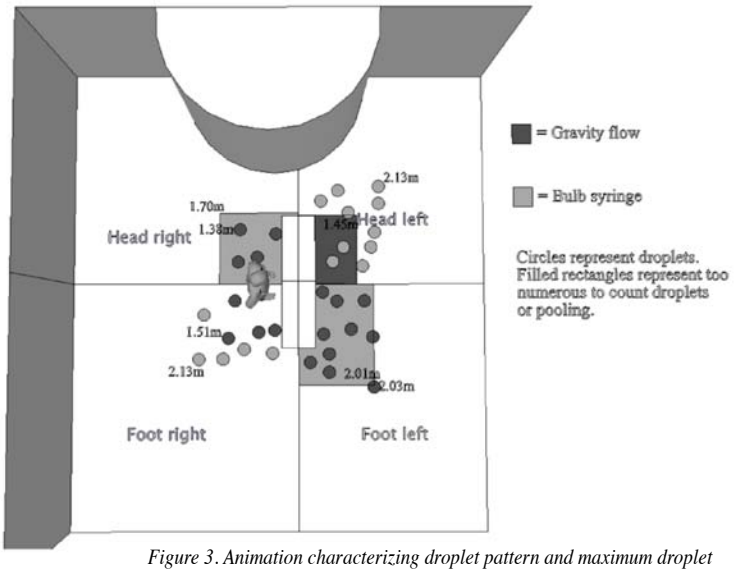


*Figure 3. Animation characterizing droplet pattern and maximum droplet displacement in four experimental quadrants for Davol® Simpulse SOLO High Flow Tip high-pressure pulse lavage with and without splash shield.*

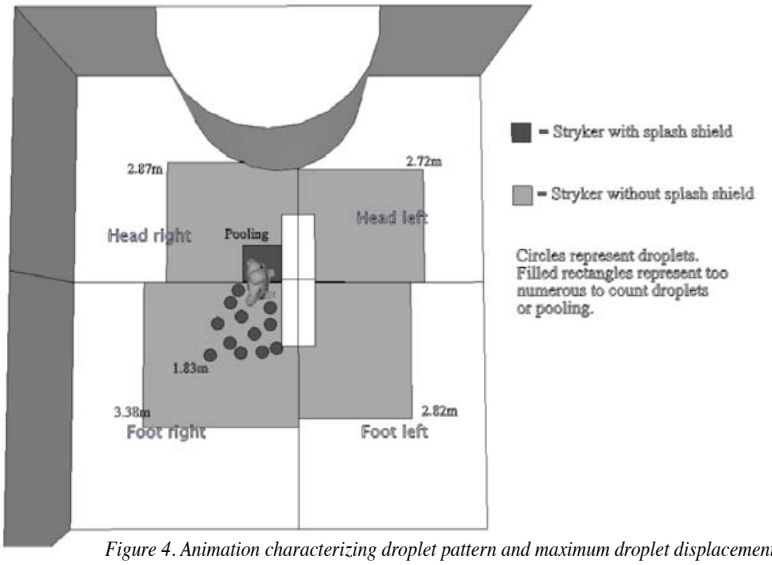


*Figure 4. Animation characterizing droplet pattern and maximum droplet displacement in four experimental quadrants for Stryker® InterPulse high-pressure pulse lavage with and without splash shield.*

To trace the irrigation fluid during all experimental models, a fluorescent chemical marker (uranine dye, yellow 73, CAS No 518-47-8, Trace-A-Leak®) was added to the irrigation and used during all iterations. 2.5 tablets of florescent dye were dissolved in 10 liters of tap water at 25C. An ultraviolet (UV) light source (a hand held lamp with 13 watt compact florescent light black light) was utilized to effectively illuminate this fluorescent liquid. A "splatter droplet" was defined as fluorescent liquid outside of the collection vessel and visible to all observers under the UV light source. The splattered liquid droplets were evaluated for number per quadrant and maximum distance from the center of the knee model.

A plastic 6-liter basin was positioned beneath the flexed knee model as a collection vessel, to gather the fluid after the irrigation simulation had washed over the knee model. The amount of fluid experimentally irrigated during each cycle was measured by mass and converted to milliliters (mL) using the density of water (1g/ml). Each trial consisted of 3Kg of the fluorescent dye-containing fluid. An electronic scale, manufacturer OXO®, was used for mass measurement. The mass of fluid was measured prior to each irrigation trial and adjusted to exactly 3Kg. The mass of collected fluid was then measured after each trial. The net difference between pre and post trial mass was assumed to be fluid lost. Fluid not gathered in the collection vessel but pooled on the table was not measured directly. Fluid splattered into the OR was evaluated by the quadrant method previously described.

