These slides excerpted to demonstrate the risk of not removing lipids and fluids from the cement interface during TKA. Full slide deck here: https://www.scribd.com/document/360403465/ATTUNE-S-Master-Content-Deck-DSUS-JRC-0517-2142-1

ATTUNE S+™ TECHNOLOGY

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People inspired

Current Prevalence and Causes of TKA Revision: Infection, Aseptic Loosening

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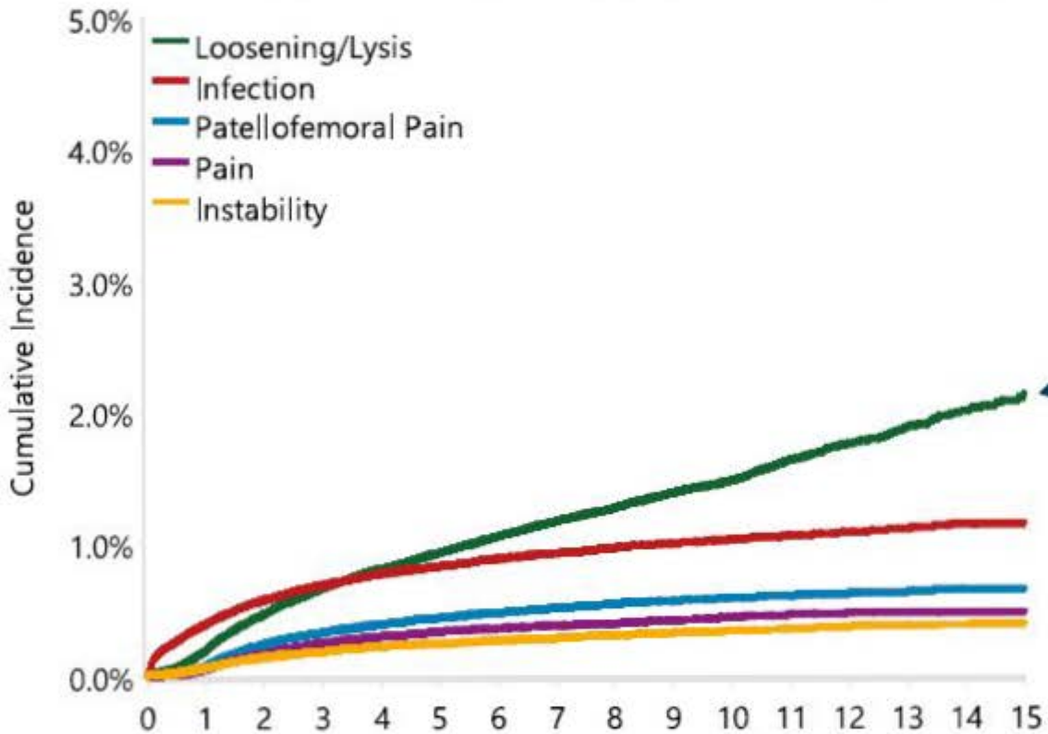
Aseptic Loosening Identified as Industry Wide Opportunity for Improvement for TKA

AOANJRR Class Data (All TKA)

Total Knee

Figure KT8 Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement



After year 2, most common reason for revision is loosening/lysis

THERE IS AN OPPORTUNITY TO IMPROVE THIS!

Full summary of all data is available on:
https://aoanjrr.sahmri.com/documents/10180/275066/Hip%2C%20Knee%20%26%20Shoulder%20Arthroplasty

