WHITE ROCK
ORTHOPAEDIC
SURGERY CENTRE

Ste 44 - 1480 Foster Street White Rock, BC V4B 3X7
Telephone: 604 . 538 . 0068 Fax: 604 . 538 . 0703
Email: frontdesk@wrosc.com www.drarnosmit.com

ARNO SMIT, M.D., F.R.C.S.(C) **ORTHOPAEDIC SURGEON**

OrthoGlide Workshop
Advanced BioSurfaces

September 17, 2012

Outline

- Introduction of decision analysis tool

- Application of decision analysis tool:

 - to assess relative merit of current technology → UKA vs TKA

 - to assess potential risks/benefits of new technology → OG vs UKA

Outline

- Review of early results of medial compartment interpositional knee arthroplasty
- Review of indications
- Review of peri-operative process
- Review of surgical technique

Introduction

- Community orthopaedic practice
- Trauma / hip / knee /shoulder
- Approximately 120-150 knee arthroplasties per year

Introduction: knee OA

- Progressive degenerative process
- Progressive intervention
- Approx 30% ‘predominantly’ unicompartmental
- Medial:Lateral? (lateral underdiagnosed?)
- Demographic/ethnic variability?
- Metro Vancouver: diaspora (China, India)

Introduction

- Councelling (expectations, lifestyle)
- Injections: corticosteroid, viscosupplement (PRP, Botox)
- Functional unloading bracing
- Arthroscopy (more pain if meniscal tear)
- High tibial osteotomy
- OG/UKA/TKA

Introduction

Evidence based surgical decision making:

- Multiple variables and parameters
- Ranges of reported outcomes
- Various sources of evidence

Individual surgeon belief system

- Belief system continuously updated and modified
- Multiple permutations: intuitive assessment difficult

Methods

- Cohort decision analysis
- assume 100 patients
- age 60 y
- end-stage anteromedial gonarthrosis
- define initial and subsequent procedures
- quantify procedure related parameters
- assume linear procedure attrition rate
- assume mortality of 2.5 % per year