## Results

The data collected from each trial is supplied in Table 1. The data collected includes: initial weight of irrigation in mL, recovered weight of irrigation in mL, fluid lost in mL (difference from initial and recovered irrigation), surgeon splash pattern, number of droplets in quadrant (HR, HL, RF, LF), and furthest droplet in quadrant distance (HR, HL, RL, LF).

### *FLUID LOST*

The gravity flow had the least amount of fluid lost at 47 mL whereas the Stryker® InterPulse without splash shield had the most fluid lost at 869 mL. In comparing the Styker without splash shield to the Davol without splash shield, an additional 366 mL of irrigation was lost (869 mL vs. 503 mL), an amount that cannot be accounted for by a change in methods and likely due to differences in engineering specifications of the HPPL. The addition of the splash shield drastically reduced fluid lost in both the Stryker with splash shield and the Davol, comparable to the ABS trial (222 ml vs. 209 ml vs. 248 ml, respectively).

### *QUADRANT DROPLET NUMBERS*

The number of droplets in the quadrants varied with each trial (Table 1). With exception of the gravity flow trial, most trials had frank pooling in the HR quadrant at the feet where the surgeon stood. Frank pooling was also noted at the RF quadrant during the asepto bulb syringe trial. The HPPL without splash shield contaminated the entire room with droplets that were too numerous to count. The HPPL-S trials reduced the number of droplets in quadrants, outside of the HR quadrants, to a range of 0 to 12 droplets.

### *DROPLET DISTANCE TRAVELLED*

The furthest distance droplets travelled in the quadrant was more predictable. The gravity flow trial furthest droplet distance ranged from 138 cm in the HR quadrant to 201 cm in the LF quadrant. The asepto bulb syringe trial droplet distance ranged from 170 cm in the HR quadrant to 213 cm in both the HL and RF quadrants. The HPPL trials droplet distance ranged from 272 cm (HL) to 412 cm (RF). Droplets were recorded on the overhead light positioned above the patient's head (Stryker: 2 droplets, Davol: 20 droplets). 15 droplets were recorded on the elbow of the overhead light fixture (Stryker). On the plastic sheeting covering the anesthesia equipment, there were 5 droplets recorded at a maximum height of 179 cm during the Stryker trial and too numerous to count during the Davol trial at a maximum height of 122 cm. The HPPL-S reduced the droplet distance to levels comparable to or below the gravity flow and asepto bulb syringe droplet distance with no contamination of anesthesia equipment or overhead lights. The Stryker with splash shield droplet distance ranged from 0 cm (HL and LF) to 183 cm (RF). The Davol with splash shield droplet distance ranged from 0 cm (HR and LF) to 150 cm (RF).

## Discussion

Operative site lavage is an effective, regularly used intraoperative procedure with wide surgical application. Advancement in technology of lavage systems has produced more effective means of wound debridement and decontamination. It has become common practice for orthopedic surgeons to utilize these technologies in many procedures such as septic joints, abscesses, and osteomyelitis in addition to aseptic procedures such as total joint arthroplasty and open reduction internal fixation. Although the positive and deleterious effects of operative site lavage have

*Table 1. Raw data depicting droplet counts and distance during gravity flow, asepto bulb syringe, high-pressure pulsatile lavage (Stryker pulse lavage and Davol Simpulse), and high-pressure pulsatile lavage with splash shielding (Stryker pulse lavage and Davol Simpulse).* During trial, the sound of splashing against the plastic sheeting could be heard in hall. 2 droplets were recorded on the backside of the overhead light positioned above the patient's head. 15 droplets were recorded on the elbow of the overhead light fixture. 1 droplet was recorded on the video recorder's device. On the plastic sheeting at the head of the surgical table, covering the anesthesia equipment, there were droplets that were too numerous to count with the highest droplet recorded at 179 cm.** During trial, 5 droplets were recorded on the plastic sheeting covering the anesthesia equipment with the highest particle at 122 cm. 3 droplets were recorded on the face of the overhead light above the patient's feet. 20 droplets were recorded on the face of the overhead light above the patient's head.*

