Ethical/Moral Dilemmas in complex reconstructive surgery: Cost considerations

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Disclosures

- Editor – JBJS Essential Surgical Techniques
- Innomed, Inc.
- Musculoskeletal Transplant Foundation – Medical Board of Trustees
- US FDA
- Musculoskeletal Tumor Society – past president

Orthopaedics and ethics: computerized navigation for TKA

Ethics in Practice

The Ethical Implications of Recent Innovations in Knee Arthroplasty

Informed Consent: What does it mean? The absolute requirement is informed consent. When does a new technique represent unacceptable experimentation rather than innovation? A new technique may not be better than the standard procedure. Therefore, true informed consent is absolutely essential.
In health care, what is value?

Value = \frac{Outcomes achieved}{unit cost}

How can one measure the value of a treatment?

Types of outcomes achieved:

Outcome

Hierarchies for Breast Cancer and Knee Osteoarthritis

Health policy analyst viewpoint

- Reconstructive surgery: impacts quality, not only length of life, therefore, need metric for:
  - Health related quality of life (HRQoL)
- Quality Adjusted Life Years (QALYs)
  - 1 QALY = 1 year of life lived in perfect health x utility value
How much is 1 QALY worth?

“If one had to select a single threshold outside the context of an explicit resource constraint or opportunity cost, we suggest using either $100,000 or $150,000.”


Cost-effectiveness: comparing interventions

- Cost effectiveness measure: Incremental cost-effectiveness ratio (ICER) = cost per QALY gained.

\[
\text{ICER} = \frac{\Delta \text{Cost}}{\Delta \text{Quality}}
\]

Cost effectiveness threshold (when to pay for a treatment)

- Value based judgment
- General guidelines dependent of the decision maker:
  - Patient: willingness to pay
  - Insurer: market demand
  - Gov't: societal consensus

- <$50k/QALY: reasonable efficient
- $60k-175k/QALY: sufficiently efficient
- >$175k/QALY: not justifiable
TJA: $/QALY

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Joint</th>
<th>Time duration</th>
<th>ICER / QALY gained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruiz/2013</td>
<td>TKA vs non-op</td>
<td>15 yrs</td>
<td>$18,930, mean QALY gain of 2.4</td>
</tr>
<tr>
<td>Lawless/2012</td>
<td>THA</td>
<td>10 yrs</td>
<td>$9,773</td>
</tr>
<tr>
<td>Lavernia/2011</td>
<td>THA, rev THA</td>
<td>1 yr</td>
<td>$5,672 primary, $10,775 revision THA</td>
</tr>
<tr>
<td>Losina/2009</td>
<td>TKA vs non-op</td>
<td>lifetime</td>
<td>$18,300 TKA, $28,100 hi risk TKA</td>
</tr>
</tbody>
</table>

TJA: $/QALY ~ $10k - $30k

Cost effectiveness of some non-TJA surgeries

- Reverse TSA: Cost utility at 2 years was $26,920/quality-adjusted life-year by the Short Form 6 Dimensions and $16,747/quality-adjusted life-year by the EuroQol.
- Lumbar discectomy vs non-op Rx: At 2 years, $60k/QALY gained [Spine Patient Outcomes Research Trial (SPORT)]
Patient viewpoint:
cost in terms of medical risk, $

Patient viewpoint:
demand and expectations changes over time/age

Case scenarios
58F, failed R multiply revised THA, pelvic discontinuity

DX:
1. Bilateral hip Osteonecrosis due to steroids 1990's for MS
2. Multiple sclerotics
3. Failed Right hip Arthroplasty
4. R sciatic n injury with foot drop
5. Long term tobacco usage
6. HTN
7. Body mass index is 34.51 kg/(m^2)

TREATMENTS:
1. 1996 - Right THA, (Dr. R)
2. 1997 - Left THA (Dr. R)
3. 2/27/2013 - Left THA cup Revision, allografting behind cup. (Dr. N)
4. 7/18/2014 - attempted Right THA revision, temporary cup, but had to close due insufficient implants. Intraop cultures: P.Aacnes x 1, CNS (3 strains) x 1, (Drs. T and N)
5. 8/7/2014 - Right THA Revision, Stryker MaxTi 60 mm cage, 6.5 mm screws x 4. ArCom Hi wall poly cup 32/36 mm, Stryker V-40 36mm head, +10 neck. Intraop cultures x3 (-), sciatic nerve injury, (Drs. T and N)

