ON-Q
PAIN RELIEF SYSTEM

California Orthopaedic Association

2018 Annual Meeting & QME Course
June 1, 2018

Daniel Matthews, MD
Alabama Orthopaedic Sports Medicine

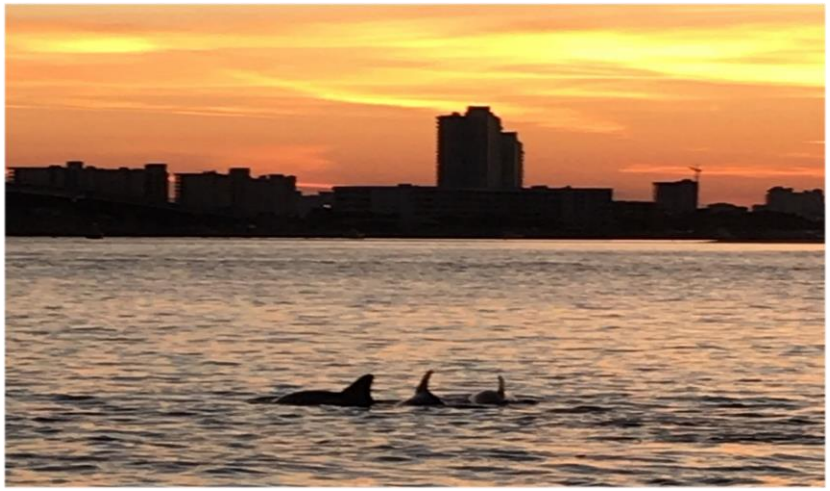
ON-Q®
PAIN RELIEF SYSTEM

Acute Pain
Perioperative Management

Daniel Matthews, MD

AOSM
Alabama Orthopaedic Sports Medicine

Greetings from LA (Lower Alabama)



We have some of the best fishing in the world

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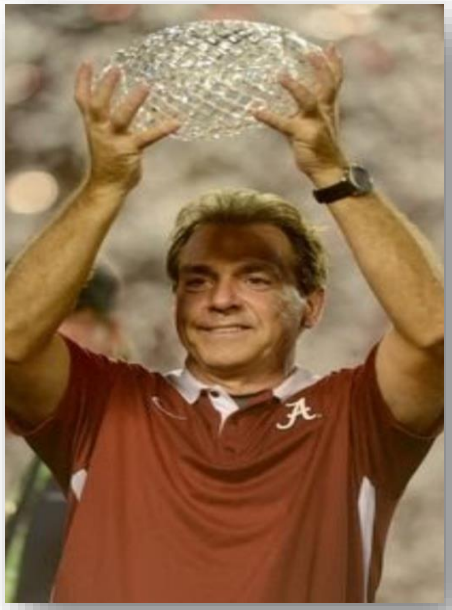
Lower Alabama…we love to do football



And we love to be innovative in our patient care

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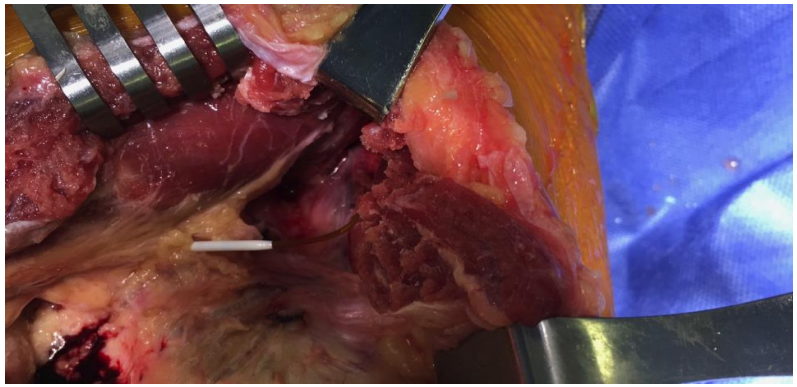

Disclosures

- Halyard Health, Inc. is sponsoring this presentation, and I am being compensated by Halyard to make this presentation.
- The information provided in this presentation is intended for health care professionals and is intended for training and education purposes.
- For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the IFU for the respective product(s).
- The information provided in this presentation represents my surgical technique. Surgical techniques can vary depending on the individual expertise, experience, and school-of-thought of the physician utilizing the respective product(s).

How did we get here?

Despite ongoing reform efforts over the past 5 decades, the U.S. expenditures on healthcare as a percentage of GDP are still rising.[1]

Where have we been?

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History of Solutions

1960s	**CON (Certificate of Need)[2]**
1970s	**DRG (Diagnostic Related Groups)[3]**
1970s – 1990s	**HMO/Managed Care[4]**
2013	**BPCI[5]**
2016	**Initiation of "Value Agenda"[6]**
April 1, 2016	**CJR[7]**

Where are we now?

Value Agenda

Redefining Health Care

The Strategy That Will Fix Health Care 2013[8]
by Michael E. Porter and Thomas H. Lee
originally introduced in 2006, book published by Michael Porter and Elizabeth Teisberg

"Inadequate, unnecessary, uncoordinated, and inefficient care and suboptimal business processes eat up at least 35%— and maybe over 50%—of the more than $3 trillion that the country spends annually on health care. That suggests more than $1 trillion is being squandered."[9]

"Under the prevailing fee-for service and per case payment methods, health care providers don't get the savings generated by their efforts to reduce waste, which undermines their financial health and their ability to invest in programs that cut costs by improving quality." [9]

Bundled payments will finally unleash the competition that patients want.

"We need a better way to pay for health care—one that rewards providers for delivering superior value to patients." [10]

Comprehensive Joint Replacement (CJR)

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Overview

- CMS has chosen Orthopaedic procedures as the first step in this incremental change to our Healthcare delivery model.
- First focus is on **lower extremity joint replacement** surgery including TKA, THA, and Ankle Arthroplasty.[11]
- Formally and currently, Surgeons were and are paid for performing a surgery and providing pre-op and post-op care under a global payment DRG, in a fee for service model.
- Other providers, Hospital, Therapy, Rehab Facilities (inpatient and outpatient) and home health agencies are all paid separately.

Comprehensive Joint Replacement (CJR)

ON-Q® PAIN RELIEF SYSTEM

Overview

In the new CMS: Comprehensive Joint Replacement Program

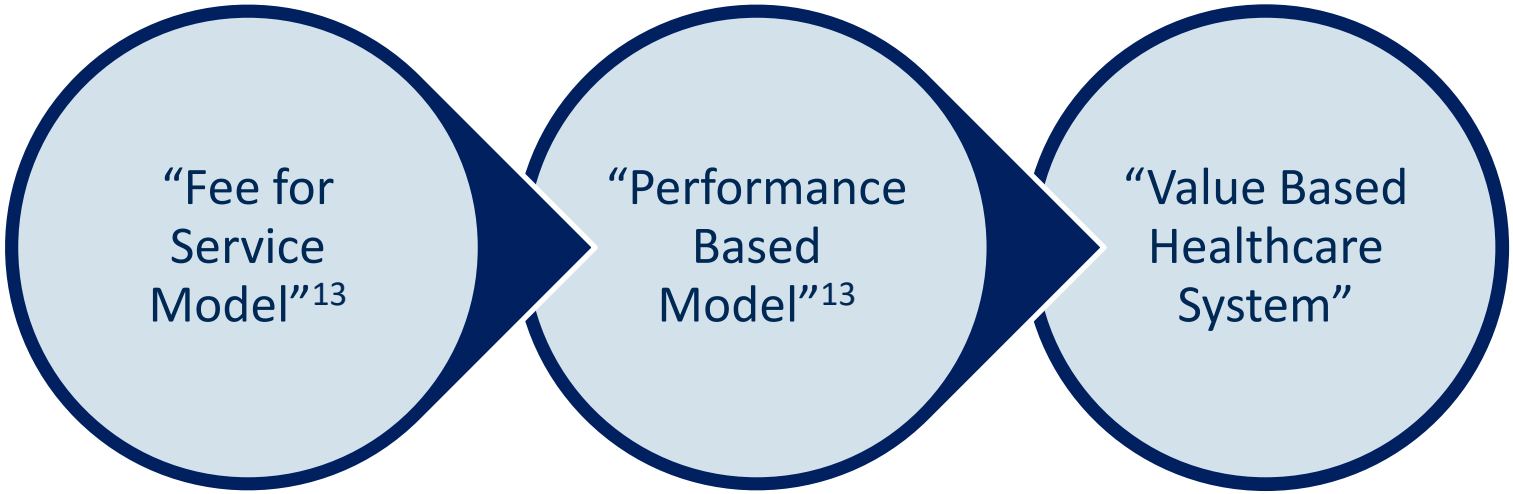
- ALL payments for the episode of care (90 days from index procedure, i.e. DRG 469, 470) will be paid in a **SINGLE BUNDLE PAYMENT**[12]
- Payment of the bundle will also depend on a **QUALITY SCORE**[11]

Quality Score

CJR participants Quality Score[12]

- 50% Hospital Complication Rates
- 40% HCAHPS score
- 10% Additional Voluntary data from the Hospital

BPCI/CJR – A Fundamental Change



While still in transition and not complete at this time…
The transformation is well underway.

Opioid Epidemic in the United States[14]

Sources: [1] 2015 National Survey on Drug Use and Health (SAMHSA). [2] MMWR. 2016; 65(50-51):1445–1452 (CDC). [3] Prescription Overdose Data (CDC). [4] Heroin Overdose Data (CDC). [5] Synthetic Opioid Data (CDC). [6] The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Florence CS, Zhou C, Luo F, Xu L. Med Care. 2016 Oct;54(10):901-6.

