FORCE-TJR: platform for national and international TJR outcomes

Competitive Application: $12 million AHRQ P50 award
Department of Orthopedics and Physical Rehabilitation
University of Massachusetts Medical School (2011-14)

1. Developed a comprehensive TJR registry with sustainable data infrastructure for comprehensive TJR outcome monitoring.
   – Enrolling new sites to participate now.
   – UMass serves as data coordinating center for the next 20+ years for original cohort

2. UMass TJR expert team conducting comparative effectiveness research in TJR quality and outcomes.
   – Supplemental grants awarded/under review.
Beyond Joint Implant Registries
A Patient-Centered Research Consortium for Comparative Effectiveness in Total Joint Replacement

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Despite the proven effectiveness of total joint replacement (TJR) surgery in relieving advanced knee and hip arthritis pain, TJR outcomes have come under intense public scrutiny in recent years. The 2010 recall of ASR metal-on-metal hip implants heightened awareness of the importance for implant safety surveillance for this high-cost and high-use procedure and exposed the need for a national systematic patient-centered outcomes monitoring system. These safety concerns and the exponential growth in TJR use—given the demographics of the baby boomer generation—emphasize the need for systematic comparative effectiveness research (CER) to inform patients, physicians, and policy makers about the optimal practices in TJR surgery.

Recent estimates suggest that up to 500,000 US patients received a metal-on-metal hip implant between 2003 and 2010.\textsuperscript{1} Prior to the recall, case reports from across the globe documented unusually high rates of early postoperative revision surgery among patients with these implants. National registries of England and Wales, Australia, and New Zealand reported greater revision surgery rates with metal-on-metal implants\textsuperscript{2} compared with conventional metal-on-polyethylene implants. In hindsight, the first sign of implant failure was atypical patient-reported pain, followed by pathologic soft tissue changes. However, at the time, registries were not systematically documenting longitudinal patient-reported symptoms (eg, pain and physical function) after knee and hip surgery. The existence of such systematic patient-reported data may have brought attention to these implants earlier. There is a current need, in the United States in particular, for an efficient monitoring infrastructure of population-based, longitudinal, patient-reported outcomes to provide evidence to inform patient and clinician decisions about optimal TJR timing, implant selection, surgical technique, and likely functional outcomes.

To address this need, the Agency for Healthcare Research and Quality funded a 4-year $12 million research program, Function and Outcomes Research for Comparative Effectiveness in TJR (FORCE-TJR).\textsuperscript{3} Led by a team of researchers at the University of Massachusetts Medical School in cooperation with a national network of surgeons, FORCE-TJR assembled a consortium of orthopedic practices to serve as a research laboratory to generate CER to guide surgeon and patient decisions. The FORCE-TJR has a national scope, is representative of US practices, includes longitudinal patient-reported outcomes, and has the ability to measure implant failure as well as important clinical outcomes and complications.

The FORCE-TJR Approach
The FORCE-TJR model goes beyond the traditional implant failure or revision registry and integrates the principles of population-based prospective research based on patient-centered outcomes. The FORCE-TJR is planning to enroll more than 30,000 diverse patients receiving care from more than 100 orthopedic surgeons representing all regions of the country and varied hospital and practice settings to ensure that data reflect typical US practice. Specifically, the study will include the following:

- **Diverse Orthopedic Practice Settings.** Typically, TJR outcomes research is conducted in high-volume practices, often in academic medical centers. However, the majority of TJR surgeries in the United States are performed by general orthopedic surgeons in community practices. By design, 67% of the 101 surgeons who have joined the FORCE-TJR consortium to date practice in community settings in 27 states. In aggregate, consortium surgeons perform more than 14,000 TJR procedures each year using devices made by each of the 5 leading device manufacturers.\textsuperscript{4} With more surgeons joining the study each month, FORCE-TJR is expected to exceed target patient enrollment. Varied practice size, financing (eg, private, health maintenance organization, Medicare), and geographic settings will ensure that this consortium includes diverse patient populations, practice settings, and health care delivery and financing models.