Methods

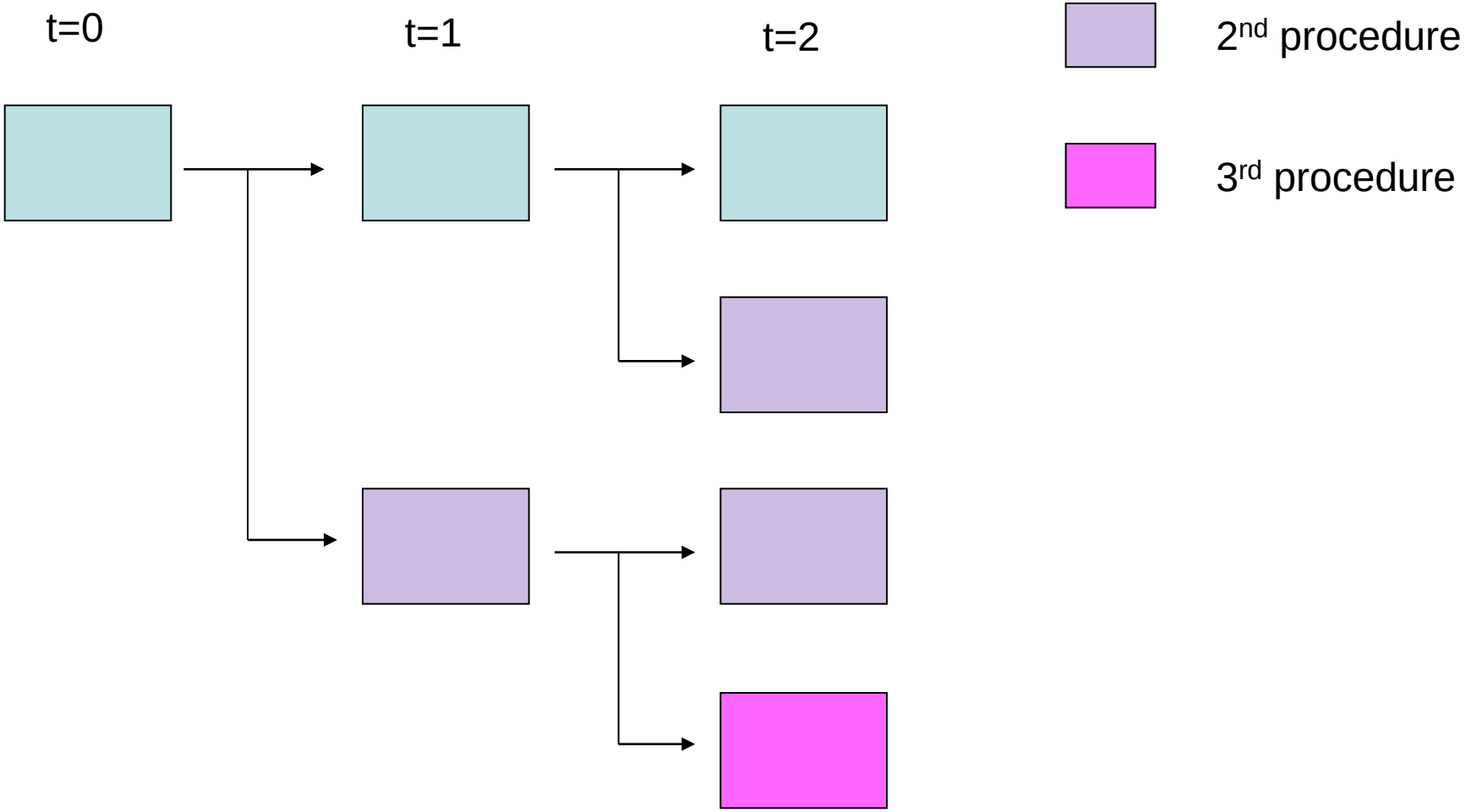
- each revision creates a new sub-cohort
- each sub-cohort has a linear attrition rate
- tabulate various procedures:

  determine total cohort morbidity

  determine cohort resource utilization

Methods

- General principle



•Methods

- Current model:
  - intervals user defined
  - user defined cap on revision number
    → ‘salvage’
  - allows more flexibility

- Initial modelling suggested:

  70 % 10 y implant survival of UKA would yield similar hospital utilization and infection rate as TKR

Methods

- Group of 8 orthopaedic surgeons
- Decision analysis model discussed
- Consensus:

- linear attrition rate was realistic.
- revision of UKR -> TKA is similar to primary TKA.
- 2nd and higher total knee revisions could be lumped together.
- outcomes & resource utilization defined

Results: surgeons' consensus

	10 y attrition(%)	*cost($)*	*hosp* **(days)**	*infection*
• ***UKR***	10%	$11,000	1	0.5%
• ***TKR***	5%	$13,400	3	1%
• ***U ->TKR***	5%	$13,400	3	1%
• ***TKA R1***	15%	$17,500	4	3%
• ***TKA R>1***	25%	$20,000	7	5%

Results: cohort decision analysis

	Primary procedure UKA	***Primary procedure TKA***
Procedures	115	108
Cost, excl infections	$ 1,299,558	$ 1,492,763
Hospital days	145	336
Infections	0.66	1.27

Discussion

UKR was considered a valid option for treatment of medial compartment gonarthrosis, as assessed by this group of BC surgeons, based on consideration of reduced cost, hospitalization and total infection burden, ***despite a higher re-operation rate.***

UKA vs TKA:

- Decision analysis/ cohort modelling allows assessment of implications of surgeon's perception of relevant outcome parameters
- Results of cohort modelling after consensus seeking confirm that UKA as primary treatment for medial OA of the knee can reduce cost, cohort infection and hospital utilization, despite a higher number of total procedures.