| | Initial weight of irrigation (milliliters) | Recovered weight of irrigation (milliliters) | Fluid lost (milliliters) | Surgeon splash pattern | Head right droplet number | Head right droplet distance (cm) | Head left droplet number | Head left droplet distance (cm) | Foot right droplet number | Foot right droplet distance (cm) | Foot left droplet number | Foot left droplet distance (cm) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Gravity flow from 15 cm | 3000 | 2953 | 47 | 25 droplets on anterior right | 4 | 138 | Too numerous to count | 145 | 4 | 151 | 10 | 201 |
| Asepto bulb syringe from 15 cm | 3000 | 2778 | 222 | 10 droplets bilateral feet, 3 droplets chest, 10 droplets bilateral gloves | Frank pooling | 170 | 10 | 213 | Frank pooling | 213 | 5 | 203 |
| Stryker pulse lavage interpulse without splash shield * | 3000 | 2131 | 869 | Too numerous droplets throughout gown, exhaust hood and face shield, gloves, pooling at bilateral feet | Too numerous to count, frank pooling | 287 | Too numerous to count | 272 (On wall) | Too numerous to count | 338 | Too numerous to count | 282 |
| Stryker pulse lavage interpulse with splash shield | 3000 | 2791 | 209 | Too numerous droplets on right arm, right axilla, and frank pooling on right foot | Frank pooling | 137 | 0 | 0 | 12 | 183 | 0 | 0 |
| Davol the Simpulse solo system without splash shield ** | 3000 | 2497 | 503 | Too numerous droplets throughout gown, exhaust hood and face shield, gloves, pooling at bilateral feet | Too numerous to count, frank pooling | 343 | Too numerous to count | 272 (On wall) | Too numerous to count | 412 | Too numerous to count | 290 (On wall) |
| Davol the Simpulse solo system with splash shield | 3000 | 2752 | 248 | 5 droplets on right arm, frank pooling at right foot | Frank pooling | 0 | 1 | 48 | 10 | 150 | 0 | 0 |

been well characterized in the literature, there is a paucity of data investigating contamination of the intraoperative surrounding environment due to lavage back splash. Several reports have demonstrated the risk of nosocomial infection due to residual contamination on surfaces in hospitals [12,14,28,29]. With risk of splash back from lavage and subsequent surrounding surface contamination, investigation of OR contamination with different lavage systems is warranted. The current investigation characterizes the splash pattern and resultant OR contamination of GF, ABS, HPPL, and HPPL-S lavage techniques. The resultant data effectively demonstrates that among all trials, HPPL trials demonstrated the highest contamination and fluid loss, whereas the addition of a splash shield to the HPPL exhibited the least amount of surrounding contamination and a drastically reduced fluid loss.

Historically, low-pressure devices including gravity based fluid delivery systems and hand pressured bulb syringes have been used to flush contamination from the operative field. More recently, utilization of small electrically powered mechanical pumps (HPPL) has become a commonplace method of delivering pressurized inter-

mittent flow of fluid in order to wash contamination and debris from wounds. HPPL systems have been shown to have positive long-term effects on bacterial reduction and wound infection [10,22]. HPPL is a more effective method of irrigation to overcome bacterial soft tissue adherence than low-pressure systems such as gravity flow and bulb syringe methods [8,30]. Although many beneficial effects of HPPL systems have been documented, there have been studies that have documented deleterious effects of these systems including significant delays of early bone healing in comparison to conventional syringe [15]. In addition, Bhandari et al showed that HPPL resulted in bacterial propagation inside the intramedullary canal of a fractured tibia up to 4 cm from the fracture site [6]. The purpose of this study was not to characterize effectiveness of wound decontamination with each lavage technique; but rather, to illustrate dramatically different splash patterns of lavage techniques. With the continued use and development of HPPL systems, it is important to recognize that among all techniques tested, HPPL systems resulted in the greatest amount of OR environment contamination and fluid lost. With the use of a simple splash shield, we were able to drastically reduce splash amount, splash distance, and fluid lost. Although the effectiveness of a splash shield on in vivo intraoperative splash reduction has not been studied, we speculate that this could result in a significant reduction in OR environmental contamination and subsequent nosocomial infection.