American Academy of Orthopaedic Surgeons[15]

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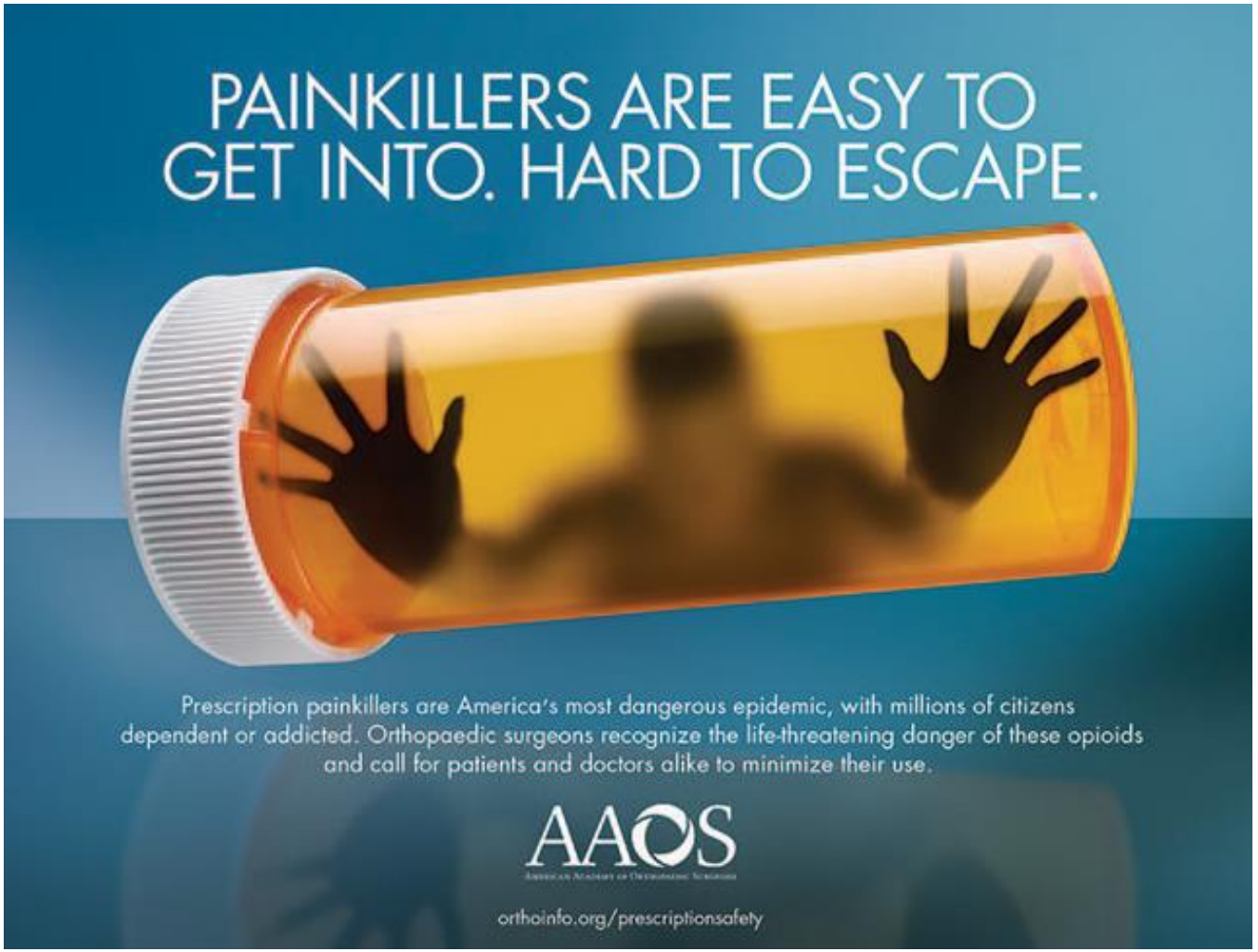
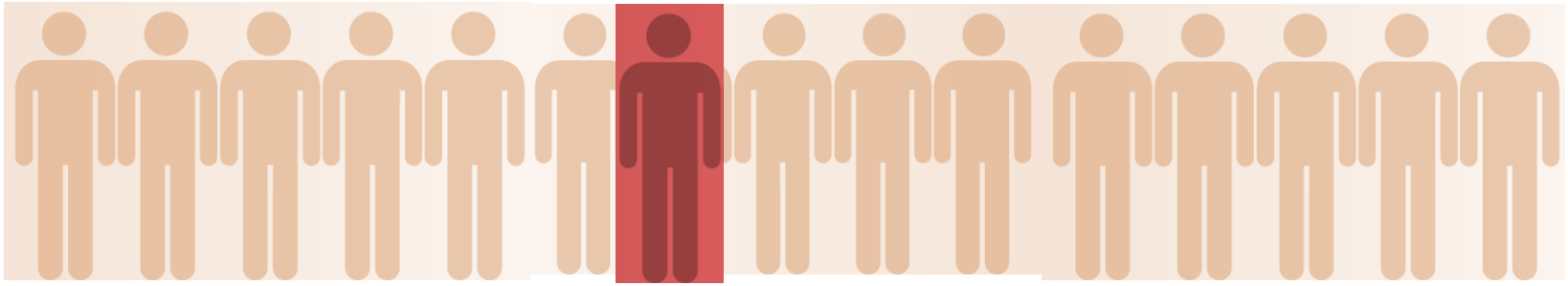


Perioperative Opioid Epidemic

- Greater than 70 million patients are prescribed opioids for postsurgical pain management.[16]
- 1 in 15 go on to long term use or abuse[17,18]



- New opioid users are coming from acute care setting

Where are we going?

Breaking News: TKA removed from CMS IPO list (11/15/17)

CMS proposal represents critical initiative to provide best care possible

by Anthony A. Romeo, MD


Anthony A. Romeo

The *Federal Register* recently published a CMS notice about potential changes to the inpatient-only list for surgical procedures. CMS has proposed the removal of total knee arthroplasty from the inpatient-only list. In addition, CMS asked for comments on the removal of partial and total hip arthroplasty from the inpatient-only list and its addition to the ambulatory surgery center covered surgical procedures list.

According to the CMS proposal, in 2018 appropriately selected Medicare patients who would benefit from total knee arthroplasty (TKA) will have the option of having the procedure performed in an outpatient setting. More than 400,000 TKA and total hip arthroplasty (THA) procedures are performed on Medicare patients each year.

Outpatient TKA and THA has been performed for almost 2 decades by innovative surgeons, but the CPT codes have remained on the CMS inpatient-only list. Some surgeons have worked around this requirement for Medicare patients by performing surgery in the hospital, admitting patients to the hospital, and then discharging later the same day. Once CMS officially removes TKA from the inpatient-only list, it is likely all insurance companies will allow TKA to be performed in the outpatient setting. During the next few years, it is also anticipated that CMS will remove the inpatient-only list status of other total joint arthroplasty (TJA) procedures, including shoulder and elbow, as well as many routine spine procedures.

Tipping point

This decision is a tipping point for orthopedic surgical services and the entire ambulatory surgery center service (ASC) line. This relatively small shift in hospital-based procedures has created a seismic shift in the outlook for hospitals and hospital-based care. For decades, hospitals have regarded inpatient surgical services as the key component for financial stability and revenue. The most lucrative part of surgical service lines is typically orthopedic care, with an average of $2.7 million of revenue per orthopedic surgeon based on a Merritt-Hawkins survey of hospital chief financial officers.

The landscape for the future of surgical care, especially orthopedic care, will be disrupted by the removal of joint replacement procedures from the

▸ Proposal continues on page 8

Healio.com/Orthopedics
Orthopedicstoday®

Anthony A. Romeo, MD
Chief Medical Editor

MUSCULOSKELETAL ONCOLOGY SPINE

Where are we today?

- BPCI/CJR
  - New payment model
- Opioid epidemic
  - A growing concern
- Outpatient Joint Arthroplasty
- Outcomes
  - CMS Quality Scores / HCAHPS

So how do we avoid disaster?

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AOSM Comprehensive Plan

TJA Program - “Overnight Outpatient”
Pre-operative
OR Time Efficiency
Turnover Time
Operative Time
Blood Management
DVT Prophylaxis
Pain Management
Implants
OUTCOMES
ON-Q* TRAC

Pain Management

Narcotics?

Post-surgical Opioid Use

- Prolonged use is the number one cause of post operative complications[19]
- Common source of dizziness/urinary retention/respiratory depression/Nausea/Emesis[20]
- Pain is among the primary reasons for hospitalization after TKA.[21] Non-opioid analgesia associated with reduced LOS by 1-2 days.[22]

AOSM Action Plan

- Intra-op
- OR Efficiency
- Blood Management
- Pain Management (3 phase Plan)
  - **Pre-op medication (NSAID, Narcotic, GI protector, nausea)**
  - **Intraoperative management**
    - **Plasma Blade (literature support, anesthesia observance)**
    - **Intra-op Capsular injection cocktail (introduced in 2005)**
  - **Postoperative management**
    - **Selective Regional anesthetic blocks, by Anesthesia**
    - **Surgeon placed adductor block I initiated in early 2016**
    - **Surgeon Placed Continuous Adductor /Saphenous Nerve Block using the ON-Q pain pump (late 2016)**
- DVT Prophylaxis
- Inpatient Care
- Post op Care
- Reduction of Readmissions and ED visits
- Outcomes

Pain Management All Arthroplasty: Phase 1

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Pre-op Management
All Arthroplasty (TKA, THA, TSA, RTSA)

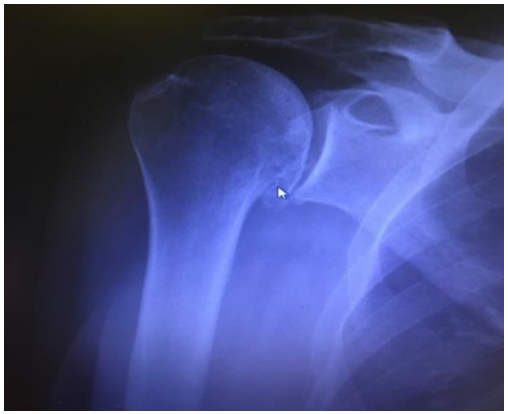
- NSAID Cox 2
- GI Protective
- Opioid
- Anti nausea

Pre-op Management
Shoulder Arthroplasty

- **Pre-op Anesthesia**
  - Inter-scalene Block
  - (anesthesia provided)

