AQUACEL® Ag Surgical Dressing and the Current American Joint Care Climate

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Previous Medicare Payment Model for Hip and Knee Replacement

- Inpatient prospective payment system (*IPPS*)
  - One of two Medicare Severity-Diagnosis Related Groups (MS-DRGs):
    - » MS-DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) or
    - » MS-DRG 470 (Major joint replacement or reattachment of lower extremity without MCC).
  - Provider fees in addition

The average Medicare expenditure for surgery, hospitalization, and recovery ranges from $16,500 to $33,000 across geographic areas.

*CMS.gov

CMS.gov
Centers for Medicare & Medicaid Services

Comprehensive Care for Joint Replacement (CJR or CCJR)

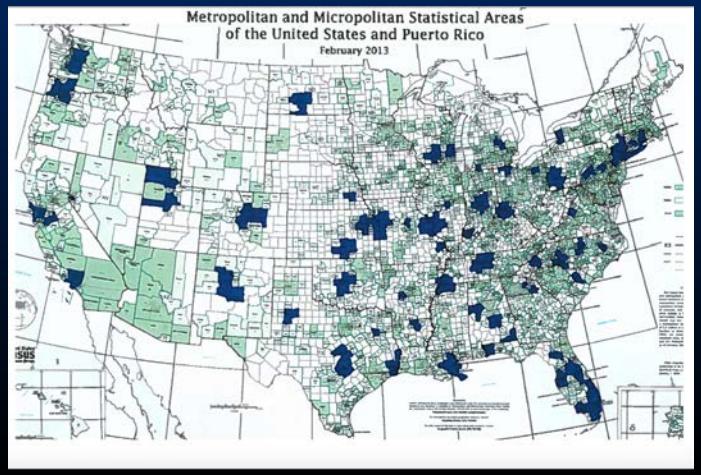
On April Fools Day 2016, The Centers for Medicare and Medicaid Services initiated the Comprehensive Care for Joint Replacement program

- Shift the payment model for Lower Extremity Joint Replacements from traditional fee-for-service to a retrospective bundled payment
- Incentivize hospitals, physicians, suppliers, and post-acute care providers to work together to lower costs, decrease complications, and improve quality
- The program will run for 5 years.

*CMS.gov

What is the CJR Program?

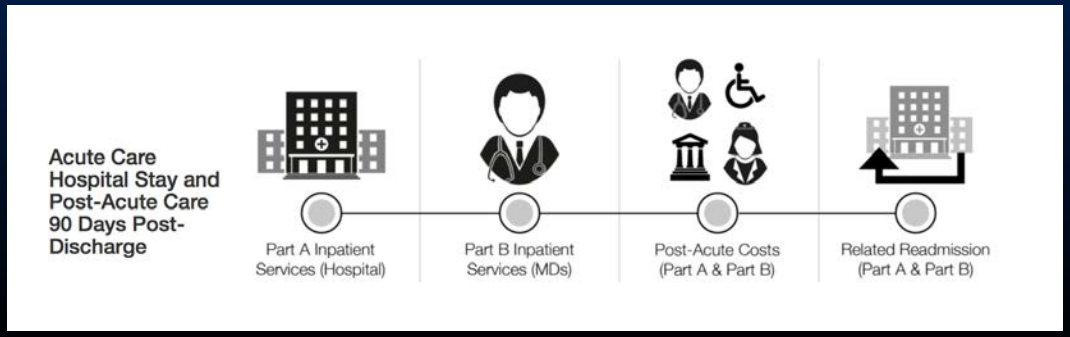
- CMS will retrospectively bundle the *entire* payment for:
  - Procedure that is assigned to MS-DRG 469 or 470 upon beneficiary discharge and paid under the hospital inpatient prospective payment system (*IPPS*)
  - Episodes will begin with admission to an acute care hospital
  - Episodes will end 90 days after the date of discharge
- A target price will be set based on historical and regional data
- Hospitals with then share in the gains or in the losses
- Participation is mandatory for all *IPPS* hospitals (791) in 67 Metropolitan Statistical Areas (*MSAs)* with no ability to opt out (unless participating in BPCI)



*CMS.gov

What Comprises the CJR Episode / Bundled Payment?

- LEJR procedure and all related costs within 90 days of discharge, including:
  - Medicare Part A & Part B Costs:
    - » Inpatient Hospital care
    - » Post-acute care (PAC) (including the skilled nursing facility (SNF) stay)
    - » Related readmissions
    - » Physician services
    - » Long-term care hospital services
    - » Inpatient rehabilitation facility services
    - » Home health agency services; hospital outpatient services
    - » Independent outpatient therapy services
    - » Clinical laboratory services
    - » Durable medical equipment
    - » Part B drugs
    - » Hospice



*CMS.gov

How is the CJR Target Price Set?

- Hospital-specific and regional pricing data determines the value
  - Historic price is based on last 3 years of spending
  - Historical benchmarks will be rebased every two years.
  - Risk stratification for hip fractures (only)
- The target price will include a 2% discount over expected episode spending, in an attempt to lower the price per episode over time.
- Throughout the year, Medicare would continue to pay providers and suppliers using existing Medicare payment models.