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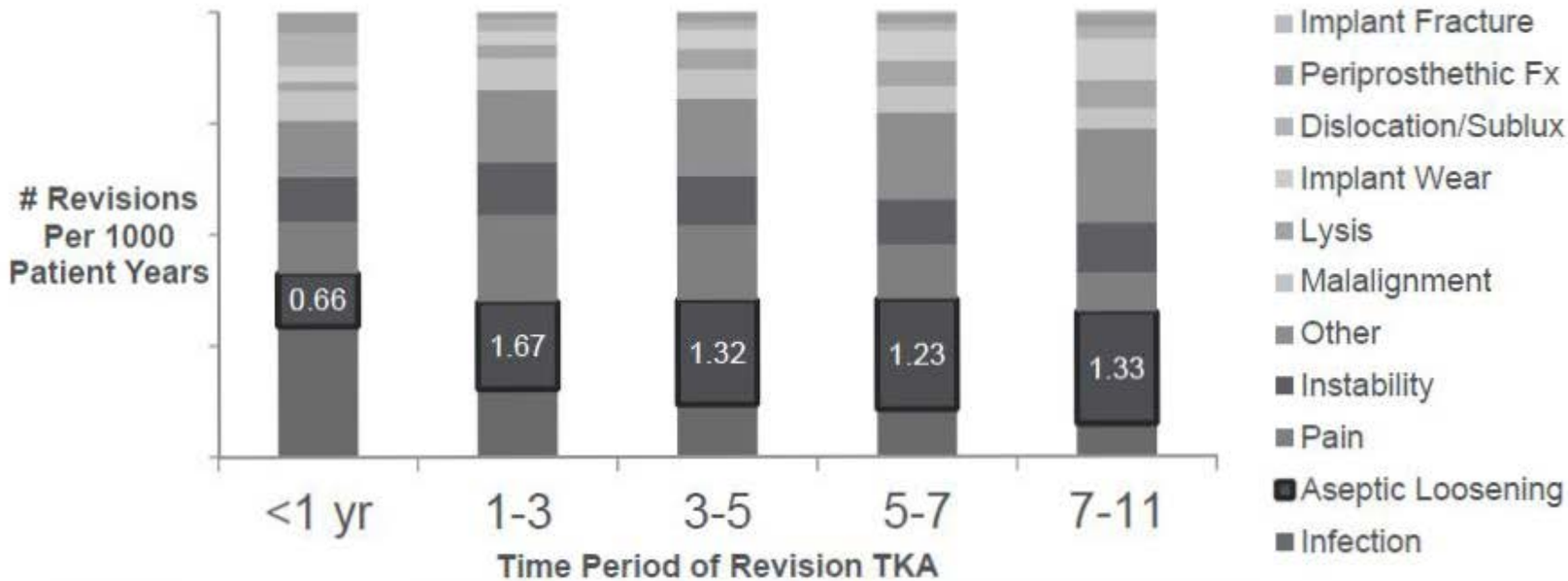
Aseptic Loosening Identified as Industry Wide Opportunity for Improvement for TKA

UK, Class (all TKA) Data, Distribution of Reasons for Revision

Revision Rates by Time in which Primary was Revised, all TKA[1]

Adapted from Table 3.27 National Joint Registry for England and Wales, 13th Annual Report. (2016)



Loosening is the 2nd most common reason for revision after infection during the first year, and the most common after 1 year.

1. *National Joint Registry for England, Wales, Northern Ireland and the Isle of Man* .13th Annual Report Table 3.27. Retrieved from http://www-new.njrcentre.org.uk/ njrcentre/Default.aspx., 2016.

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Financial Impact of Aseptic Loosening to WW Healthcare Systems

Impact of Aseptic Loosening to Patient

- Estimated 162K patients Worldwide Revised for Aseptic Loosening over 10 years, 63.5K in US[1,2,3]
- Impact to patient may include:
  - Pain which requires narcotic medication
  - Swelling, stiffness and clicking in the knee
  - Occupational disability and impairment in activities of daily living
  - Additional visits to clinic

1. 2016 SunTrust Data
2. 2016 GlobalData
3. Khan, M., Osman, G., Green, G., Haddad F., S. The epidemiology of failure in total knee arthroplasty. *The Bone & Joint Journal* 2016. 98-B, No. 1, 105-112.