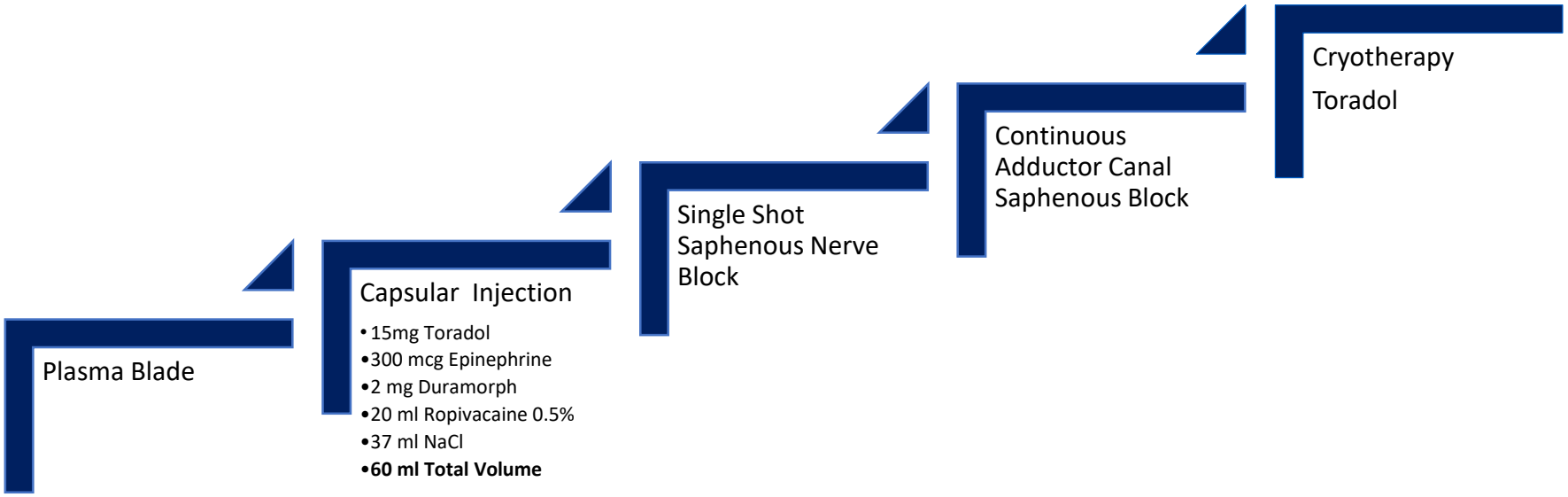
Intra-op Surgeon

- ON-Q* pain pump Sub-acromial space



Pain Management TKA Phase 2-3

Intra-op / Post-op Management TKA



Intraoperative Pain Management

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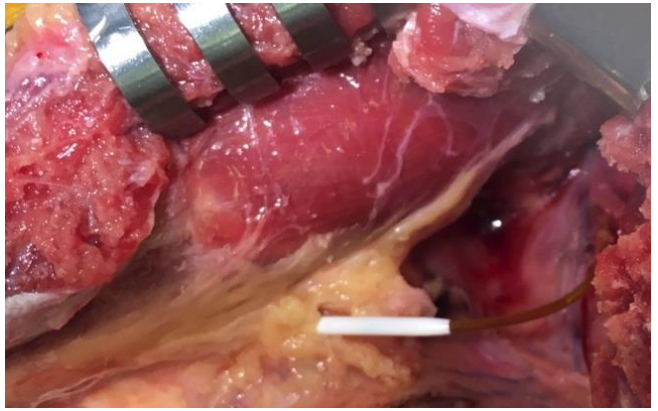
Capsular Injection

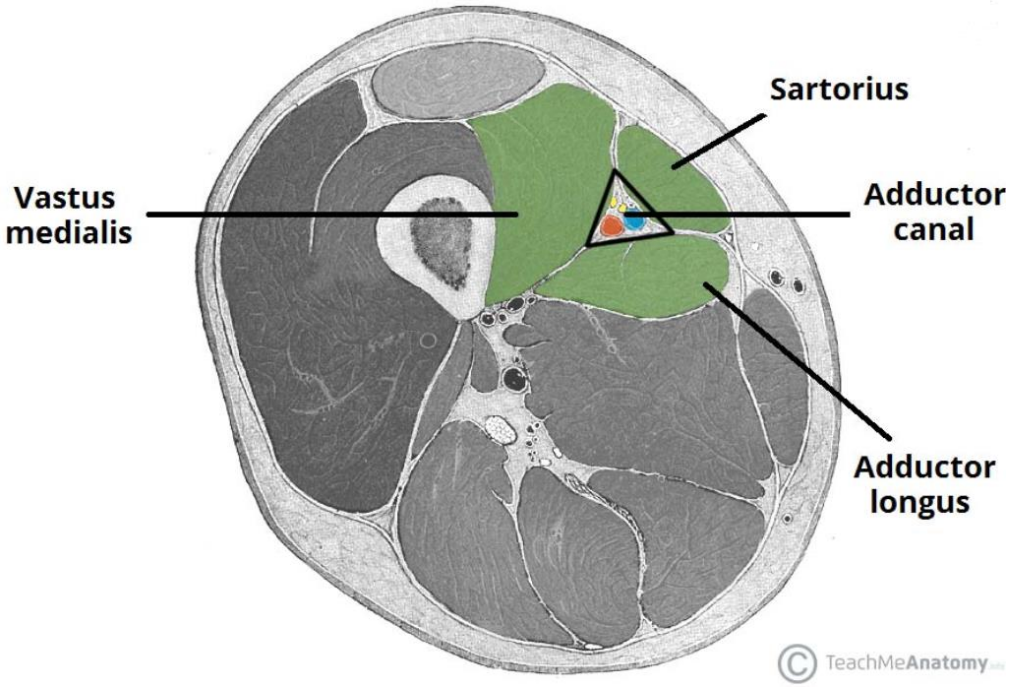
- Toradol 15mg
- Epinephrine 300 mcg
- Duramorph 2mg
- Ropivacaine 0.5% 20ml
- NaCl 37ml
  - Total volume 60ml