It has been widely accepted that environmental contamination plays an important role in the transmission of pathogens such as Methicillin-Resistant Staphylococcus Aureus (MRSA), vancomycin-resistant Enterococcus species (VRE) species, Clostridium difficile spores, Pseudomonas species, Actinobacter species and Norovirus in the hospital setting. These known high-risk nosocomial infection pathogens have been shown to survive on dry surfaces for as long as 5 months [26,34]. With many infected operative cases per week, one can see how this may easily add up to a highly contaminated surgical suite if not appropriately addressed. Improved surface decontamination has been shown to decrease environmental contamination of MRSA and VRE [17] and decrease the likelihood of patients acquiring VRE [25] and developing MRSA infections [13]. There continues to be a much-needed emphasis placed on primary preventative measures of infection such as hand washing, proper sterile technique, and specific airflow patterns in operating rooms. However, the current data clearly demonstrates the significance of OR contamination, particularly with use of HPPL, and therefore the inferred increased risk of contamination to health care workers and patients that are in cases "to follow". The data presented here clearly demonstrates a need for greater emphasis on preventing OR contamination via surgical site splash back with methods such as the lavage shield. Further in vivo investigations are warranted to elucidate the potential beneficial effect on reducing pathogen dissemination with the use of these techniques.

We recognize there are weaknesses of this study. We used an artificial model, the Sawbone® knee, without normal tissue wound complexities and angled surfaces. The typical soft tissue envelope acts somewhat as a barrier in itself. The amount of fluid lost was very likely more extensive than one would have seen with an actual wound. We chose the Sawbone® model to act as an approximation and to avoid contamination of an OR in-service during unscheduled time. Another weakness was the sampling size. We completed each method only once and we recognize greater precision of data and statistical power can be created across multiple trials during each testing scenario. Nevertheless, we feel the controlled environment and rigorous execution of this study effectively demonstrates a characterization of splash patterns. The results of repeated trials under these testing circumstances are still yet to be seen. Lastly, splash patterns of normal saline with fluorescence serve as simulation for what occurs within actual surgery. We recognize that blood and contaminated irrigation fluids may not travel in the same manner due to different densities and droplet heterogeneities. Further in vivo investigations are needed to characterize these dynamic parameters.

This study illustrates splash patterns seen with both high-pressure and low-pressure irrigation systems that are utilized today. With the use of an inexpensive splash guard during high-pressure irrigation, we were able to drastically reduce splash displacement with this trial. Decreased splash displacement could theoretically reduce operating room contamination and resultant nosocomial operative site contamination and translate to lower infection rates, shorter hospital stays, and ultimately to substantial financial savings. Currently, the impact of splash shield use during operative site irrigation on infection rates is unclear. However, we hypothesize that the benefits will substantially outweigh the cost.

***Acknowledgments***

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Anazonwu [1]; Tuttle [1]; Rubin [1]

Article 2, page 20.
Murphy [1]; Fraser [1]; Mihalko [1]

Article 3, page 24.
Waterman [1]; Minter [1]; Ghattas [1]; Green [1]

Article 4, page 29.
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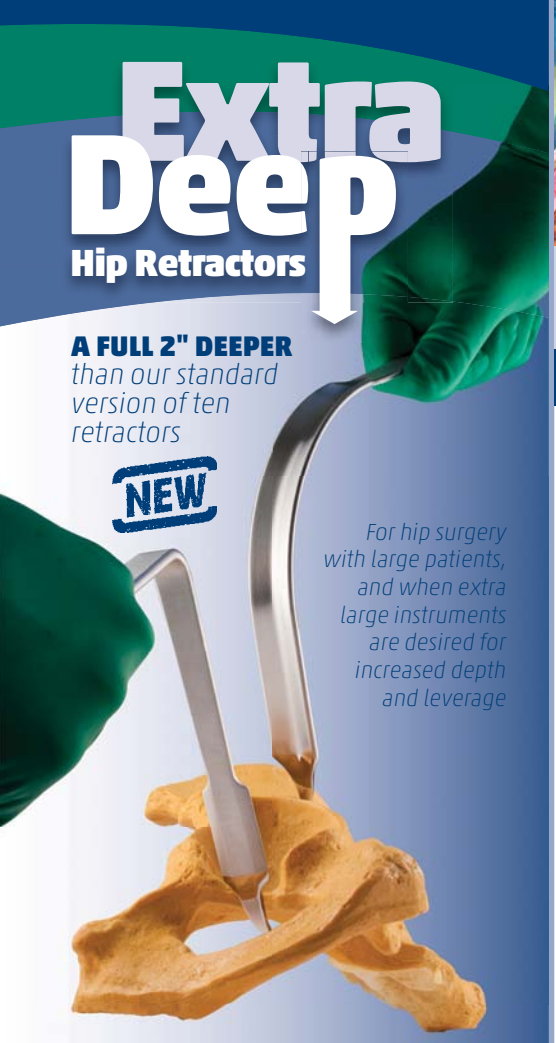