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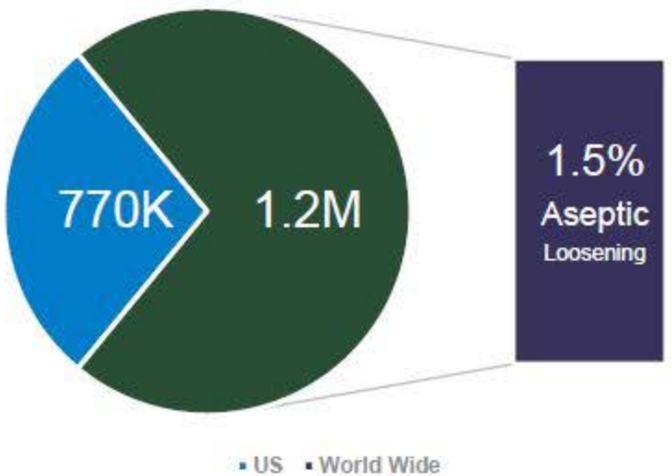
Financial Impact of Aseptic Loosening to WW Healthcare Systems

The global estimated financial burden over the next 10 years is $3.0B with US $1.5B, EMEA $0.5B and rest of world (ROW) contributing $1.0B. Even modest improvements to aseptic loosening can have significant financial savings.

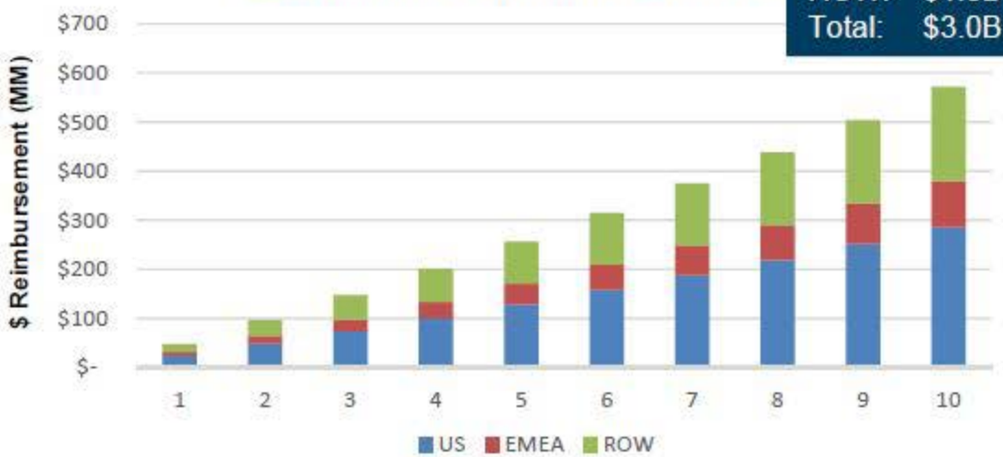
Total TKA Volume



- Projected 2016 US TKA Volume: 770k[1]
- Projected 2016 WW TKA Volume: 1.97M[2]
- TKA Aseptic loosening incidence: 1.5% at 10 years[3]

Estimated Financial Burden

US: $1.5B
EMEA: $0.5
ROW: $1.0B
Total: $3.0B



Revision Data based on Hip, Knee DRG 2017 Reimbursement for Revisions.[4] US Data Only.

DRG Code and Severity	2017 Reimbursement	% of Cases
468 No CC/MCC	$ 16,659	39%
467 CC	$ 20,521	52%
466 MCC	$ 29,966	9%

- Applied 11,430 Euro to USD for EMEA[5] and ROW
- Assumed 2.2% Inflation

1. 2016 SunTrust Data
2. 2016 GlobalData
3. Khan, M., Osman, G., Green, G., Haddad F., S. The epidemiology of failure in total knee arthroplasty. *The Bone & Joint Journal* 2016. 98-B, No. 1, 105-112.
4. Hip, Knee, and Shoulder Medicare Reimbursement Rates
5. Data calculated from five country tariff reports (Italy, France, United Kingdom, Switzerland, Germany) (see notes section for report references)

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Cement Technique in Total Knee Arthroplasty

Good fixation to the bone and implant surface is achieved when the cement is handled and applied properly.