*CMS.gov

Physician Payments

- Payments to Providers
  - All providers (including SNFs) and suppliers will continue to be paid under the usual fee-for- service payment system rates, rules and procedures of the Medicare program for episode services throughout the year.
  - After the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, will be combined to calculate an actual episode payment.

*CMS.gov, AHCA.com

CMS.gov
Centers for Medicare & Medicaid Services

Hospital Payments / Losses ("The Back End")

- At the end of the year, the actual episode payment will then be reconciled against the established CJR target price
- The difference, if positive, will be paid to the participant hospital ("reconciliation payment"), as long as quality outcome measures are met.
- The difference, if negative, CMS will require the hospital to pay back some or all of the difference (starting PY 2 [grace period for repayments in year 1])

*Data not yet submitted for publication

Outcomes Linked to Payment

- Composite Score Methodology
  - The quality composite score is based on the three quality measures and how the hospital ranks on the program's quality measures relative to other CJR hospitals in the program.
    - » THA/TKA Complications (NQF #1550): 50%
    - » HCAHPS Survey (NQF #0166): 40%
    - » Patient Reported Outcomes Data (Reporting Only): 10%
      - PROMIS Global, Veterans Rand, HOOS Jr, HOOS, KOOS Jr
  - The composite quality score is based out of 20 total points.

Percentile Rank	Points for THA/TKA Complications	Points for HCAHPS Survey	Points for submitting PRO Data
≥90th	10	8	2
≥80th and <90th	9.25	7.4	"
≥70th and <80th	8.5	6.8	"
≥60th and <70th	7.75	6.2	"
≥50th and <60th	7	5.6	"
≥40th and <50th	6.25	5	"
≥30th and <40th	5.5	4.4	"
<30th	0	0	"

Outcomes Linked to Payment

- If the overall composite score is "below acceptable," the hospital will be ineligible to receive reconciliation payments regardless of their performance on the cost measures.
- The composite score will determine the "effective discount percent" for both reconciliation payments (in PYs 1-5) and repayments (PYs 2-5 only). If a hospital performs very well on the quality composite score, their effective discount percent to the episode target price will be reduced to 1.5%. Conversely, if a hospital does poorly on the quality composite score, the effective discount percent will be increased to 3%.

Quality Composite Score Range out of 20	Quality Category	Eligible for Reconciliation Payment	Effective Discount % for Reconciliation Payment	Effective Discount % for Repayment Amount
>13.2	Excellent	Yes	1.5%	PY1: N/A* PY2-3: 0.5% PY4-5: 1.5%
≥6 and <13.2	Good	Yes	2%	PY1: N/A PY2-3: 1% PY4-5: 2%
≥4 and <6	Acceptable	Yes	3%	PY1: N/A PY2-3: 2% PY4-5: 3%
<4	Below Acceptable	No	3%	PY1: N/A PY2-3: 2% PY4-5: 3%

*CMS.gov, AHA.org

Gain and Loss Limits

- Stop-Loss and Stop-Gain Policies
  - CMS will limit how much a hospital can gain (in reconciliation payments from Medicare) or lose (in repayments back to Medicare) based on its actual episode payments relative to the target prices. Both stop-gain and stop- loss limits gradually increase over the course of the CJR program.

Year	Stop-Gain Limit	Stop-Loss Limit
PY 1 (Apr-Dec 2016)	5%	N/A
PY 2 (CY 2017)	5%	5%
PY 3 (CY 2018)	10%	10%
PY 4 (CY 2019)	20%	20%
PY 5 (CY 2020)	20%	20%

Example 1: A hospital treats 10 LEJR episodes in PY 1 with a target price of $10,000 each, for a total of $100,000. Actual spending across all 10 episodes was only $85,000, leaving a difference of $15,000. The stop-gain limit in PY 1 is 5%, so the hospital would receive a $5,000 reconciliation payment.

Example 2: A hospital treats 10 LEJR episodes in PY 3 with a target price of $10,000 each, for a total of $100,000. Actual spending across all 10 episodes was $120,000, leaving an overage of $20,000. The stop-loss limit in PY 3 is 10%, so the hospital would be required to pay back Medicare a total of $10,000.

CJR "Sharing"

- Hospitals may have certain financial relationships with collaborators (they can share reconciliation payments and internal cost savings with collaborators who furnish care during the episode)
- Collaborators may include:
  - Physicians and non-physician practitioners
    - Home health agencies
    - Skilled nursing facilities
    - Long-term care hospitals
    - Physician group practices
    - Inpatient rehabilitation facilities
    - Providers or suppliers of therapy services
- Sharing Limits
  - A CJR hospital must retain at least 50 percent of its total risk
    - » It cannot share more than 50 percent of that repayment responsibility with Collaborators
    - » It cannot share more than 25 percent of its responsibility with any single CJR Collaborator
    - » Providers cannot receive more that 50% of the original fee rate

*CMS.gov, AHA.org

CMS Waivers Under CJR

- The SNF 3-day rule can be waived if SNF is rated 3 stars or higher on Nursing Home Compare.
- The "incident to" rule for physician services can be waived to allow clinical staff of a physician to furnish home visits
- Originating-site requirements for telehealth may be waived to allow services to be originated in patient's home.