Extra Deep Single Prong Soft Tissue Retractor
***Product #6450-01***

Extra Deep Mueller-type Femoral Neck Elevator
***Product #3418***

Extra Deep Single Prong Acetabular Retractor
***Product #6570-01***

Extra Deep Modified Hohmann Retractor
***Product #4535-01***

Extra Deep Modified Wide Hohmann Retractor
***Product #6595-01***

Extra Deep Long Narrow Blunt Hohmann Retractor
***Product #4540-01***

Extra Deep Bent Hohmann Retractor
***Product #7115-03***

Extra Deep Modified Blunt Hohmann Retractor
***Product #4550-01***

Extra Deep Large Cobra Retractor
***Product #7630-03***

Extra Deep Hohmann Retractor
***Product #4558-01***

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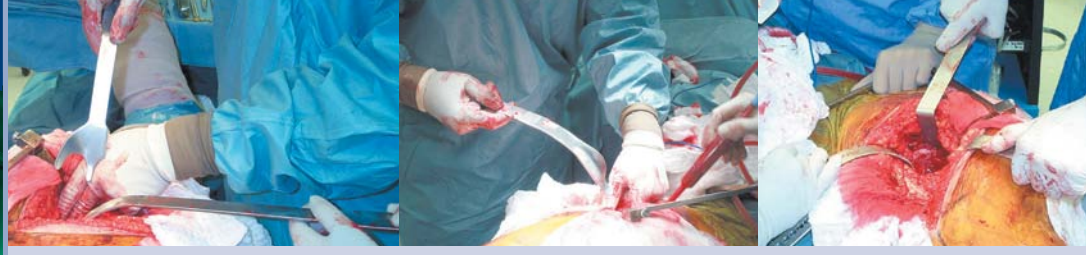
Extra Deep Mueller-type Femoral Neck Elevator modified by Tom Eickmann, MD



# Extra Large Hip Retractors

*For hip surgery with large patients and when extra large instruments are desired for more depth and leverage*

Designed by Wayne Goldstein, MD

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## *Large Cobra Retractors*

| PRODUCT NO'S: | |
|---|---|
| 7630-01 [Standard] | *Overall Length: 17.5" Handle Length: 14"* |
| 7630-02 [Wide] | *Overall Length: 17.5" Handle Length: 14"* |

## *Infero-posterior Acetabular Capsule Retractors*

| PRODUCT NO'S: | |
|---|---|
| 7620-01 [Right] | *Overall Length: 12" Handle-to-Bend Length: 6"* |
| 7620-02 [Left] | *Overall Length: 12" Handle-to-Bend Length: 6"* |

## *Extra Leverage Proximal Femoral Elevator*

| PRODUCT NO: | |
|---|---|
| 7640 | *Overall Length: 17.5" Handle Length: 13" Blade Width at Widest: 63mm* |

## *Extra Leverage Femoral Neck Elevators*

| PRODUCT NO'S: | |
|---|---|
| 7650-02 [Short Handle] | *Overall Length: 15.25" Handle Length: 6.25" Blade Width: 38mm* |
| 7650 [Standard] | *Overall Length: 18.25" Handle Length: 9.25" Blade Width: 38mm* |

## *Large Soft Tissue Retractors*

| PRODUCT NO'S: | | |
|---|---|---|
| 7670-01 *Blade Depth: 3" Blade Width: 50mm Handle-to-Bend Length: 10.5"* | 7670-02 *Blade Depth: 3.5" Blade Width: 50mm Handle-to-Bend Length: 10.5"* | 7670-03 *Blade Depth: 4" Blade Width: 50mm Handle-to-Bend Length: 10.5"* |

## *Deep Cobra Retractors*

| PRODUCT NO'S: | |
|---|---|
| 6135 [Standard] | *Overall Length: 14.5" Blade Width at Widest: 33mm* |
| 6135-L [Lighted] | *Overall Length: 14.5" Blade Width at Widest: 33mm* |

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## *Extra Large Hibbs Retractor*

| PRODUCT NO'S: | |
|---|---|
| 6230 [Extra Large] | *Overall Length: 14.25" Handle Length: 13" Blade Depth: 6.5" Blade Width: 38mm* |

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