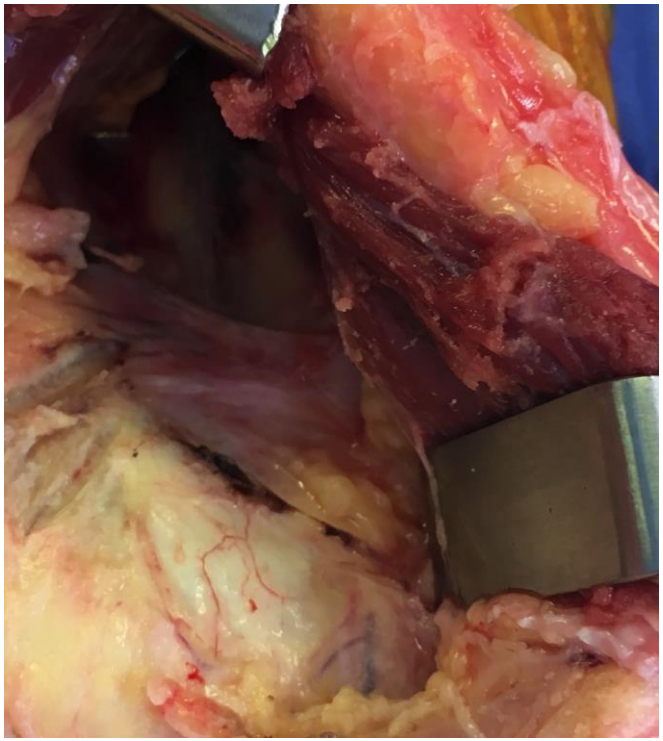
Surgeon Placed

- Single Shot Adductor Saphenous Block
- Continuous Saphenous Nerve block



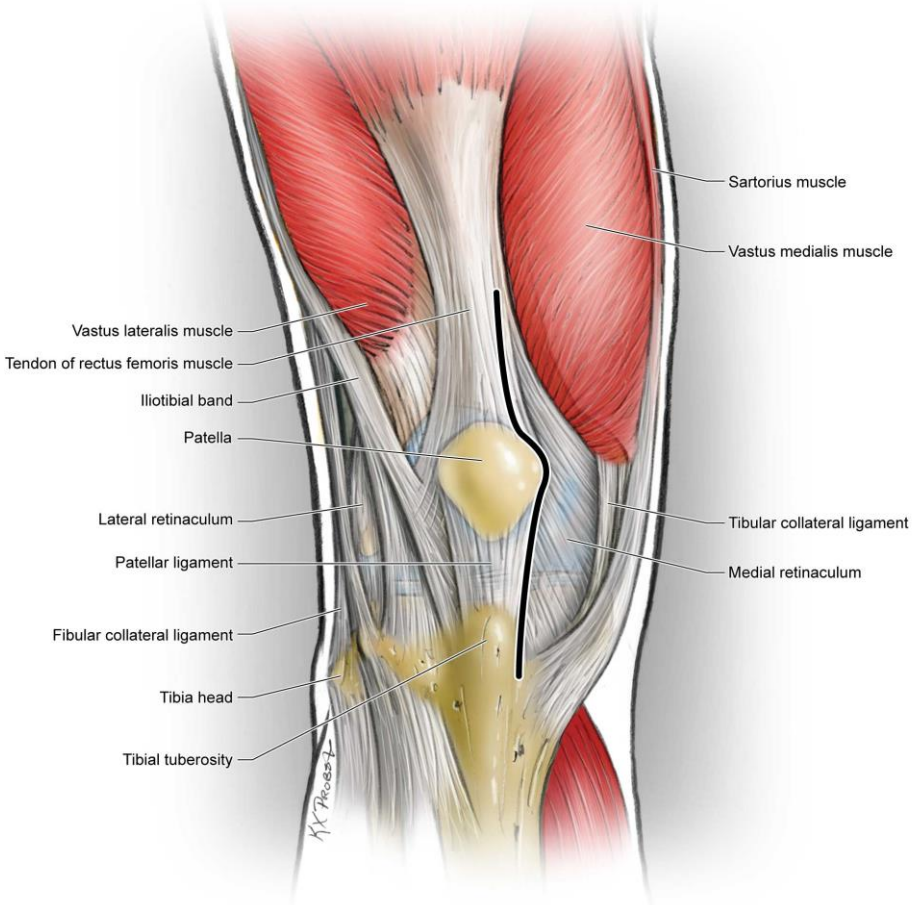
Anatomy Around the Incisional Knee





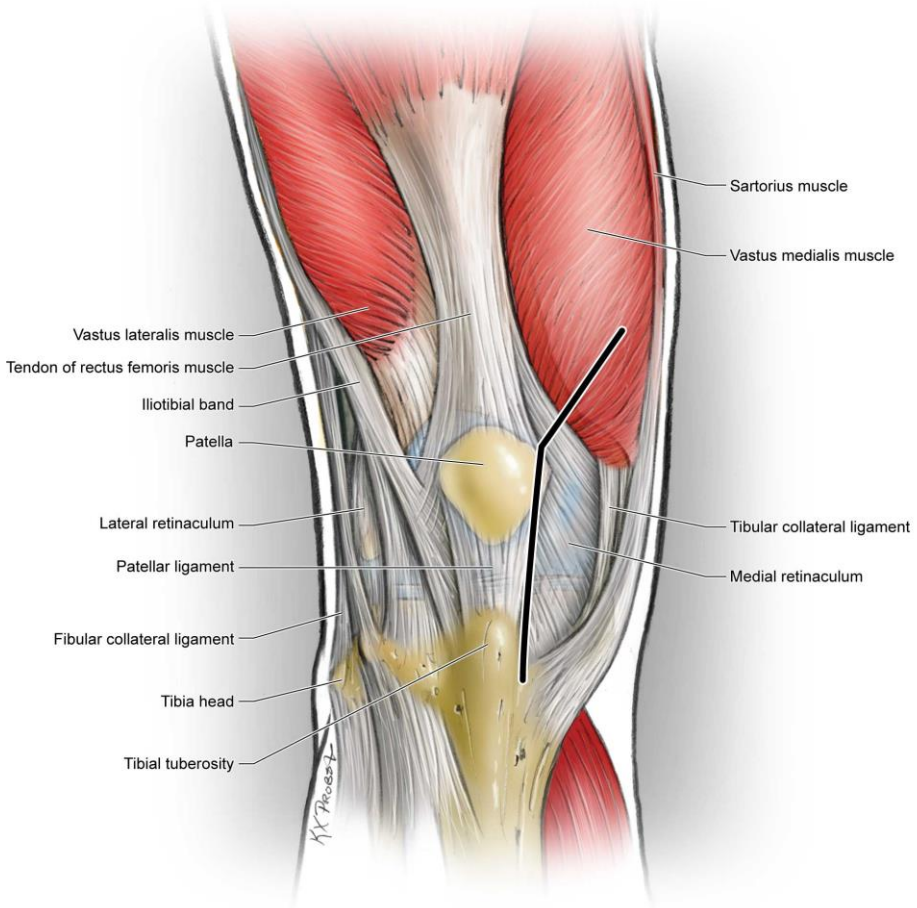
TKA Approach

Standard Medial Parapatellar Approach



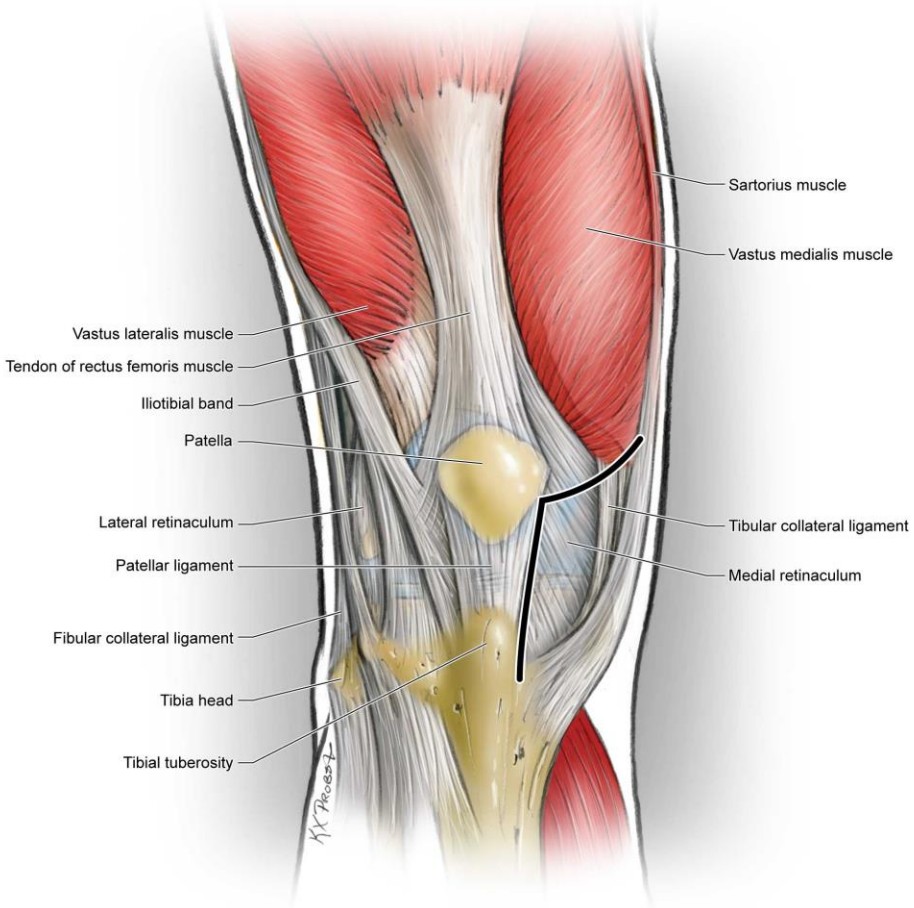
TKA Approach

Midvastus Approach



TKA Approach

Subvastus Approach



Surgical Approach

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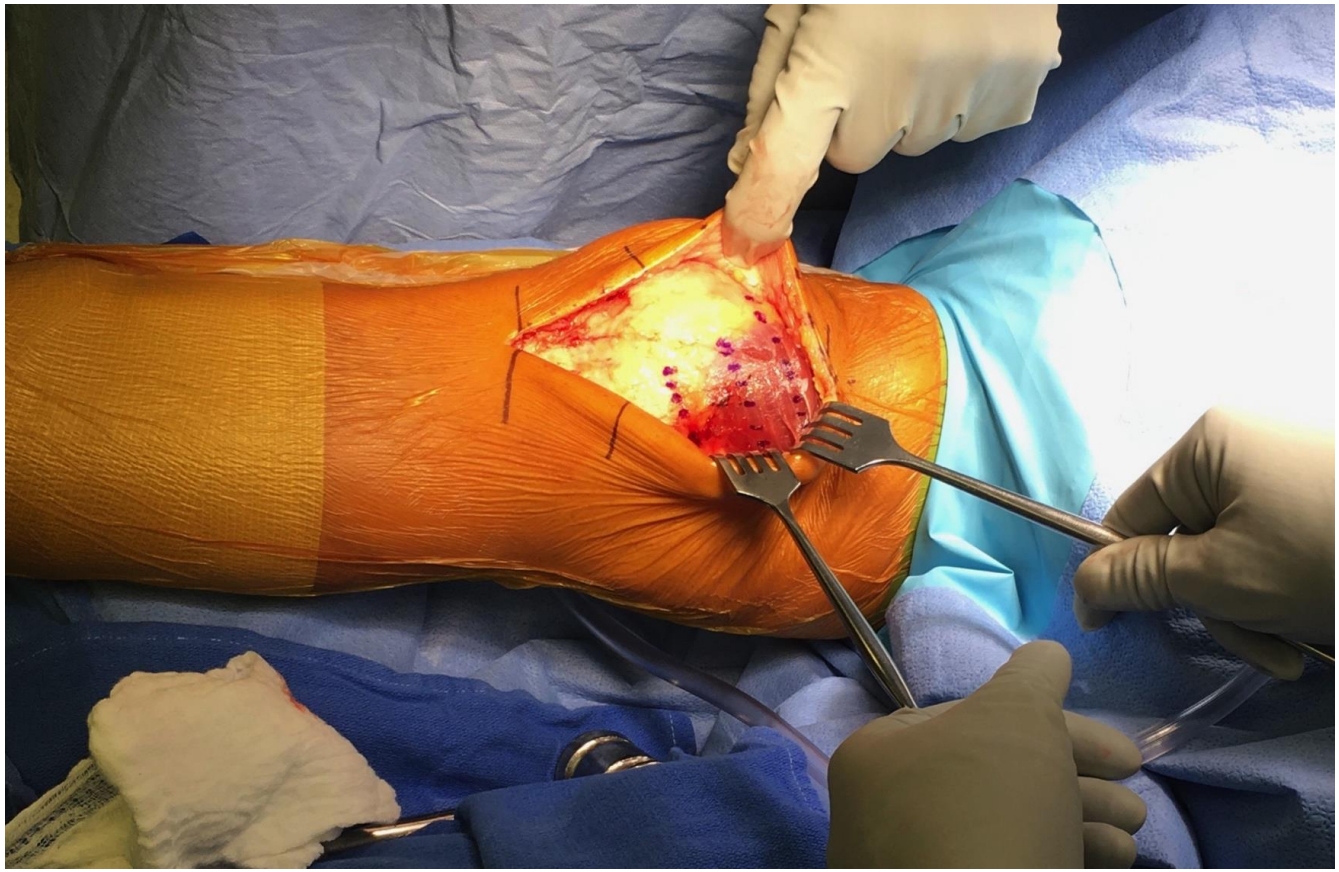
Matthews Modified Midvastus