*CMS.gov

CMS.gov
Centers for Medicare & Medicaid Services

Bundled Payments Care Improvement (BPCI)

- Voluntary
- Consists of 4 models of varying involvement (Model 2 is very similar to CJR)
- The cost of an episode of care is standardized, and providers / hospitals share in the savings or losses
- Target prices are set by same-hospital and regional standards
- Consists of over 48 types of care / procedures
- Gains / Losses capped at 20%, based on final cost compared to target pricing
- 3 year time period (? What happens after this period)
- Lower extremity joint replacement was the most popular of all BPCI procedures

*CMS.gov

Gainsharing

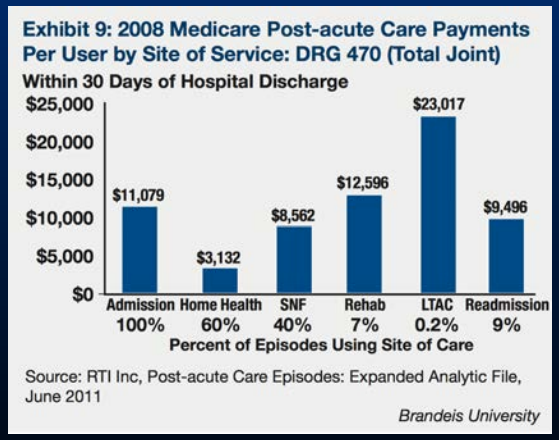
- BPCI and CJR participants may share incentive payments they receive with partners, including physicians and post-acute providers. Physician gainsharing cannot exceed 50 percent of the regular Medicare fees that they receive in CJR / BPCI episodes.

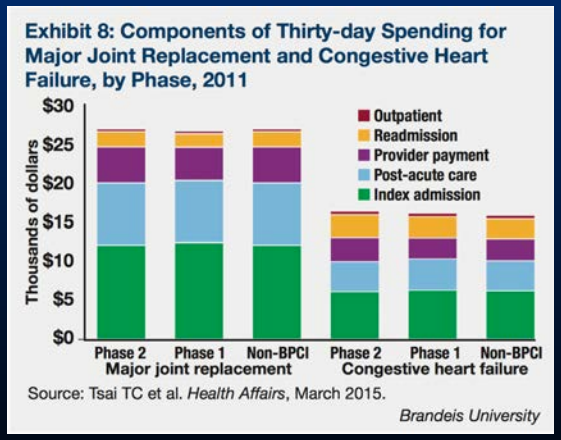
- For both CJR and BPCI, CMS and the HHS Office of Inspector General have waived the physician self- referral and anti-kickback laws with respect to financial arrangements that otherwise comply with the programs' requirements.

*CMS.gov, AHA.org

CJR Bottom Line

- We have no choice
- Physician and hospital alignment is crucial to success
- The financial burden rests with the hospital (unless the hospital decides to contract with other stakeholders)
- The main target for efficacy in this model seems to be post-discharge care
- Patient experience and satisfaction is important to success under this model





*CMS.gov, AHA.org

CJR Subjective Thoughts

- No risk stratification (except for hip fracture pts)
- The "Target Prices" and benchmark will likely only get lower with time
- Margaret Thatcher:
  - "The problem with socialism is that eventually you run out of other people's money."
- Private insurance will follow suit

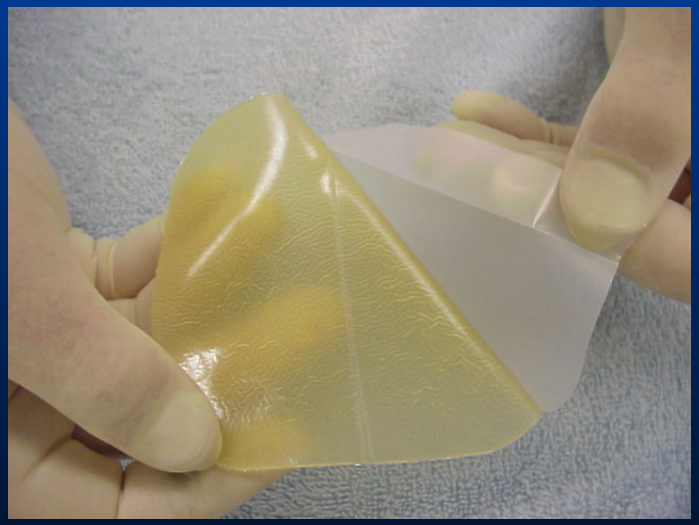
Opportunities to Excel Under CJR

- Patient satisfaction
- Decreased readmissions
- Decreased complications (wound problems and surgical site infections)
- Decreased cost of post-discharge care