- Cement technique may be affected by the surgeon's experience and training and evaluation of patient bone quality.
- Follow manufacturer's recommendation on preparation and working time of the cement.
- Lavage and dry the cortical bone thoroughly to remove lipids. Avoid mixing lipids into the cement. In areas of dense or sclerotic bone, drilling keying holes in the bone will assist in creating a greater degree of cement interdigitation.[1]
- Remove extruded cement using an edged instrument that will cut and remove the cement without dragging it from under the prosthesis.
- Avoid motion of the knee during hardening of the cement which can interfere with the implant/cement interface due to motion of the base relative to the cement.
- For additional guidance and details, please refer to:
  - Guidance for Cementing Primary Total Knee Replacements. *DePuy Synthes Companies*. 2015. DSUS/JRC/114/0580.

Dennis D.A., MD, Kowalski R., PhD. Cement Technique in Total Knee Arthroplasty. *DePuy Synthes Companies White Paper*. 2015. DSUS/JRC/1114/0581.
Guidance for Cementing Primary Total Knee Replacements. *DePuy Synthes Companies*. 2015. DSUS/JRC/114/0580.

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Developing a Stronger Understanding of the Causes of Aseptic Loosening

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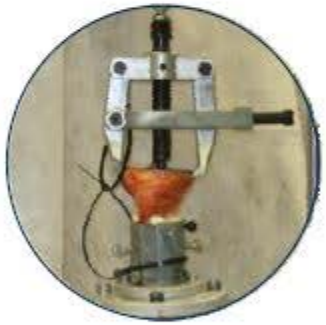
Understanding Fixation: Lipids, Pull Out Strength, and Osteolysis

- Understanding of Lipids/Fluids[1]
- Pull Out Strength[2]
- Clean Tibial Base[3,4]
- Osteolysis and loosening[5]

1. Billi F, et al. Factor influencing the initial strength of the tibial tray-PMMA cement bond. *ORS 2014 Annual Meeting*. 2014;Poster Number 1854.
2. Schlegel U.J., Siewe J., Delank K.S., Eysel P., Puschel K., Morlock M.M., Gebert De Uhlenbrock A. Pulsed lavage improves fixation strength of components. *International Orthopaedics (SICOT)* 2010 Aug; 35(8): 1165–1169.
3. Kopinski J.E., MD, Aggarwal A., MD, Nunley R.M., MD, Barrack R.L., MD, Nam D., MD, MSc. Failure at the Tibial Cement Implant Interface With the Use of High-Viscosity Cement in Total Knee Arthroplasty. *The Journal of Arthroplasty*. 2016; 31: 2579-2582.
4. Hazelwood K.J., O'Rourke M., Stamos V.P., McMillan R.D., Beigler D., Robb III W.J. Case series report: Early cement – implant interface fixation failure in total knee replacement. *The Knee*. 2015; 22: 424-428.
5. Collier, M.B. MS; Engh, C.A. Jr. MD; Mcauley, J.P. MD; Ginn, S.D. BA; Engh, G.A. MD, Osteolysis after total knee arthroplasty: influence of tibial baseplate surface finish and sterilization of polyethylene insert. Findings at five to ten years postoperatively. *Journal of Bone & Joint Surgery - American* 2005; 87(12): 2702 - 2708.

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The Influence of Lipids on Tibial Fixation- ORS 2014

Fat contamination of the metal-cement interface reduced the interface strength to practically zero.

Research study conducted in a laboratory model using two popular bone cements - Simplex® and Palacos® - investigating effect of cement and lavage techniques on strength of tibial tray-cement interface. (48 Size 4 Triathlon™ tibial baseplates).

Variables evaluated:

- Three cementing times: early (low viscosity), per manufacturer (normal, med viscosity) and late (high viscosity)
- Two cementation techniques: cement on tibial plateau only *vs* tibial plateau and keel
- Two fat (marrow) contamination conditions: metal/cement interface and cement/cement interface

Results:

- "Early cementing increased interface strength of Simplex® by 48% (p=0.011) and Palacos® by 72% (p=0.049)"
- "Late cementing reduced the interface strength of Simplex® by 47% (p=0.004) and Palacos® 73% (p=0.034)"
- "Cementing the keel increased the bond strength of Simplex® 153% (p=0.010) and Palacos 147% (p=0.005) *vs* cementing plateau only"
- "Fat contamination of the metal-cement interface reduced the interface strength to practically zero (-99% (p=0.003) , Simplex®, and -94% (p=0.030) Palacos)."