Matthews Adductor Canal Placement

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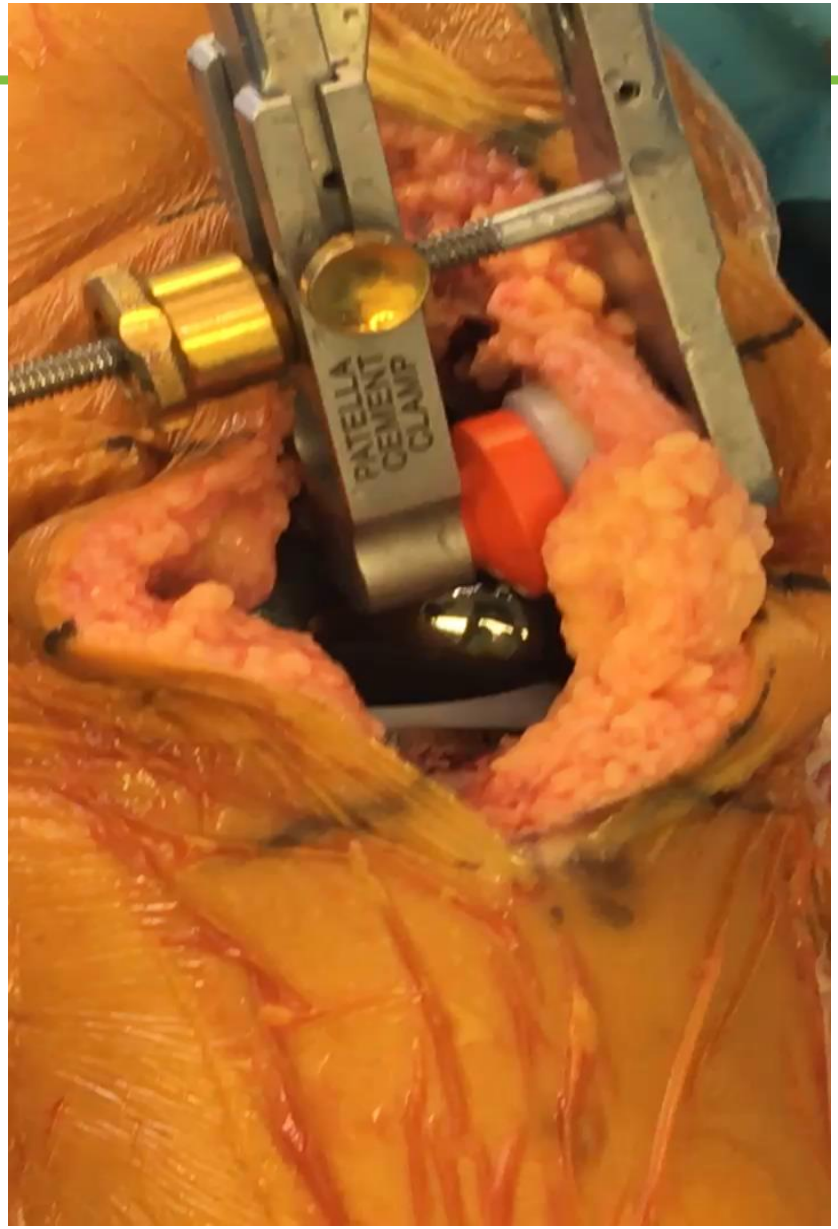


ON-Q*
PAIN RELIEF SYSTEM

Outcomes

CMS Quality Score

- 50% Hospital Complication Rates
- 40% HCAHPS score
- 10% Additional Voluntary data from the Hospital

ON-Q* TRAC

Results “Overnight Outpatient TJA” 23-hour Stay

TKAs: 225

(September 2016 – December 31, 2017)

- All (but 3) went home post-op day 1 as “23-hour outpatient”
- All (but 1) discharged to home with 6 consecutive days of home PT prior to going to outpatient PT

Complications: 5

(none related to ON-Q*)

- **4 outpatient setting**
  - 3 wound complications office care
  - 1 pre-patellar bursa infection presented 6 weeks po

  Required outpatient I&D of Bursa in OR, did not involve joint, IV ABX x 2 weeks (redhead?/hospital employee)

- **1 re-admission**
  - Deep wound infection (smoker, low pre-albumin)
  - Removal implant, ABX cement spacer, 6 weeks IV antibiotics, infection cleared
  - Re-implanted revision TKA October 2017 as “overnight outpatient” using ON-Q*

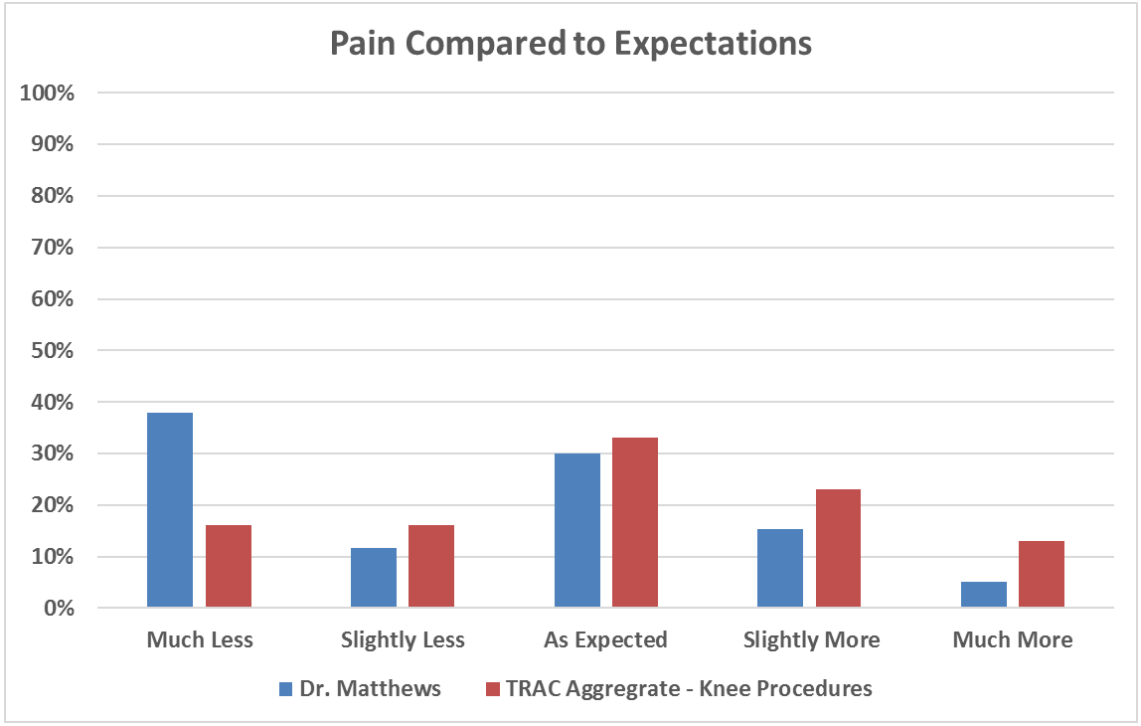
ON-Q* TRAC Data
90 Day Progress Report

Concentration on POD 1-7

Outcomes Data

ON-Q* TRAC

- 6 month trial
- Staff enrolls patient
- Email/Text based data collection
- Patients receive email / text reminders to input data
- Data collected first 7 days post op



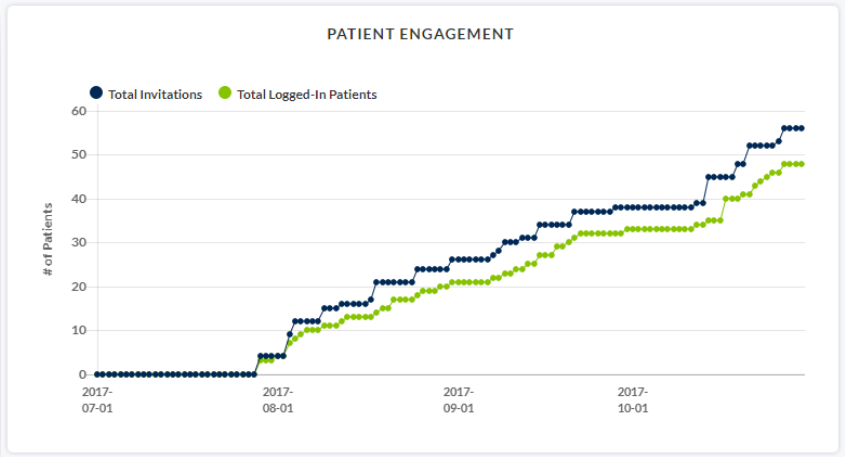
Dr. Matthews ON-Q* TRAC Account Status

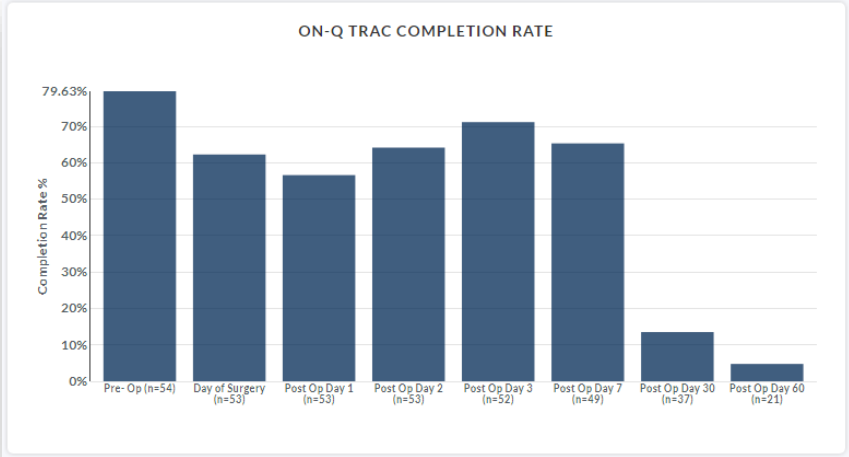
- **Start date:** July 28, 2017
- **End date:** November 17, 2017
- **ON-Q TRAC licensed users:**
  - Chason Pizzoth (Site Admin)
  - Angie Frego (Enroller): Enrolling patients into the ON-Q TRAC platform
  - Daniel Matthews, MD (Surgeon)
- **Physicians in ON-Q TRAC: Tracking patients of the following physicians**
  - Daniel Matthews, MD (Ortho)

Dr. Matthews ON-Q* TRAC Account Status

As 10/30/2017:

- 56 patients enrolled with 48 patients taking the surveys (86% participation rate)
- ~ 65% survey completion rate overall – excellent survey completion rate



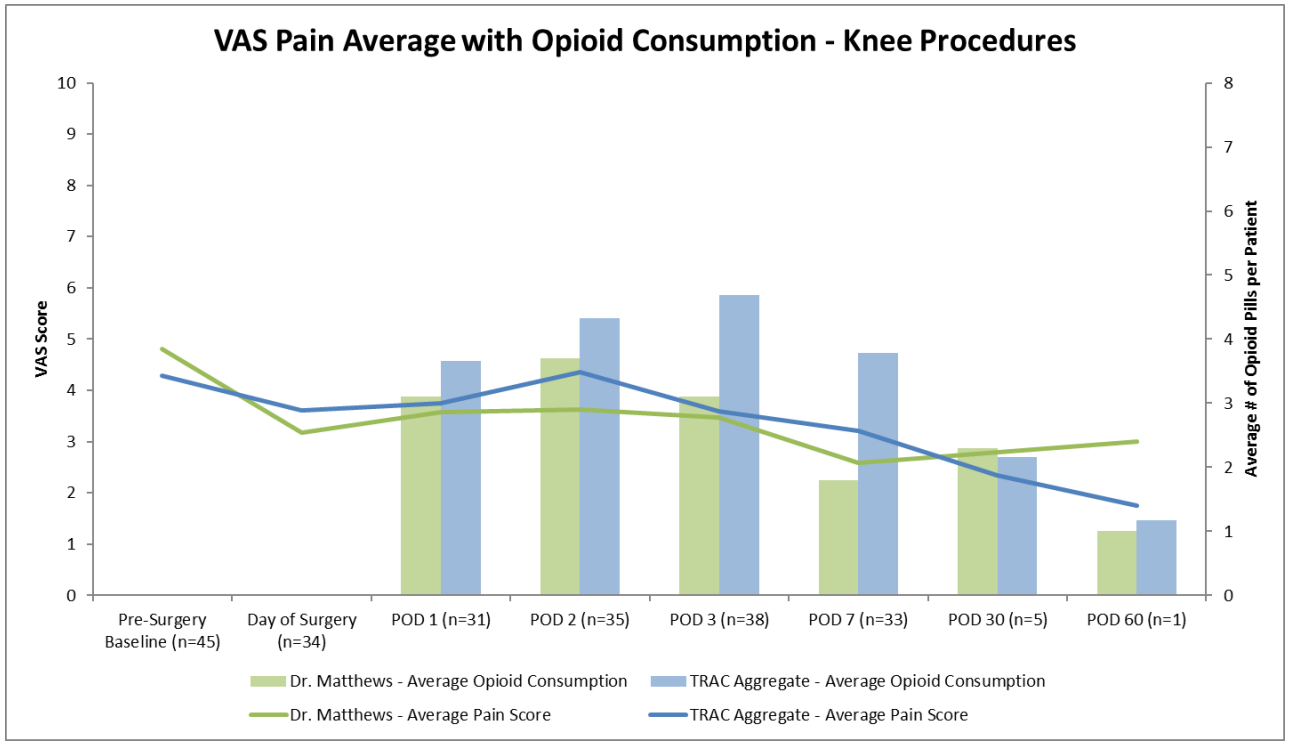


VAS Pain Score and Opioid Consumption

Dr. Matthews Compared to ON-Q* TRAC Aggregate Data

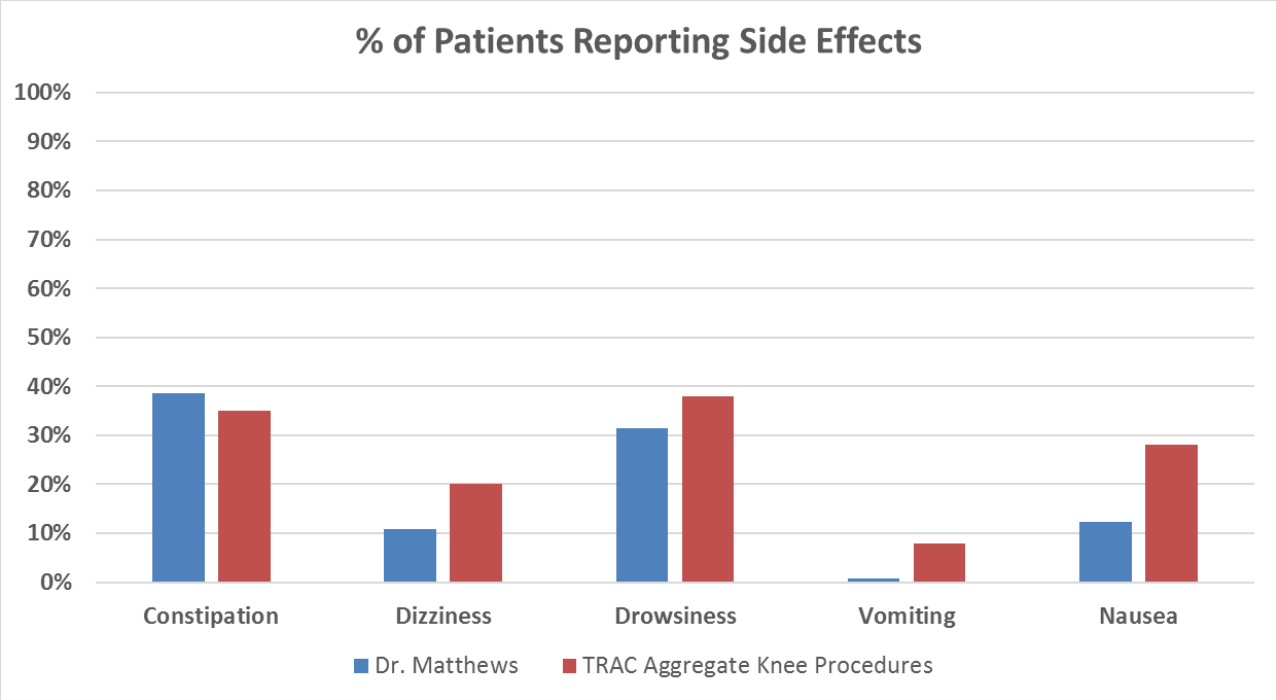
Pain score lower than aggregate **(25% reduction)**

Opioid consumption lower than aggregate POD 1 to 7 **(24% reduction)**



% of Patients Reporting Side Effects

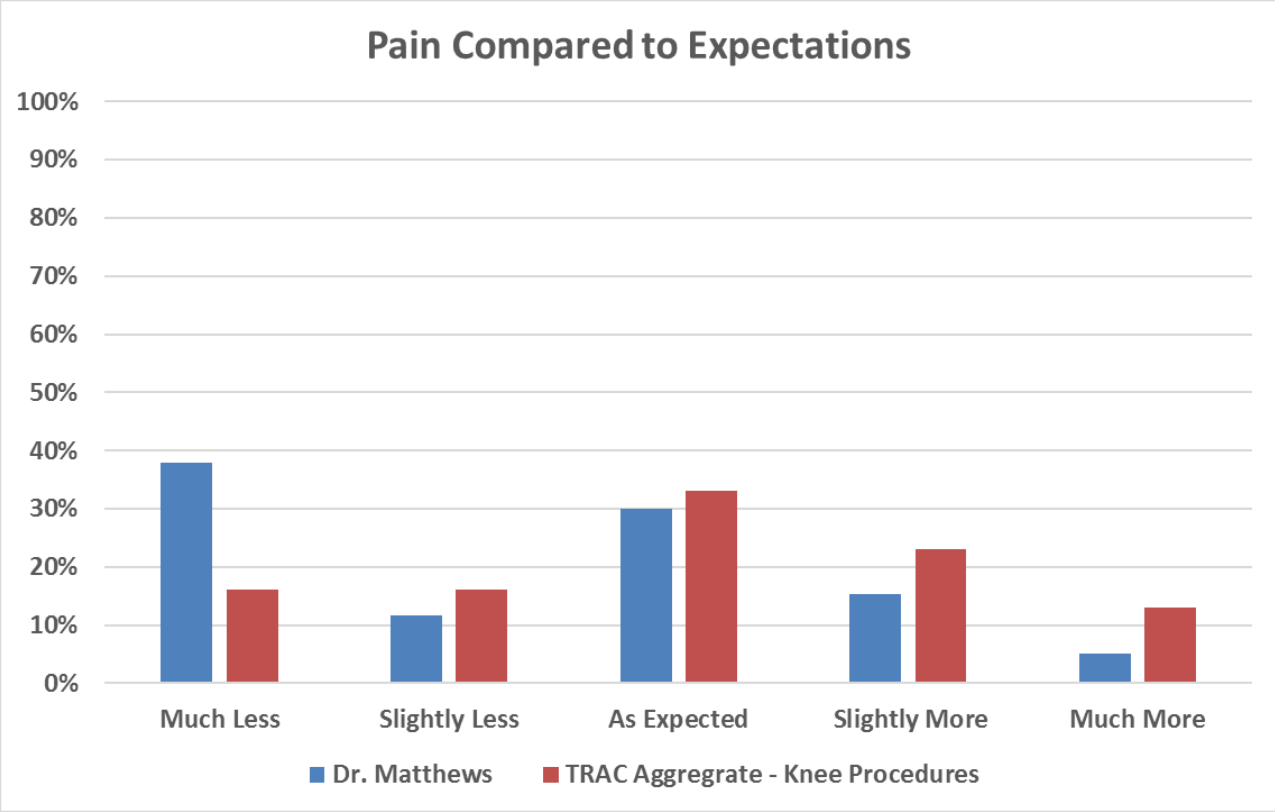
Dr. Matthews Compared to ON-Q* TRAC Aggregate Data