Additional considerations:

- Unloading bracing:

  assuming 20% per year attrition rate, uncomplicated conversion to UKA

  → favourable
- HTO:

  ‘for another day’

Assessment of new treatment options

- Clinical outcome not known
- Range of possible outcomes can be assessed
- May help establish preliminary balance between risks and benefits
- May help anticipate resource utilization

Example:
Metallic interpositional arthroplasty

Historical background:

→ MacIntosh, McKeever

→ Sbarbaro, Swanson

- used initially in OA and RA
- as far back as late 1950's
- required some bone preparation

Metallic interpositional arthroplasty

- Unispacer (Sulzer, Zimmer)

- brief period of interest in early 2000's
- quick, relatively wide acceptance by US surgeons
- minimal reporting
- issues: implant instability, overstuffing (?), arthrofibrosis
- relied on femoral congruency for stability
- 1 year revision rates ? 20-30% ?

Unispacer

Metallic interpositional arthroplasty

Contemporary use:

- Dr. R. Scott, Boston
- ‘may be considered as a bridging measure in the treatment of unicompartmental OA’
- 70-86% implant survival at 8 y → not unlike HTO
- 10 out of 24 doing well at 16 years
- McKeever

Metallic arthroplasty -OrthoGlide

- Development history

  2003 – trial of a polyurethane interpositional arthroplasty (Advanced BioSurfaces)

- Minimally invasive procedure
- Stable implant
- Initial recovery OK
- Synovitis due to wear after 2-3 months
- Trial stopped

Metallic arthroplasty -OrthoGlide

- Development history:
- Evaluation of lessons learned
- Metallic implants made of same configuration
- 3 and 4 mm implants, various AP sizes
- early experience reported in 2007 (300 implants, 92 patients with functional scores, mainly USA, Arnold)
- 10% revision rate at 1 y, functional scores acceptable, WOMAC 32 → 72 at 6m, 1/300 dislocation, 1/300 infection.
- To date: approximately 500 implants placed

OrthoGlide - medial

Metallic arthroplasty -OrthoGlide

- Considerations for community orthopod:
- Is it safe?
- Is it effective?
- What about long-term management?
- Is it acceptable to the health care system?
- Cost and other resource utilization?
- Health Canada licencing status?

Metallic interpositional arthroplasty - OrthoGlide

- Medial implant licenced by HPB, Health Canada in 2009
- Changed to Special Access in 2011 (insufficient data)
- Lateral implant: Special Access in Canada.

Metallic interpositional arthroplasty - OrthoGlide

- Safety:
- potentially minimally invasive surgery
- potentially minimal hospital stay
- No violation of subchondral bone → potentially ‘reversible’ (management of infection etc)

Metallic interpositional arthroplasty - OrthoGlide

- Assume following range of parameters for medial Orthoglide:
- Revision rate 5% or 10% per year
- Revision
  - to UKA, no compromise
  - to primary TKA, no compromise
- Daycare surgery under local anesthesia with IV sedation
- Infection rate 0.5% (same as UKA) or 0.25%
- Treatment of infection: removal of implant with IV antibiotics only, ***NO PROSTALAC*** .

Metallic arthroplasty -OrthoGlide

- Initial working assumptions
- Infection rate ½ of UKA → 0.25%
- Revision rate 5% per year
- Revision to UKA (for majority)
- Function at 1 y similar to UKA / TKA

OrthoGlide: outcome analysis over 20 years

(5% / year revision, mortality 2.5% / year, revision to UKA)