SURGICAL WOUND CARE

Occlusive Dressings

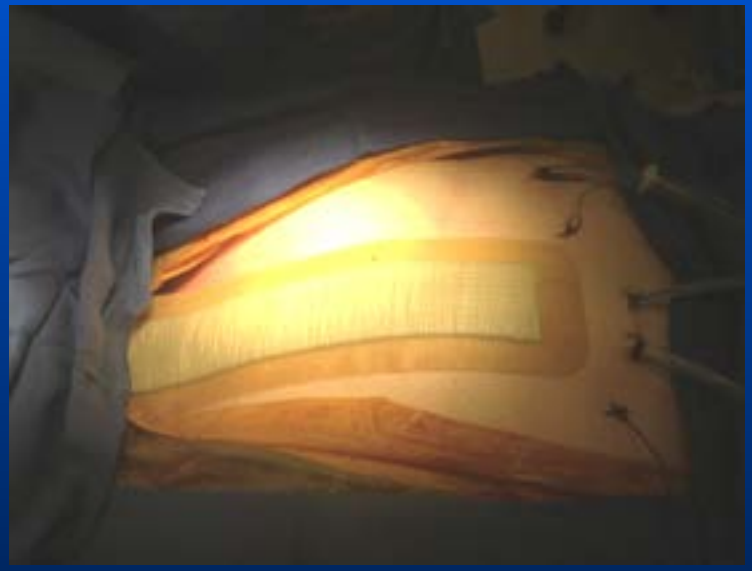
- Improved re-epithelialization
- Increase in collagen synthesis by 2-6x compared to wounds open to the air
- Lower rate of wound infection (Hutchinson *et al.* 1990)
  - With occlusive dressing 2.6%
  - With non-occlusive dressing 7.1%



Patel C, Surgical Wound Infections. Current Treatment in Infectious Diseases. 2000;2:147-153. Michie D. Influence of Occlusive and Impregnated Dressings on Incisional Healing: Ann Plastic Surg. 1994. Hulten L. Dressings for Surgical Wounds. Am J Surg. 1994. .Xi et al Wound Repair, 2000. Hutchinson, JJ, McGuckin, M, Occlusive dressings: A microbiologic and clinical review, American Journal of Infection Control, Aug 1990

AQUACEL® Ag Surgical Dressing
Advantages

- Barrier to pathogen transmission[1]
- Microbicidal effects of silver ion[2]
- Dressing may be left in place for 7 days (or longer based on provider preference
  - Less environmental exposure
  - Improved patient comfort
  - Decreased manpower / resources
- Patient satisfaction
  - Immediate showering

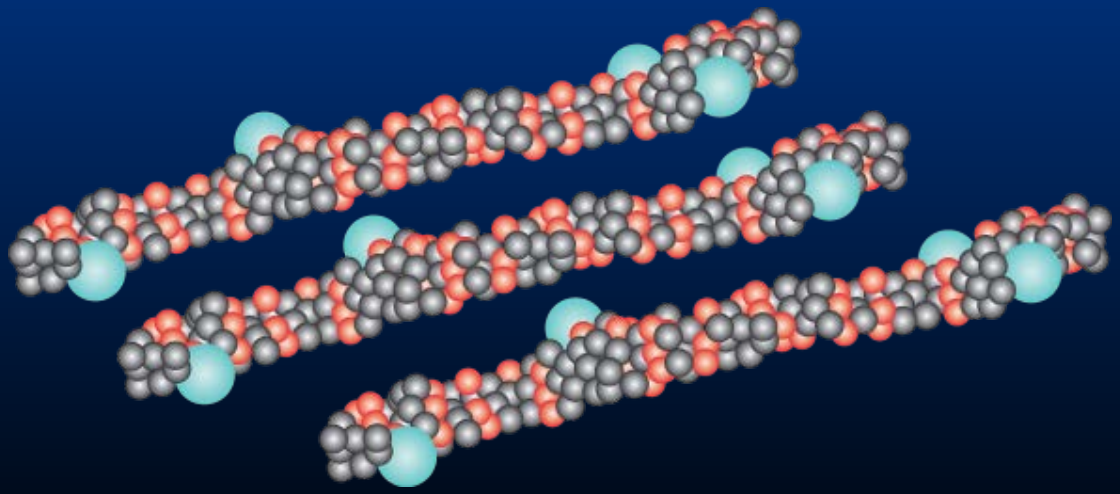


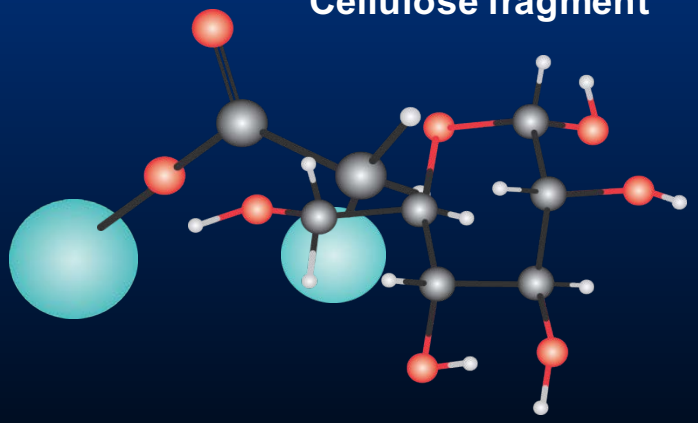
[1] Nelson Laboratories Report, Viral Penetration ASTM Method F1671, Procedure Number :ST0062 Rev07, Protocol Detail Sheet No. 200902139 Rev 1, Laboratory no. 483744, 7th August 2009

[2] Jones SA, Bowler PG, Walker M, Parsons D. Controlling wound bioburden with a novel silver-containing Hydrofiber dressing. Wound Repair Regen. 2004;12(3):288-294.