Pre-op w/u

Lab Test 06/16/16
FTYP Synovial fluid
R HIP
FNEU 56
FCOL Red
FAPR Turbid
FWBC 36
Alpha defensin (-)
Culture (-)

Sed Rate Latest Ref Range: 0.30/30 mph 20
CRP Inflammation Latest Ref Range: 0.0-8.0 mg/L <2.9
Interleukin 6 Blood Latest Ref Range: <3.01 pg/mL 1.42
Vid D defic screening (-)

Prior revisions before referral
Questions to panel

- What surgery do you advise?
  1. Revision TM cup with augments
  2. Cup/Cage construct
  3. Cage/allograft construct
  4. Custom periacetabular/triflange implant
  5. Girdlestone

- Do you require pt to change modifiable preop factors? 1. Yes 2. No Nicotine? BMI?

- How do decide between modular revision cups/augments vs custom implant?

Preop model video

3D model of custom implant
Panel questions:

- Estimated custom implant cost?
- Does your hospital pass actual implant charge on to pt?
- Does your hospital add a surcharge to the implant cost?
- Who pays the implant cost? Patient/hospital/insurer/gov’t?

Treatment charges (3 days)

- Total hospitalization: $120,000
  - Navigation (spheres, tracker pins) $1900
  - Custom Triflange ($13,400 cost to hosp) $33,500
  - Screws, fem head, drill bits $18,198
- Surgery time: 8 h 7 min
  - (incl adductor tenotomy)
- Given the charges, was the decision to do a custom implant appropriate?
Similar case treated without custom implant
65F: multiply failed R THA, pelvis discontinuity

Diagnosis:
1. Kidney transplant in 1970 (19 years old) at HCMC and U of M for unspecified nephritis
2. R hip avascular necrosis 1970
3. R THA femoral and acetabulum aseptic loosening 1994
4. L knee osteoarthritis 1998
5. L hip osteoarthritis 1998
6. Failed multiply revised R THA, acetabular loosening

TREATMENTS:
1. R THA 1980 by Dr. RCT
2. 4 R THA revisions in 1994 by Drs. RCT and RG
3. L TKA in 1998 by Dr. B
4. L supracondylar femur ORIF in 2012 by Dr. OD
5. 1/19/2016, ORIF transverse acetabular fracture with GFP cage. Structural distal femoral allograft to R pelvis acetabulum. Revision of multiply revised right THA (Cheng) UMMC.

Structural Allograft/cage/antibx PMMA

- Total hosp charges (3 days): $90,540
  - Total Implant related: $36,955
    - Implant/allograft/cement: $33,698
    - Norian graft: $3257
  - Surgery time: 5 h 26 min

Panel questions:
- Is the non-custom implant more cost effective than a non-custom implant?
  1. Yes
  2. No
- Does the potential enhanced stability, durability of a custom implant provide sufficient value to warrant usage?
  1. Yes
  2. No
56M, failed allograft hemipelvis after hemipelvectomy 13 years ago

**Dx:**
1. Chondrosarcoma left pelvis
2. Multiple Sclerosis
3. DM

**Surgeries:**
1. 2003, left hemipelvis chondrosarcoma excision with allograft reconstruction by Dr. RCT.
2. March 12, 2008, removal of fractured left pelvis allograft and reimplantation of second left hemipelvis allograft with internal fixation and revision left total hip arthroplasty (Cheng)
3. 9/25/2015, Revision failed L hemipelvis allograft/THA composite to custom R hemipelvis and THA prosthesis (Biomet pelvis, viE poly liner, CoChr 36mm +9 head) with Sacral ala and pubic symphysis fixation.