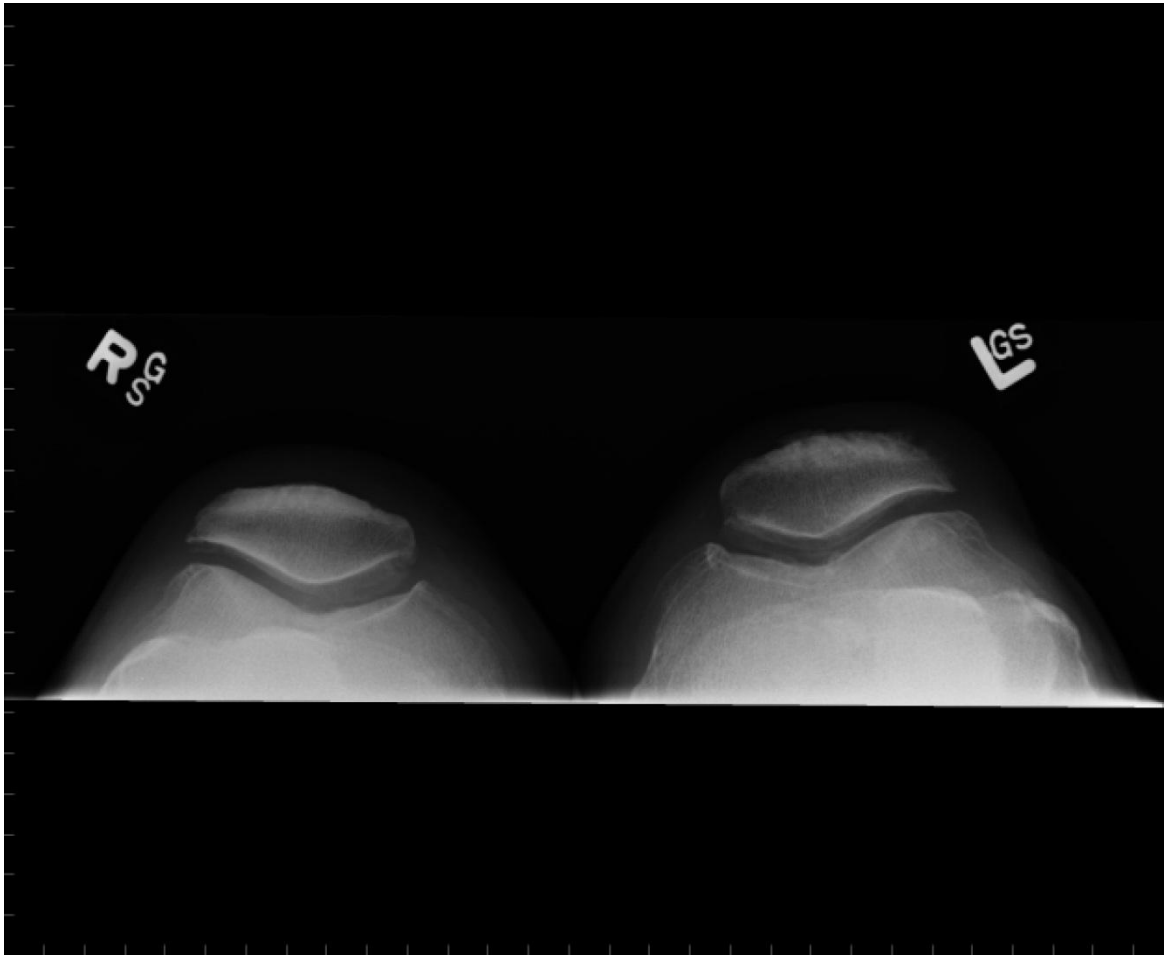
	OG	UKA
• Total procedures	176	115
• Hospital days	93	145
• Infection rate	0.67	0.66