Advanced Dressings
Hydrofiber® Technology

- Basic component is cellulose
- Carboxymethylation* process alters the absorption capacity
- Hydrofiber® technology allows for fluid to be absorbed directly into the fibers
- A bond is formed with the absorbed fluid to hold it within the fiber





*Carboxymethylation: addition of sodium carboxymethyl

[1]Waring MJ, Parsons D. Physico-chemical characterisation of carboxymethylated spun cellulose fibres. *Biomaterials*. 2001;22:903-912.

AQUACEL® Ag

Broad-spectrum Antimicrobial Activity

Aerobic Bacteria

Staphylococcus aureus (NCTC 8532)
Staphylococcus aureus (clinical isolate)
Pseudomonas aeruginosa (clinical isolate, x2 strains)
Enterobacter cloacae (clinical isolate)
Streptococcus pyogenes (clinical isolate)
Klebsiella pnuemoniae (clinical isolate, x3 strains)
Enterococcus faecalis (clinical isolate)
Escherichia coli (NCIMB 8545)
Escherichia coli (NCIMB 10544)
Acinetobacter baumannii (NCIMB 9214

Antibiotic-resistant Bacteria

MRSA (NCTC 10442)
MRSA (NCTC 12232)
MRSA (clinical isolate, x8 strains)
VRE (NCTC 12201)
VRE (clinical isolate, x2 strains)
Serratia marcescens (clinical isolate)
Pseudomonas aeruginosa (NTC 8506)

Anerobic Bacteria

Bacteroides fragilis (clinical isolate)
Peptostreptococcus anaerobius (clinical isolate)
Clostridium ramosum (clinical isolate)
Clostridium clostridioforme (clinical isolate)
Clostridium cadaveris (clinical isolate)
Clostridium perfringens (clinical isolate)
Tissierella praeacute (clinical isolate)

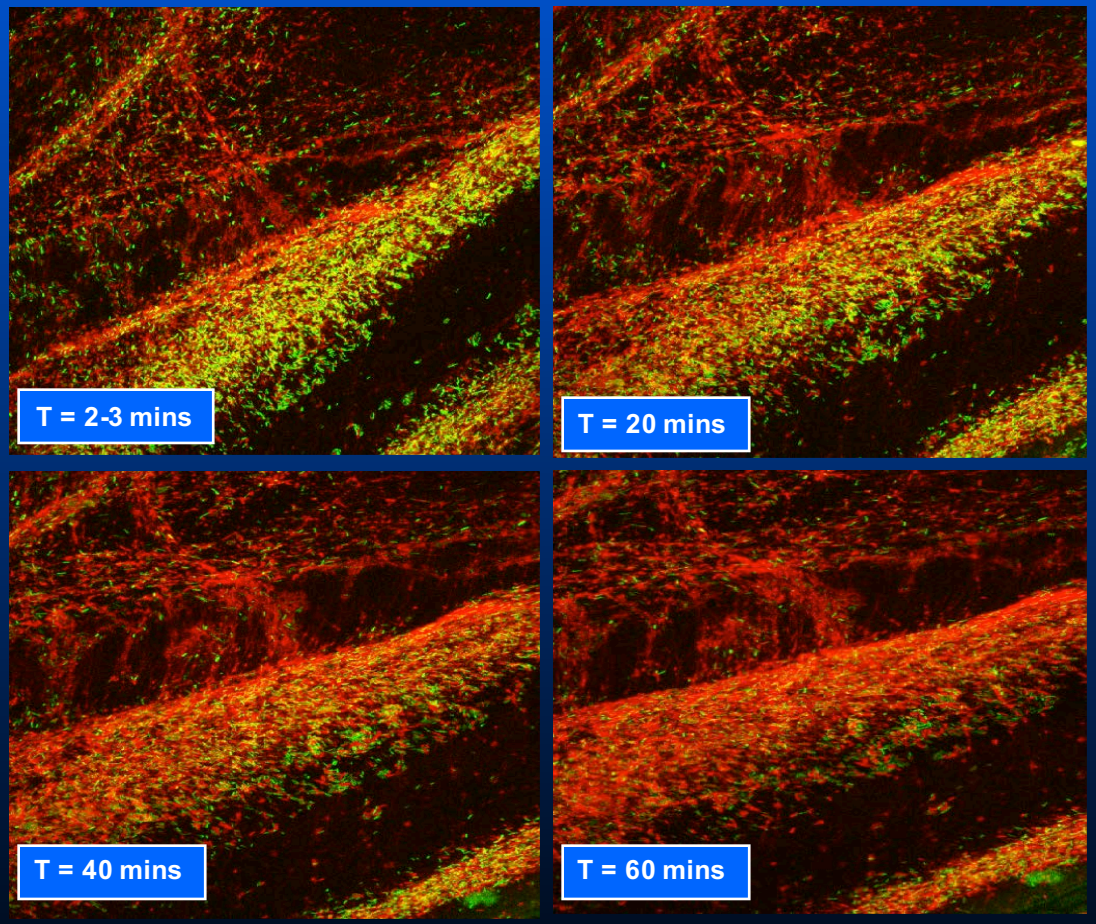
Yeasts

Candida albicans (NCPF 3179)
Candida albicans (NCPF 3265)

Jones SA, Bowler PG, Walker M, Parsons D. Controlling wound bioburden with a novel silver-containing Hydrofiber® dressing. *Would Repair Regen*. 2004;12:288-294.