Pain Compared to Expectations

Dr. Matthews Compared to ON-Q* TRAC Aggregate Data

Significantly less pain compared to expectation versus aggregate data

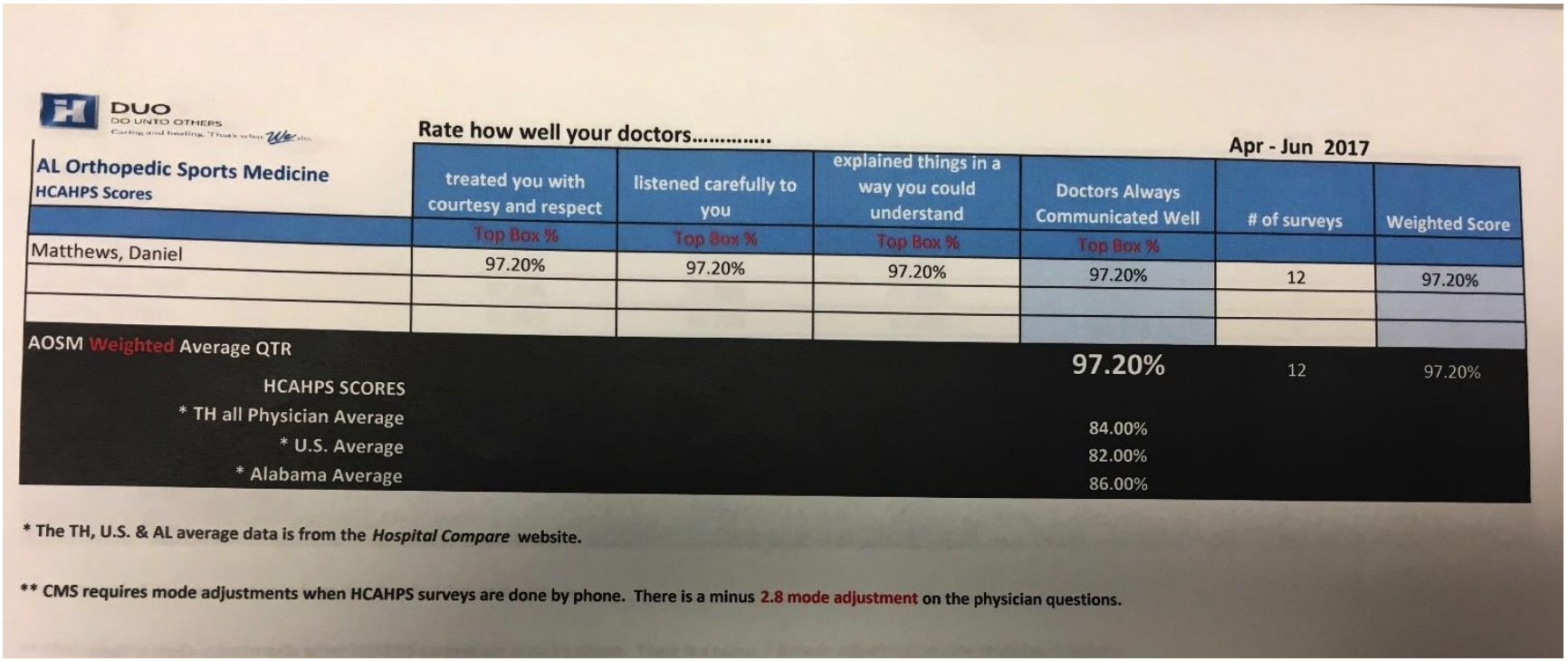


HCAHPS

Hospital Consumer Assessment of Healthcare Providers and System

- CMS Quality Score
  - 50% Hospital Complication Rates
  - 40% HCAHPS score
  - 10% Additional Voluntary data from the Hospital
    - ON-Q* TRAC

HCAHPS



DUO
DO UNTO OTHERS
Caring and healing. That's what We do.

Rate how well your doctors..... Apr - Jun 2017

AL Orthopedic Sports Medicine HCAHPS Scores	treated you with courtesy and respect	listened carefully to you	explained things in a way you could understand	Doctors Always Communicated Well	# of surveys	Weighted Score
	Top Box %	Top Box %	Top Box %	Top Box %		
Matthews, Daniel	97.20%	97.20%	97.20%	97.20%	12	97.20%
AOSM Weighted Average QTR				97.20%	12	97.20%
HCAHPS SCORES						
* TH all Physician Average				84.00%		
* U.S. Average				82.00%		
* Alabama Average				86.00%		

* The TH, U.S. & AL average data is from the *Hospital Compare* website.

** CMS requires mode adjustments when HCAHPS surveys are done by phone. There is a minus 2.8 mode adjustment on the physician questions.

Clinician Testimonial

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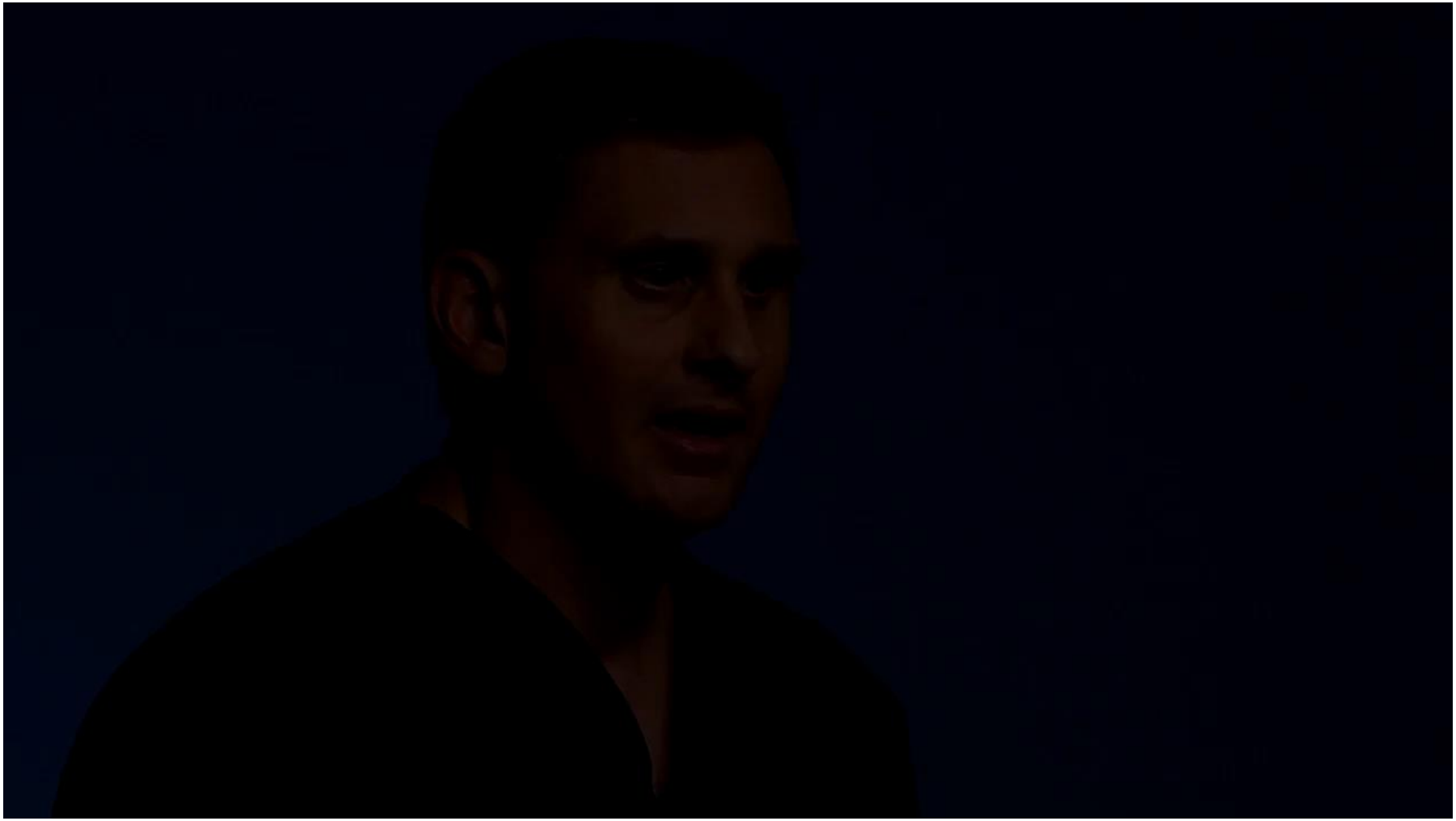
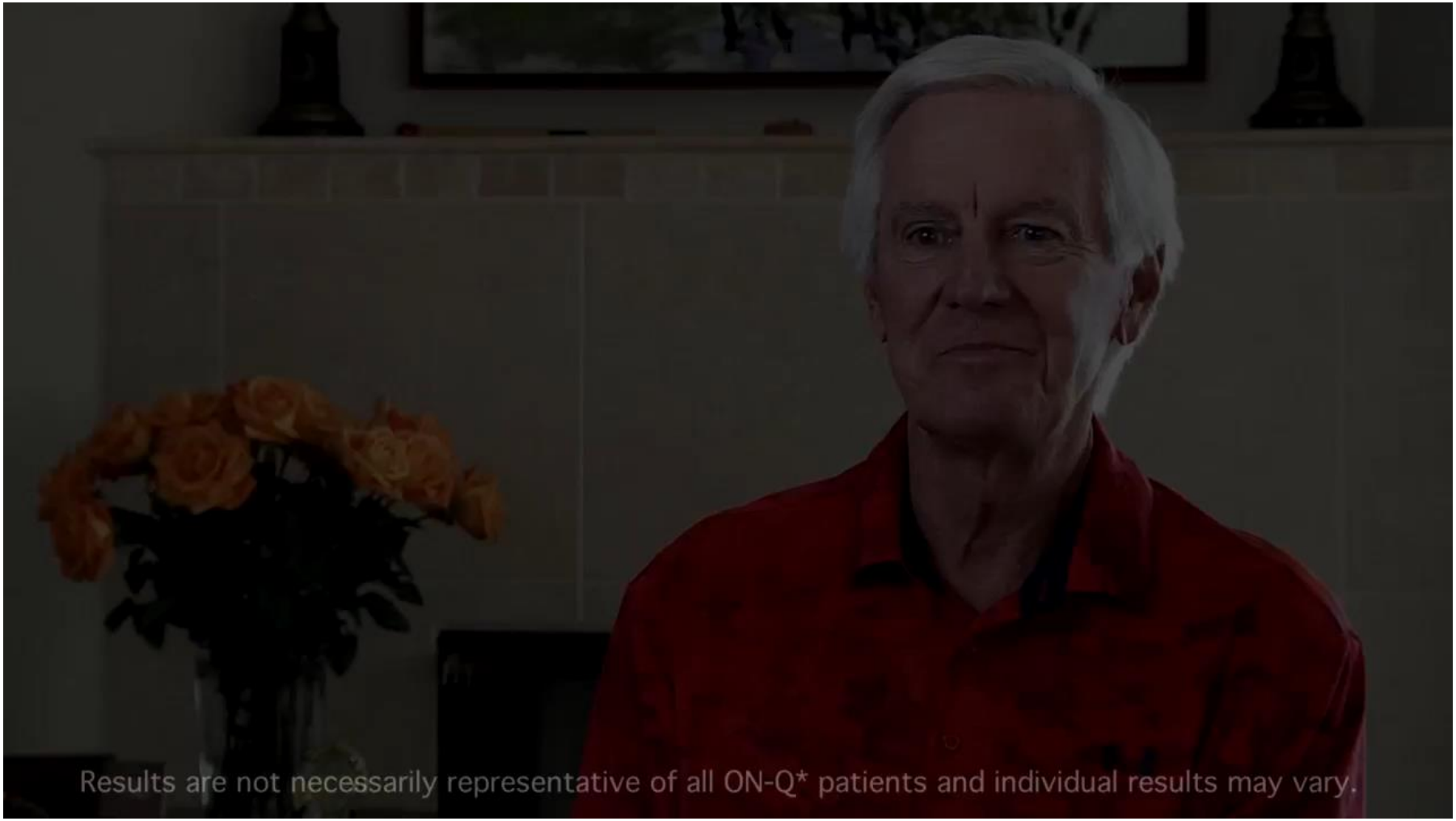
ON-Q* for TKA Physical Therapy with Patient 3 hours post op