OrthoGlide - medial

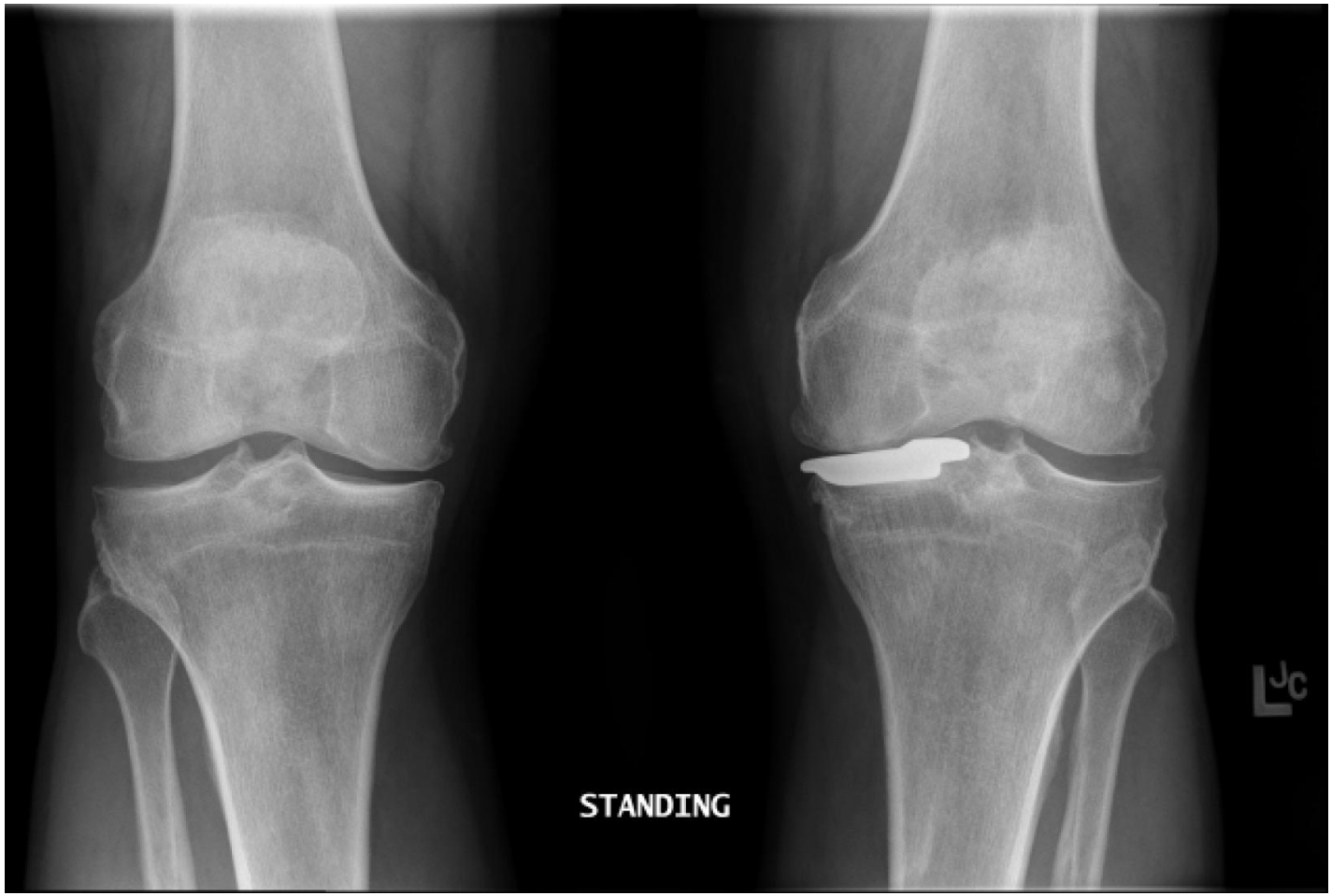
62 y old male, framer

62 y old male, framer

62 y old male, framer



62 y old male, framer



62 y old male, framer

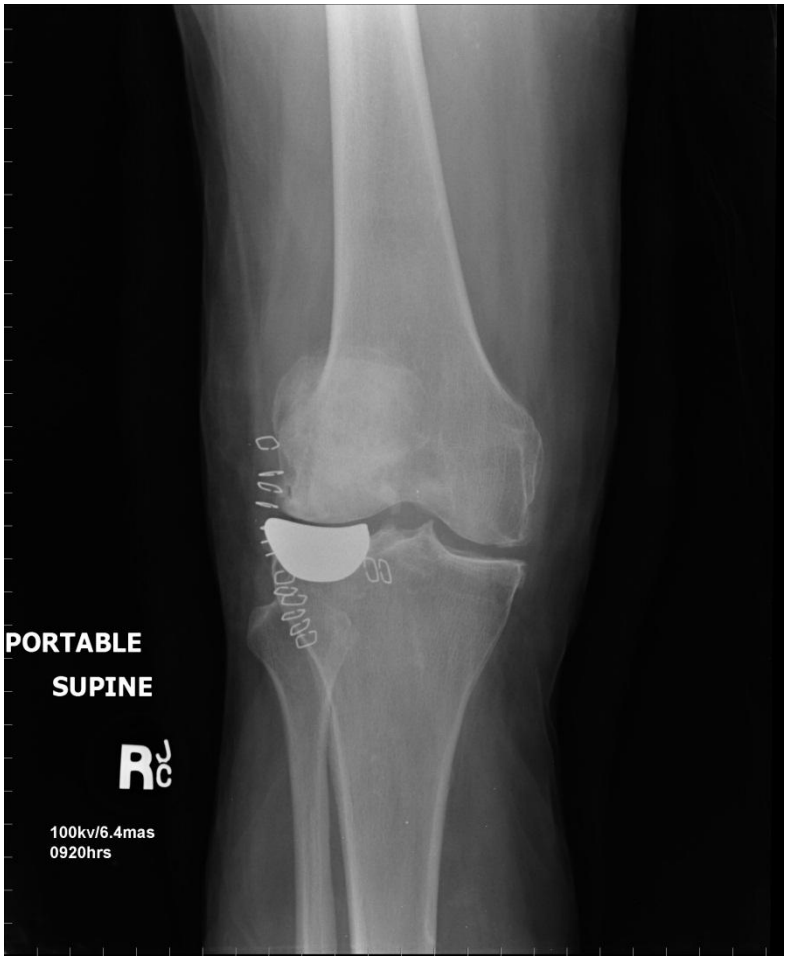
What if expected lifespan is short?

- 82 y old female with lateral OA / RA
- Evaluated for TKA
- CXR → lung carcinoma
- Experimental chemo
- Immuno compromised
- Frail
- Pain +++, depressed +++

Lateral OrthoGlide: 82 y old female with lateral OA / RA

82 y old female with lateral OA / RA

82 y old female with lateral OA / RA PARR



82 y old female with lateral OA / RA
10 w postop

Metallic interpositional arthroplasty - OrthoGlide

- Current practice (2012):

- ‘ideal’ candidate for UKA → consider Oxford

  (reduce fracture risk: proximal tibia contour ‘champagne glass’ vs ‘stove pipe’), bone quality

- ‘too early’ or ‘not well enough’ for TKA, but ‘not ideal’ for Oxford → consider OrthoGlide

- Patient preference → tolerance for uncertainty of effectiveness of implant, exposure to surgical risk vary widely. Surgeons underestimate pt interest in risk avoidance

- INFORMED CONSENT of high quality

Metallic interpositional arthroplasty - OrthoGlide

- Early results:
- Gradual introduction as of July 2009
- Total: 54 patients with medial OrthoGlide
- Arthoscopically assisted, local anesthesia with IV sedation, day care surgery
- One hematoma, washed out

Metallic interpositional arthroplasty - OrthoGlide