Hydrofiber® Ag Dressing

Bacterial Sequestration & Bactericidal Activity



Green = **Alive**
Red = **Dead**
T = **Time in minutes**

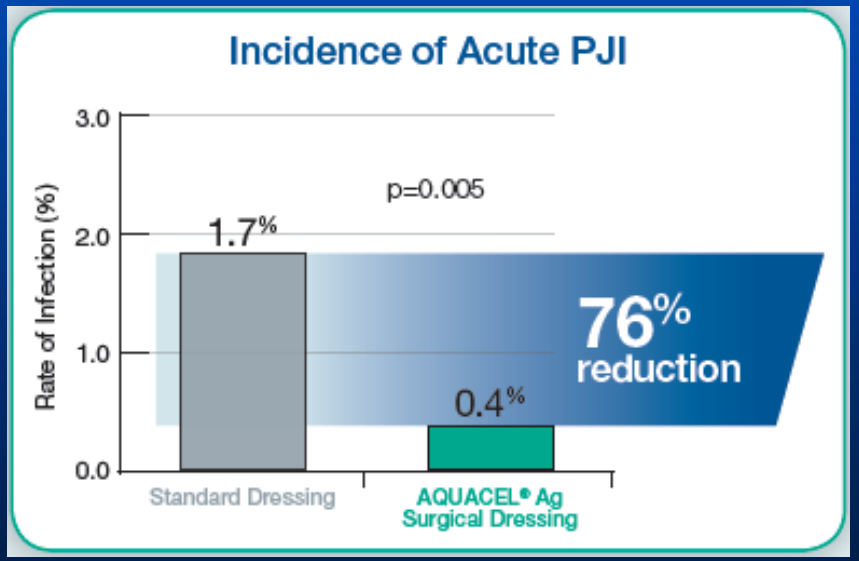
Confocal microscopy of *Pseudomonas aeruginosa* on hydrated Hydrofiber® Ag dressing fiber

Newman GR, Walker M, Hobot J, Bowler P. *Biomaterials*. 2006;27(7):1129-1139.

AQUACEL® Ag Surgical Dressing CLINICAL RESULTS

Rothman Institute

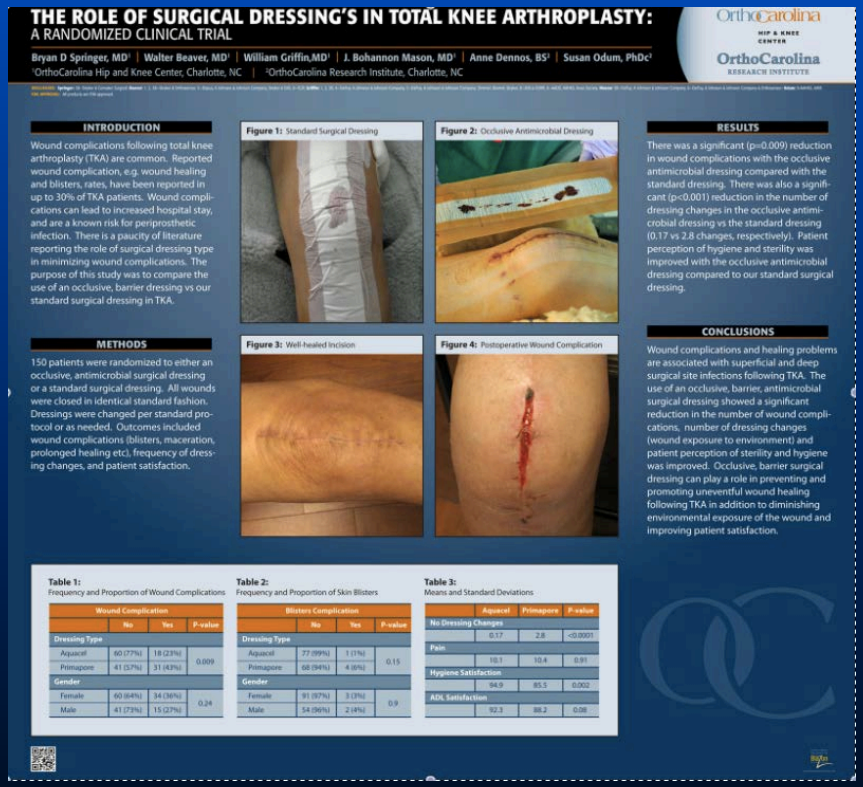
- Retrospective study- Journal of Arthroplasty, 2014
- 1,778 patients undergoing primary THA/TKA
  - 875 standard gauze dressing
  - 903 AQUACEL® Ag Surgical dressing
- 76% reduction in incidence of surgical site infection in AQUACEL® Ag Surgical group
- Multivariate analysis
  - no other independent variables such as patient co-morbidities, age, or BMI impacted the reduction in infection



Cai J, Karam JA, Parvizi J, Smith EB, Sharkey PF. The Aquacel® Ag Hydrofiber Wound Dressing with Ionic Silver Reduces the Rate of Acute Periprosthetic Joint Infection Following Total Joint Arthroplasty., Poster presented at 22nd annual AAHKS meeting, Nov 2-4, 2012.