See also pp 1227 and 1266.

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FORCE-TJR: Patient-reported outcomes

Traditional TJR registries focus on implant failure defined as surgical revision. FORCE-TJR monitors patient-reported outcomes, adverse events, and implant failure.

WHY?

1. Pain relief and improved physical function are the patients’ and surgeons’ primary goals.

2. US adoption of PROs as quality measure is emerging.
   - UK mandates PROs after TJR; CMS exploring.
   - PQRS quality measures include PROs

3. Post-TJR pain or poor physical function can signal risk of future revision surgery
FORCE-TJR: Implant Performance and Revision

• Metal on metal demonstrated early pain/disability can be signal for implant failure.

• New Zealand registry reports 7 times increased risk of 5 year revision when persistent pain at 6 and 12 months after TJR.

• In FORCE-TJR, implant design, material, and component details can be analyzed for both revision rates and sub-optimal performance in early post-operative years.
FORCE-TJR addresses traditional registry limitations

FORCE-TJR data base includes:

1. **Disease burden**: OA severity; medical and musculoskeletal comorbidities
2. **Comprehensive, longitudinal outcomes**
   - patient, surgical, implant
   - Annual direct to patient assessment indefinitely
3. **Merge** registry data and other data sets
   - Patient-level FORCE-TJR and CMS data are merged to track revision surgery
National Norms on 24,000+ patients; 150 surgeons; 22 states

- 75% of surgeons are community-based
- Fellowship-trained, general orthopedic surgeons
- High and low volume surgeons/hospitals; urban and rural hospitals
- Teaching hospitals, non-teaching hospitals
- Patients with private, public and HMO insurance
- All major implant manufacturers
- Primary TJR, revision TJR, Uni, PF, HR, all types of procedures

Map of Participating Core Centers and Community Sites

Core Clinical Centers
- UMass Medical School, Worcester, MA
- Connecticut Joint Replacement Institute, Hartford, CT
- The University of Rochester Medical Center, Rochester, NY
- Medical University of South Carolina, Charleston SC
- Baylor College of Medicine, Houston, TX

Community Sites
- Community Sites currently enrolled
Proven processes for complete PRO collection

• Utilize FORCE-TJR expertise
  • 96% pre-TJR
  • 85% completion post-TJR*
  • Completed in Office or at Home
  • PC or Tablet
  • Web-based surveys with real-time scores
• Scannable Paper optional

*typical US registry PRO follow-up rates from 20-30%. JBJS, 2014.
FORCE-TJR QI data collected across TJR Care Cycle

**PATIENT**
- Before Surgery
  - **PRO** VR12 HOOS/KOOS
  - **CLINICAL** Medical & MSK risks Demographic

**Hospital**
- Surgery
  - **OR Implant** Operative Note

**PATIENT (validate EHR)**
- 30 -90 days
  - **PRO** VR12 HOOS/KOOS
  - **CLINICAL** Complication? Readmission?

- 6 -12 months
  - **PRO** VR12 HOOS/KOOS
  - **CLINICAL** Complication?

- Annual?
  - **PRO** VR12 HOOS/KOOS
  - **CLINICAL** Complication?
  - **CLINICAL** Revision?
PROs are real-time scored for Tended individual patient reports

Hip **pain** pre-post THR: HOOS improved from 35-97

Global **function** pre-post THR: PCS improved from 37-53

Pain in R knee (stable):

Pain in L knee (stable):

Pain in R hip (stable):

Pain in L hip pre-post THR: Improved from

Scale 0-100 best

Scale 0-50 norm
**Post-TJR FORCE-TJR risk-adjusted outcomes compared to national norms**

**Outcome: Function (SF/PCS)**
- Site pre-op mean PCS = 27
- US pre-PCS = 30

- Site post6m mean PCS = 43
- Site post6m risk-adjusted PCS = 46
- US post 6m PCS = 45

- Site pre-post PCS gain = 19
- US pre-post gain = 15

*THR patient gain in function exceeds national norm.*

Risk adjustment is critical if change scores are to be used for public reporting or reimbursement.