- Early results – 1 year follow-up:
- 30 patients
- No revisions
- 1 lost to follow-up immediately
- 4 poor, 3 fair, 22 good
- ROM at 2m:125 degrees (sd 10)
  at 6m: 128 degrees (sd 7)
  at 1y: 131 degrees (sd 7)

Metallic interpositional arthroplasty - OrthoGlide

- Early results – 1 year follow-up:

‘Poor’ results:

- 2 patients: early progression of lateral compartment OA
- 2 patients with unrelenting medial joint pain
- Revision offered

Metallic interpositional arthroplasty - OrthoGlide

- Early results – 2 years follow-up:

- Assessment complete in 20 / 30 patients
- 5 known revisions (AS)
- 15 implants confirmed to be in situ at 2 y:
  - 11 good
  - 3 fair
  - 1 poor

Metallic interpositional arthroplasty - OrthoGlide

- Early results – 2years follow-up

  - ‘good’ outcome:

- Improvement from 1 y to 2 y
- Stairs, inclines, pivoting → remains difficult for some
- Preservation of treatment options important to patients satisfied with procedure

Metallic interpositional arthroplasty - OrthoGlide

- Early results – general observations

- Quick initial recovery phase
- Quick recovery of ROM (weeks)
- But: persistent pain with weight bearing

→ ROM OK → Pt and surgeon expect pain relief

→ cycling OK, swimming OK, no pain at rest

Metallic interpositional arthroplasty - OrthoGlide

- Early results - persistent pain

→Improves with time:

? Increasing sclerosis of femoral surface?