OrthoCarolina Prospective, Randomized Clinical Trial

- Prospective Randomized Study – American Journal of Orthopedics, 2015
- AQUACEL® Ag Surgical vs. Control
- 300 pts
- Midterm analysis of 150 TKA (AAOS 2013)
- Significant reduction in wound complications (p=0.009)
- Significantly less # dressing changes (p<0.001)
- Improved patient satisfaction, perception of hygiene



THE ROLE OF SURGICAL DRESSING'S IN TOTAL KNEE ARTHROPLASTY:
A RANDOMIZED CLINICAL TRIAL

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[1]OrthoCarolina Hip and Knee Center, Charlotte, NC | [2]OrthoCarolina Research Institute, Charlotte, NC

OrthoCarolina HIP & KNEE CENTER — OrthoCarolina RESEARCH INSTITUTE

INTRODUCTION

Wound complications following total knee arthroplasty (TKA) are common. Reported wound complication, e.g. wound healing and blisters, rates, have been reported in up to 30% of TKA patients. Wound complications can lead to increased hospital stay, and are a known risk for periprosthetic infection. There is a paucity of literature reporting the role of surgical dressing type in minimizing wound complications. The purpose of this study was to compare the use of an occlusive, barrier dressing vs our standard surgical dressing in TKA.

Figure 1: Standard Surgical Dressing

Figure 2: Occlusive Antimicrobial Dressing

RESULTS

There was a significant (p=0.009) reduction in wound complications with the occlusive antimicrobial dressing compared with the standard dressing. There was also a significant (p<0.001) reduction in the number of dressing changes in the occlusive antimicrobial dressing vs the standard dressing (0.17 vs 2.8 changes, respectively). Patient perception of hygiene and sterility was improved with the occlusive antimicrobial dressing compared to our standard surgical dressing.

METHODS

150 patients were randomized to either an occlusive, antimicrobial surgical dressing or a standard surgical dressing. All wounds were closed in identical standard fashion. Dressings were changed per standard protocol or as needed. Outcomes included wound complications (blisters, maceration, prolonged healing etc.), frequency of dressing changes, and patient satisfaction.

Figure 3: Well-healed Incision

Figure 4: Postoperative Wound Complication

CONCLUSIONS

Wound complications and healing problems are associated with superficial and deep surgical site infections following TKA. The use of an occlusive, barrier, antimicrobial surgical dressing showed a significant reduction in the number of wound complications, number of dressing changes (wound exposure to environment) and patient perception of sterility and hygiene was improved. Occlusive, barrier surgical dressing can play a role in preventing and promoting uneventful wound healing following TKA in addition to diminishing environmental exposure of the wound and improving patient satisfaction.

Table 1:
Frequency and Proportion of Wound Complications

Wound Complication	No	Yes	P-value
Dressing Type			
Aquacel	60 (77%)	18 (23%)	0.009
Primapore	41 (57%)	31 (43%)	
Gender			
Female	60 (64%)	34 (36%)	0.24
Male	41 (73%)	15 (27%)	

Table 2:
Frequency and Proportion of Skin Blisters

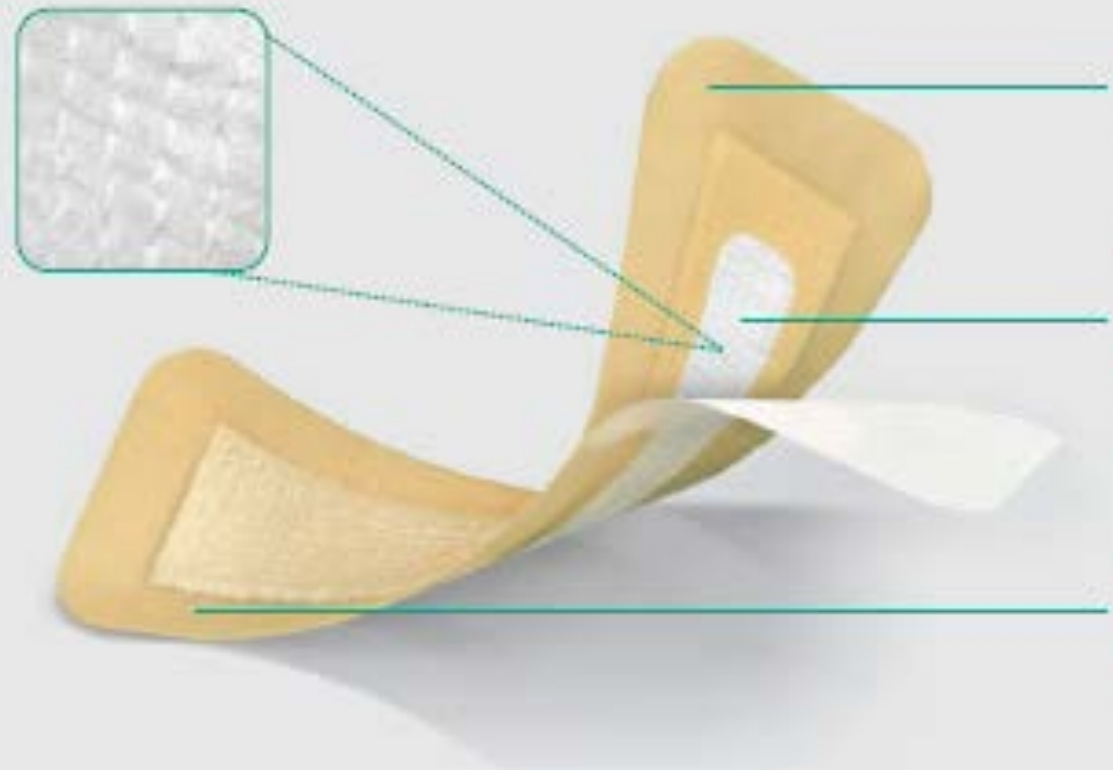
Blisters Complication	No	Yes	P-value
Dressing Type			
Aquacel	77 (99%)	1 (1%)	0.15
Primapore	68 (94%)	4 (6%)	
Gender			
Female	91 (97%)	3 (3%)	0.9
Male	54 (96%)	2 (4%)	