Patient Testimonial

ON-Q* for TKA



Advantages

Surgeon Placed Single Injection & Continuous Adductor Block Using ON-Q*

Placed in OR by surgeon

- Advantages based on my experience: time efficient, cost efficient, efficacious, novel but simple placement

Patient Friendly

- Patient opens clamp to ON-Q* pump when Saphenous Nerve block wears off or post op day 1 at home

Excellent pain relief for up to 3 - 5 days

- Dial setting at 6-8

Catheter Removal

- Patient/family, home health PT may remove when empty

Minimal Management

- Pre-op consulting “bulb won’t go down”
- May drain a bit of bloody fluid at removal
- Halyard Health’s 24-hour Clinical Hotline

Where are we going?

ON-Q PAIN RELIEF SYSTEM

What is next?

Submission for Publication of this Prospective study investigating efficacy of this novel placement:

Prospective Analysis of Surgeon Placed Saphenous Nerve Block and Continuous Indwelling Catheter in the Adductor Canal in TKA

Daniel E. Matthews MD, Jordan Smith MS

Podium Presentation at Joint Annual Alabama/Mississippi Orthopaedic Society Meeting
May 19,2018

Investigation and all Surgeries were performed by the senior author at Thomas *Hospital in association with the University of South Alabama Department of Orthopaedic Surgery*

Where are we going?

ON-Q PAIN RELIEF SYSTEM

Future Studies

Prospective Randomized Double Blinded studies investigating efficacy of this novel placement with addition of Toradol, Duramorph.

Prospective Double Blinded Analysis of Surgeon Placed Saphenous Nerve Block and Continuous Indwelling Catheter in the Adductor Canal in TKA. A Comparison of Ropivicaine alone and addition of Toradol

Daniel E. Matthews MD, Jordan Smith MS

Prospective Double Blinded Analysis of Surgeon Placed Saphenous Nerve Block and Continuous Indwelling Catheter in the Adductor Canal in TKA. A Comparison of Ropivicaine alone and addition of Duramorph

Daniel E. Matthews MD, Jordan Smith MS

Summing it up

- Regional Block Team?
- Efficiency?
- Efficacy?
- Financial concerns with Bundle?

- Advantages of Surgeon placed injection/catheter
  - Safety
  - Efficiency
  - Efficacy
  - Financial
- Visiting Surgeon Site Visit
- Placement Guide available
- Video Placement Guide available

Catheter Placement Guide

ON-Q® PAIN RELIEF SYSTEM

HALYARD

SURGICAL SOLUTIONS
PLACEMENT TECHNIQUE

Daniel E. Matthews, M.D.
AOSM (Alabama Orthopaedic Sports Medicine)
Daphne, Alabama

MATTHEWS ADDUCTOR CANAL BLOCK PLACEMENT GUIDE™
TOTAL KNEE ARTHROPLASTY

The information provided herein is provided for educational purposes and represents the surgical techniques used by Dr. Matthews. Catheter placement is intended for guidance only and is subject to the individual expertise, experience and school-of-thought of the surgeon placing the catheter. Always refer to the drug manufacturer's prescribing information when administering any drug with the ON-Q® Pain Relief System. This protocol is not to be construed as a specific recommendation of Halyard Health.

SAMPLE PROTOCOL

Drugs in Pump: Local anesthetic of physician's choice.

Overview: Using the placement technique described in this insertion guide, the Surgeon can place a single injection bolus and a continuous nerve block into the adductor canal under direct visualization of the nerve.

This direct visualization of the nerve is performed during open knee surgery using a standard para-patellar or vastus medialis oblique (VMO) splitting approach with no additional dissection needed. Exposure of the adductor canal is accomplished by placing blunt retractors under the VMO at the level of the patella, elevating the muscle, permitting direct visualization of the adductor canal and saphenous nerve. When performing a TKA, the single injection bolus and catheter placement can be performed while the cement (if used) is curing, adding no further time to the operative procedure.

Surgeon placement provides the advantages of peripheral nerve block including potentially reducing narcotic usage, length of stay and post-operative complication due to nausea, vomiting and constipation.

(Continued on Page 2)

CAUTIONS AND WARNINGS

- Patient may experience loss of motor control or feeling at and around the surgical area. Physician should instruct patient on appropriate measures to follow to avoid patient injury.
- Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer. Surgeon is responsible for prescribing drug based on each patient's clinical status (e.g., age, body weight, disease state of patient, concomitant medication(s)).
- Vasoconstrictors such as epinephrine or adrenaline are not recommended for continuous infusions.
- Avoid placing the catheter in joint spaces. Although there is no definitive established causal relationship, some literature has shown a possible association between continuous intra-articular infusions (particularly with bupivacaine) and the subsequent development of chondrolysis.
- Refer to ON-Q® Pump Directions for Use for full instructions on using the ON-Q® Pain Relief System.

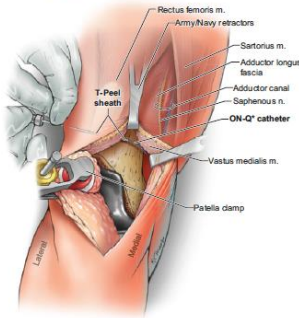
INSERTION TECHNIQUE

I **Surgical approach:** Standard anterior para-patellar approach or a VMO splitting approach to the knee is utilized to perform this placement technique. The approach to the knee involves incising the skin just above the patella and extending the skin incision to the tibial tubercle. With the standard anterior para-patellar approach, after retracting the skin, the extensor mechanism (VMO) is incised in line with the skin incision beginning medially just above the patella and extending down to the tibial tubercle, leaving a cuff of capsular tissue on the patella for repair at closure. With the VMO splitting approach, the VMO is split in line with the muscle fibers at the superior pole of the patella and then extended distally to the tibial tubercle. *(See Figure A)*

Figure A

II **Exposure:** With either approach, the adductor canal can be easily accessed by retracting the patella and elevating the VMO muscle using blunt (Army/Navy) retractors. By placing retractors under the VMO, visualization of the sartorius muscle, adductor longus muscle fascia, and adductor canal is clearly obtained. This exposure allows direct visualization of the saphenous nerve for placement of a nerve block and requires no or minimal gentle digital blunt dissection. Exposure of the nerve adds little to no time to the procedure. *(See Figure B)*

Figure B



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SURGICAL SOLUTIONS
PLACEMENT TECHNIQUE

III **Catheter placement:** Placement of the catheter for a continuous block is performed by inserting the introducer needle and T-Peel sheath from the superior lateral aspect of the knee, just above the joint at the superior pole of the patella. The introducer needle and T-Peel sheath is passed under the Rectus Femoris and into the adductor canal under the retracted VMO. The introducer needle is then removed leaving the T-Peel sheath in place. After flushing the ON-Q® catheter with normal saline on the back table, it is then passed through the T-Peel sheath and retrieved into the adductor canal using a pituitary ronguer. The T-Peel sheath is peeled away and discarded. A single injection can be performed using a needle and syringe under direct visualization of the nerve to provide initial pain relief for the patient. *(See Figure B & C)*

IV **Advancement into adductor canal:** Using the pituitary ronguer, the surgeon is able to advance the tip of the catheter proximally into the adductor canal, superior to the joint. This placement avoids involvement of the femoral nerve (found deep to adductor longus fascia) but can include the superior branches of the saphenous nerve. Once the catheter is placed, the retractors are removed and the wound is irrigated and closed in the standard fashion of choice. *(See Figure D & E)*

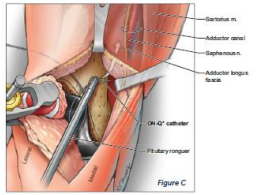

Figure C

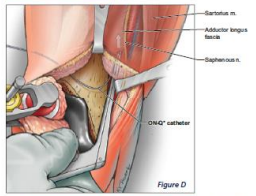

Figure D

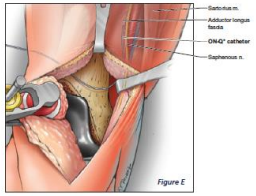

Figure E

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