? Improved stability of implant with fibrous tissue consolidation?

? Other?

→Plateau at 1 y (?), some report improvement in 2nd year (not unlike TKR?)

Metallic interpositional arthroplasty - OrthoGlide

- Early results – persistent pain

→Corticosteroid injections helpful as temporizing measure

→Quite variable

→Not predictive of final outcome (?)

→Requires ongoing assessment and communication

Metallic interpositional arthroplasty - OrthoGlide

- Early results:
- Even if good result: commonly some difficulty on stairs

→Common, not related to PF OA on X-ray

→Tolerated by most

→Has been indication for revision of otherwise well-functioning implant at 2 years

Metallic interpositional arthroplasty - OrthoGlide

- Early results
- So:

After OG → ‘good’ results at 1 y in 70-80% range (???)

After TKR → ‘good’ results at 1 y in 85-90% range (NIH, CIHI)

After UKR → similar or slightly less than TKR?

Metallic interpositional arthroplasty - OrthoGlide

- Early results

‘good’ → implant accepted by patient

steady-state

‘fair’ → implant merely tolerated by patient

not a steady-state

‘poor’ → implant NOT tolerated by patient

Is a ‘good’ TKA similar to a ‘good’ UKA similar to a ‘good’ OG ???

Metallic interpositional arthroplasty - OrthoGlide

Indications

- ‘Predominantly’ medial OA

→how much lateral OA is acceptable?

- revision to TKR easier than after UKA

→role of stress views? Prior arthroscopy?

- not essential

→PF assessment (<> Oxford)

- PF OA may not be contra-indication

Metallic interpositional arthroplasty - OrthoGlide

Indications:

→Age (frailty, need for bone preservation)

→Fitness for surgery

- ASA status (cardiac, pulmonary, DM, etc)
- pain disorder (opiates, fibromyalgia etc)
  - mixed results.
- cognitive (pt ‘buy-in’ important)

Metallic interpositional arthroplasty - OrthoGlide

Indications:

→Activity level sought

- favourable: walking, golf, cycling
- less favourable: tennis, running
- work: manual labour vs office → unclear
- social aspects of full knee flexion → religious, car, other

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process
- educate nursing, anesthesia, family physicians etc.
- ‘program’ approach may be helpful
- try and access rehab services as for UKA/TKA
- regular surgeon follow-up (2w, 2m, 6m, 1y…)

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process

- Local anesthesia with IV sedation:

→safe, patient friendly

→fentanyl, midazolam, propofol (pump)

→high volume, low concentration

→effective approx 12-16 h

→ Epinephrine → no tourniquet

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process

- 60 ml NS
- 40 ml Marcaine 0.5% (final conc: 0.2%)
- 0.5 ml epinephrine 1:1000 (final conc: 1:200.000)
- ketorolac 30 mg (1ml)

→ ‘101.5’ ml

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process
- Leg positioned: hip flexed 30-45 degrees, lower leg hanging free
- Tourniquet applied: only inflated if needed
- Non-operative leg left extended on table
- Non-operative leg ICD (my preference)

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process
- Local anesthetic infiltration under sedation
- Use:

25gx1.5in needle: patient will thank you

10 cc syringe: your thumb will thank you

3-way stopcock, IV tubing: creates closed system → contamination risk reduced

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process

3 injection technique:

1/Medial injection

- 10 ml anteromedial portal
- 10 ml wide medial portal
- 20 ml medial compartment
- 10 ml along planned incision