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L Periacetabular Chondrosarcoma

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1st pelvic allograft fx, after 3.75 yrs
2nd pelvic allograft failure, after 7 yrs

2015-03-26, CT coronal sagittal

Panel questions

- What would you do?
  1. Non-surgical
  2. Another allograft pelvis/THA
  3. Saddle prosthesis
  4. Ilio-femoral arthrodesis +/- allograft
  5. Custom implant
  6. Girdlestone
  7. External hemipelvectomy
Panel questions

• If you are a consultant for a hip implant company and you are doing a hip implant surgery, do you disclose this to patients?
  1. yes, regardless if I’m using the company’s implant
  2. yes, only if I’m using the company’s implant
  3. yes, only if the patient inquires
  4. yes, indirectly on a website
  5. no

Panel questions

• When you do a custom implant that requires multiple meetings with engineers for implant design, do you charge for your services?
  1. No
  2. Yes, I consider it part of the global surgical fee
  3. Yes, I bill the insurance company
  4. Yes, I bill the patient directly

Panel questions

• You believe the best implant option for this patient is with Company A. You are employed by the only hospital system you work at, which allows you to use Company B’s products only. What do you do?
  1. Use Company B’s product
  2. Petition hospital to use Company A’s product
  3. Refer patient to surgeon at competing hospital
  4. File complaint with Joint Commission (JCAHO) and your state’s/country’s licensing board.
Panel questions

- Do you inform the patient of your actions?
  1. Yes
  2. No
- You petition to use Company A’s product and are denied. What do you do now?
  1. Use Company B’s product
  2. Appeal the decision and engage another outside surgeon for 2nd opinion.
  3. Refer patient to surgeon at competing hospital
  4. File complaint with Joint Commission (JCAHO) and your state’s/country’s licensing board.

Custom hemipelvis implant

- sacral flanges
- SI fixation (mortise & tenon)
- locking screws
- hinged pubic extension joint

Why navigation?

- Sacral locking screw: safe passage
- Sacral ala oblique-vertical osteotomy must match implant precisely
- Flanges must abut anterior inferior sacrum to resist vertical shear
- Process:
  - Plan trajectories on pre-op CT
  - Merge intra-op & pre-op CT
  - Follow navigation plan now on intra-op CT
Intra-op osteotomy preparation

Ilio-sacral fixation
(mortise & tenon, inferior flange)
Intra-op CT confirmation

S1 screw position & length
S2 screw position & length

4 months post-op

26 F, Ewing's sarcoma
2-D planning a 3-D object

Post chemo

Allograft acetabulum, pubis, ischium + THA

Current status, 9 yrs f/u disease free

4 yrs post-op, allograft resorption, failed cage, unable to ambulate

Next option?
Next option?

Navigated placement of custom implant

- 8 yrs f/u, allograft resorption, failed cage, unable to ambulate

Next option?

Design considerations

- Cup with IM stem directed towards PSIS
- Lateral buttress w/ locking screws
- Public extension joints - allows intra-op adjustment
- Public footing with locking screws

Surgical plan

- Cranial
- Caudal
- Navigation reference array
- Navigate:
  - Iliac osteotomy
  - Stem position
Hospital charges

- Custom implant bill to hosp (less screws) $23,700
- Hosp bill to insurer (5 days) $163,522
  - Implant related 74,624
  - Implant related (incl screws) 81,134
- Gov’t insurance paid <$25,000

Surgical planning
(6 months timeline)

- IRB application
  - Mandatory 2nd opinion
- FDA application
- Multiple conference calls with engineer
- Implant company and navigation company have joint meeting to plan and test transferring digital intra-op plan from pre-op CT to intra-op CT for navigating surgical plan
- Intra-op consultation with navigation company (2 reps), implant company (2 reps) who travel from corporate offices
Hospital charges (6 days)

- Total Charges: $179,768
  - Navigation $150
  - Total implant related $71,364
    (cost to hospital $31,175)
    - Implant $42,500
    - Implant $16,250
    - Implant $3250
    - Screws, Ti cannul $9364
- Surgery time: 12 hrs
- Hospital paid by insurer < $35,000

Panel questions

- Does the outcome justify the expense?
  - ~$200k to keep a 56 M out of a wheelchair with reduction in pain for X number of years.
  - The # of QALYs is difficult to ascertain