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**PCS Function Over Time**

<table>
<thead>
<tr>
<th>Site</th>
<th>Pre-op</th>
<th>Post 6m</th>
<th>Risk Adjusted Post 6m</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

End of slide.
Readmission/complications; beyond the surgical hospital

- 25% of all 30-day readmissions go to non-surgical hospital.
- FORCE-TJR risk-adjustment can combine claims and clinical data.
- Patients over 65 years-CMS data
Monitoring implants

• Identify implant attribute(s)

• Identify patient and clinical factors (e.g., BMI, age, smoking, arthritic pain in other joints) that influence outcome

• Compare AE, PRO (pain, function), and revision trajectory post-TJR between implant X and all others
# FORCE implants matched to ICOR Implant Library

<table>
<thead>
<tr>
<th>Field Name</th>
<th>KNEE IMPLANT ATTRIBUTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>BONE_FIXATION</td>
<td>The type of fixation intended to be used to fix the component to the bone, not including cement.</td>
</tr>
<tr>
<td>ROUGHNESS</td>
<td>The surface roughness of the component, this has been assigned based on catalogue description and not necessarily the roughness value.</td>
</tr>
<tr>
<td>SIZE</td>
<td>The size of the component.</td>
</tr>
<tr>
<td>SIDE</td>
<td>Whether the component is intended to be implanted on a particular side.</td>
</tr>
<tr>
<td>PMAT</td>
<td>The polyethylene material used in the component.</td>
</tr>
<tr>
<td>MMAT</td>
<td>The metal material used in the component.</td>
</tr>
<tr>
<td>CMAT</td>
<td>The ceramic material used in the component.</td>
</tr>
<tr>
<td>COATING</td>
<td>The type of coating used on the surface of the component.</td>
</tr>
<tr>
<td>DIAM</td>
<td>The diameter of the component, measured in mm.</td>
</tr>
<tr>
<td>THICK</td>
<td>The thickness of the component, measured in mm.</td>
</tr>
<tr>
<td>LENGTH</td>
<td>The length of the component, measured in mm.</td>
</tr>
<tr>
<td>AP</td>
<td>The Anterior/Posterior length of the component, measured in mm.</td>
</tr>
<tr>
<td>ML</td>
<td>The Medial/Lateral length of the component, measured in mm.</td>
</tr>
<tr>
<td>STABILITY</td>
<td>The stability of the component.</td>
</tr>
<tr>
<td>MOBILITY</td>
<td>The mobility of the component.</td>
</tr>
<tr>
<td>MODULARITY</td>
<td>The modularity of the component.</td>
</tr>
<tr>
<td>SET</td>
<td>The setting of the component into the bone.</td>
</tr>
<tr>
<td>LOCATION</td>
<td>The location the component is intended to be implanted into</td>
</tr>
</tbody>
</table>
Primary TKR: Implant Design Y

Pre-TKR: significant pain and Functional limitation
KOOS scores 48-50
Mean >80 (minimal symptom)

PAIN (blue)
6 months: 83 mean
12 months: 77 mean

FUNCTION (red)
6 months: 86 mean
12 months: 81 mean
Implant X vs. all other Pre-TKR patients

Implant X had high revision rate in international registry.

Selected patients <65 years

Mean pre-TKR pain = 44
Both Implant X and all other

• No difference in distribution
• Significant pain
At 12 months post-TKR

Almost all pain scores improved; most >80.

More patients with Implant X have pain score <75 than all other implants

Monitor for revision
FORCE-TJR Lessons for Implant Monitoring

1. Combination of PROs, Adverse events, and Implant details supports comprehensive patient and device monitoring.

2. Implant device details are stored in OR systems; not regularly included in EMR.

3. International implant library for common device categorization/attributes is key to shared lessons.