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process

3 injection technique

2/ Lateral injection

- 10 ml anterolateral portal and lateral capsule
- 20 ml lateral compartment (ligamentum mucosum)

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process

3 injection technique

3/ posteromedial injection

- after arthrotomy, later into procedure

use long spinal needle

- 20 ml into posterior capsule

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process

3 injection technique

- After initial infiltration → **WAIT** at least 10 minutes (scrub/gown/set-up time)
- Typically no tourniquet required
- Can supplement with lidocaine → seldom needed
- Pt can often move from OR table onto stretcher when finished

Metallic interpositional arthroplasty - OrthoGlide

- Peri-operative process
- Provisions for mobility aids, dressing change etc
- DVT prophylaxis → ??? →

  ASA 325 mg PO for 6 weeks → ???
- Antibiotic prophylaxis → Ancef 1-2 g IV

  30-60 min pre-op (if not allergic)
- Physio etc

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique

Arthroscopy → why?

- Complete assessment (incl ACL, lat, PF)

- Optimize knee joint (lateral, PF)

- Prepare medial compartment

  - debride residual articular cartilage tibia/femur, remove osteophytes

  - menisectomy (white rim only?)

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique
- Arthroscopy easier with knee flexed at 90 degrees or less
- Arthrotomy and most of open portion of procedure easier with knee flexed well beyond 90 degrees
- When positioned on leg holder → Moving table up for open portion of procedure can be of help

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique

- Open arthrotomy

→ mid medial patella to just medial of tibial tuberosity

→ 5-7 cm skin incision

→ incorporate anteromedial portal if present

→ excise part of fat pad as needed for visualization

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique

- Open arthrotomy

complete menisectomy (Smiley knife can be helpful)

remove residual osteophytes, particularly in the postero-mesial aspect of the knee (towards the notch)

smooth femur, contour tibia

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique

-Open arthrotomy

Useful instruments:

straight ENT rasp: when this fits → the implant will fit

ABS size-specific femoral congruency rasp
ABS angled rasp

high-speed burr with collar

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique

- Measure AP length of tibial plateau →

obtain good spatial sense of posterior edge of tibial plateau with curved rasp or feeler, need good access.

determine anterior limit of tibial plateau

will find that width of implant is usually very satisfactory with accurate AP sizing

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique

Implant AP length determined → select thickness → ‘always’ 3 mm

Avoid overstuffing, remove adequate bone from mesial aspect of tibial plateau (‘contouring’)

Use trial implant → ‘easy’ insertion required → definitive implant has bigger posterior lip

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique

- Implant insertion → introducer works well

- Reduction maneuver →

a/ full flexion with valgus stress

b/ implant insertion parallel with tibia

c/ circumduction, extension with simultaneous pressure on inserter

d/ once ‘gives’ → inserter precludes full insertion → remove and use ‘pusher’

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique
- Insertion can be difficult
- Ensure that patient is relaxed
- MCL preservation most likely critical
- For metallic implants → judicious use of mallet on inserter or pusher can be helpful
- Careful use of off-set lamina spreader (as used in TKR) has been helpful when inserting PEEK implant

Metallic interpositional arthroplasty - OrthoGlide

- Surgical technique

- after reduction

→confirm ROM, incl extension

→implant typically stable, immobile on tibia

→routine closure: PDS, vicryl, staples

→bulky dressing

→no drain needed

Metallic interpositional arthroplasty - OrthoGlide

- Conclusion

- Interpositional arthroplasty of the medial compartment of the knee with the metallic OrthoGlide implant appears to be safe and can be effective
- uncertainty persists re. consistency and extent of functional improvement
- revision options are preserved

Conclusion

- Further assessment will require a structured roll-out with systematic data capture, best as a real-time on-line data registry with ongoing analysis
- Further refinement in implant design and materials, technique, indications etc to be based on further data collection
- Open communication in the orthopaedic community required to assess relative merit of various established and emerging technologies

THANK YOU