Table 3:
Means and Standard Deviations

	Aquacel	Primapore	P-value
No Dressing Changes			
	0.17	2.8	<0.0001
Pain			
	10.1	10.4	0.91
Hygiene Satisfaction			
	94.9	85.5	0.002
ADL Satisfaction			
	92.3	88.2	0.08

Springer, BD, Beaver, W, Griffin, W, Mason, JB, Dennos, A, Odum, S. The Role of Surgical Dressings in Total Knee Arthroplasty: A Randomized Clinical Trial, Poster presented at 2013 AAOS annual meeting; March 19-23, 2013.

AQUACEL® Ag SURGICAL Dressing



Skin-friendly hydrocolloid technology flexes with the skin during body movement[1,3]

Patented Hydrofiber® Technology absorbs and locks in fluid, including harmful bacteria.[*2]*
Unique construction enhances extensibility and flexibility

*Polyurethane film provides waterproof viral and bacterial barrier *[3]*

*As demonstrated in vitro

[1]Nelson Laboratories Report, Viral Penetration ASTM Method F1671, Procedure Number :ST0062 Rev07, Protocol Detail Sheet No. 200902139, Rev 1, Laboratory no. 483744, 7th August 2009, [2]Walker M, Hobot JA, Newman GR, Bowler PG. Scanning electron microscopic examination of bacterial immobilisation in a carboxymethylcellulose (Aquacel) and alginate dressings. *Biomaterials*. 2003; 24:883-890.8. [3]WHRI 3264 Laboratory Test Comparison of AQUACEL® Surgical Dressing 'New Design' and the Jubilee Method of Dressing Surgical Wounds . 7th Oct 2009

Dressing With Hydrofiber® Technology *

- Locks in fluid*[1]
- Sequesters bacteria[2,3]
- Traps harmful enzymes*[4,5]

Sequestration test: a simple experiment using fluids of different colors to demonstrate the ability of dressings to lock in fluid

[1]Waring MJ, Parsons D. *Biomaterials*. 2001;22:903-912;
[2]Walker M, Hobot JA, Newman GR, Bowler PG. *Biomaterials*. 2003;24(5):883-890;
[3]Newman GR, Walker M, Hobot J, Bowler P. *Biomaterials*. 2006;27(7):1129-1139;
[4]Hoekstra MJ, Hermans MHE, Richters CD, Dutrieux RP. *J Wound Care*. 2002;11(2):113-117;
[5]Walker M, Bowler PG, Cochrane CA. *Ostomy Wound Manage*. 2007;53(9):18-25.

*as demonstrated *in vitro*

Surgical Cover in Today's Joint Replacement World

- Patient satisfaction
  - Immediate showering
  - Decreased dressing changes → increased comfort
- Decreased readmissions
  - Decreased surgical site infection rates
- Decreased complications
  - Surgical site infections
  - Wound complications
- Decreased cost of post-discharge care
  - Decreased need for trained medical wound care assistance

*Data not yet submitted for publication

Additional CJR Resources

- CJR Final Rule in the Federal Register: https://www.federalregister.gov/articles/2015/11/24/2015-29438/medicare-program- comprehensive-care-for-joint-replacement-payment-model-for-acute-care-hospitals
- CMS' Comprehensive Care for Joint Replacement Resource Page: https://innovation.cms.gov/initiatives/cjr
- CMS' Technical Fact Sheet on CJR: https://innovation.cms.gov/Files/fact-sheet/cjr-providerfs-finalrule.pdf
- CMS' FAQ on CJR: https://innovation.cms.gov/Files/x/cjr-faq.pdf
- AHCA/NCAL Webinar Presentation on CJR: https://educate.ahcancal.org/products/comprehensive-care-for-joint-replacement-cjr-final-rule