Implications:

- Clinical loosening at the tibial tray-cement interface can result from applying cement too late to the baseplate, and/or interface contamination by marrow, fat or other fluids (blood or saline).
- To maximize tibial baseplate-cement bond strength: 1) thoroughly dry entire tibial interface (plateau and keel), and 2) cement keel and the plateau, and 3) apply cement to the component soon after mixing (while the cement is tacky).

Billi F., PhD, Kavanaugh A., Schmalzried H., Schmalzried T., MD. Factors Influencing the Initial Strength of the Tibial Tray-PMMA Cement Bond. *ORS 2014 Annual Meeting.* 2014; Poster Number 1854.

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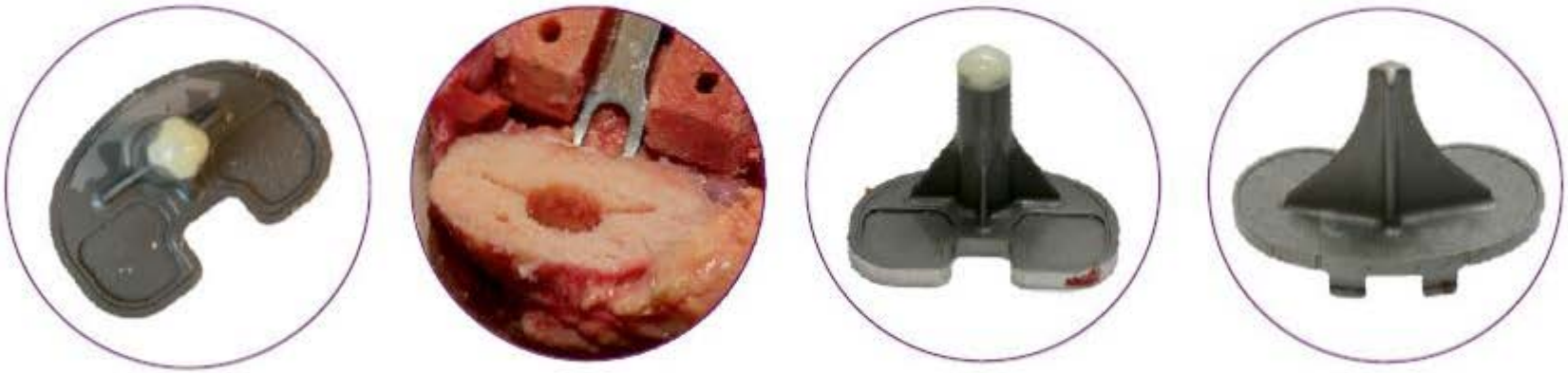
CADAVERIC OBSERVATIONS: LIPIDS & MARROW

- Simulated OR tibial cementing protocols
- Implants extracted and Lipid/Marrow Infiltration (LMI) assessed
- Innovative implant design impact on LMI evaluated



A significant reduction of implant/cement bond strength was due to the combined effect of lipid/marrow and intra-operative motion.[1]

1. Maag et al. Influence of intra-operative lipid/marrow infiltration and intra-operative motions upon cemented tibial implant fixation. *EFORT*. 2017; Poster #1239.

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Attune® Knee System

Glossary of terms

- **Lipid Infiltration**: Contamination of the bone-cement interface by fat, marrow or other body liquids through the small voids in the cement mantle, which allows lipid/marrow to infiltrate space between implant and cement. This reduces the strength of the bone-cement bond.
- **Microinch**: a measure of surface finish that is sometimes used
- **Newton**: A measurement of force.
- **Pull Out Strength**: defined as the mechanical capacity, in Newtons, of the tibial base to resist de-bonding from the cement mantle
  - *The phrases "Distraction Force", "Interface Strength" and Pull-Off are used interchangeably with Pull Out Strength