Hip Resurfacing Data - WA Agency Utilization

Updated 11-13-09

Background

Update: In preparing for agency presentations, a mistake in the final compilation of a table was identified. The original Table 2 totals inadvertently excluded Medicaid costs, which are now included in the updated Table 2 below. The other tables were independently calculated and included Medicaid procedures/costs.

In response to a selection by the health technology assessment program to complete an evidence review for hip resurfacing, the agencies provide information on current medical policy and utilization data.

Unlike total hip replacement (THR), hip resurfacing does not involve the removal of the femoral head and neck or removal of bone from the femur. Rather, the head, neck and femur bone is preserved in an effort to facilitate future surgery should it be necessary and to enable the patient to take advantage of newer technology or treatments in the future. Hip resurfacing is anatomically and biomechanically more similar to the natural hip joint.

Proposed benefits of hip resurfacing include: increased stability, flexibility and range of motion; younger patients needing full joint replacement that are expected to out-live the full replacement may benefit from symptom relief and more bone preservation to tolerate a subsequent replacement surgery later; and risk of dislocation lower and higher activity level possible with less risk than THR

However questions remain about the unknown longevity and durability of the procedure; the reported high failure rates; the appropriate patient selection criteria (e.g., age, gender, tried and failed therapies); impact on long term health outcome; higher surgical risks and complications from multiple surgeries and the health system impacts of a surgery designed to delay but not eliminate need for later surgery.

Current Data View

Table 1: Count of Procedures by Year

UMP, L&I, & Medicaid

ICD-9 Procedure Codes	2005	2006	2007	2008	**Total**
00.85 (total hip resurfacing)	0	3	20	22	**45**
00.86 (resurfacing, femoral head)	0	1	2	2	**5**
00.87 (resurfacing, acetabulum)	0	0	0	0	**0**
81.51 (total hip replacement)	432	471	487	614	**2004**
81.52 (partial hip replacement)	108	100	82	102	**392**
Total	**540**	**575**	**591**	**740**	**2446**

Table 2: Amount Paid* by Procedure by Year (updated)

UMP, L&I, & Medicaid

ICD-9 Procedure Codes	2005	2006	2007	2008	**Total**
00.85 (total hip resurfacing)	$0	$69,406	$404,120	$454,032	**$927,558**
00.86 (resurfacing, femoral head)	$0	$19,991	$36,344	$60,457	**$116,792**
00.87 (resurfacing, acetabulum)	$0	$0	$0	$0	**$0**
81.51 (total hip replacement)	$5,639,160	$6,378,458	$6,389,632	$9,036,877	**$27,444,126**
81.52 (partial hip replacement)	$1,264,504	$940,592	$957,011	$1,246,261	**$4,408,368**
Total	**$6,903,663**	**$7,408,447**	**$7,787,107**	**$10,797,626**	**$32,896,844**

* includes facility, professional and other payments

Table 3: Amount Paid* per Procedure by Year (NonMedicare)

UMP, L&I, & Medicaid

ICD-9 Procedure Codes	2005	2006	2007	2008
00.85 (total hip resurfacing)	0	$23,135	$22,451	$20,638
00.86 (resurfacing, femoral head)	0	$19,991	$18,172	$30,229
00.87 (resurfacing, acetabulum)	0	0	0	0
81.51 (total hip replacement)	$17,902	$18,650	$18,361	$20,037
81.52 (partial hip replacement)	$20,071	$17,102	$21,750	$21,487

* includes facility, professional and other payments. Amount paid divided by procedure count.

Table 4: Age and Sex by Procedure

UMP, L&I, & Medicaid

		Procedure Code				
Age	Gender	00.85	00.86	81.51	81.52	**Total**
0-19	F	0	0	1	3	**4**
	M	0	0	0	0	**0**
20-44	F	3	0	66	9	**78**
	M	6	1	116	11	**134**
45-64	F	7	2	579	74	**662**
	M	27	2	588	53	**670**
65-74	F	1	0	243	37	**281**
	M	1	0	193	10	**204**
75-84	F	0	0	115	64	**179**
	M	0	0	67	31	**98**
85+	F	0	0	26	76	**102**
	M	0	0	8	24	**32**
Total		**45**	**5**	**2002**	**392**	**2444**

Data Notes:
The data for UMP in 2008 also includes Public Employees Health Plan (formerly PEBB) members being served by Aetna. This adds approximately 25,000 people to the analysis.

Table 3 does not include UMP and Aetna Medicare patients in the analysis because Medicare is the primary payer and this skews the cost data.

Coding Information

ICD-9 Procedure Codes

00.85 - Resurfacing hip, total, acetabulum & femoral head
00.86 - Resurfacing hip, partial, femoral head
00.87 - Resurfacing hip, partial, acetabulum
Source: http://provider.medica.com/C15/PolicyIndex/Document%20Library/HipResurfacing_CP.pdf
Source: http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=26113&lcd_version=3&show=all

WA Agency Data

Hip Resurfacing: A Newer Intervention for Advanced Arthritis/Degeneration of the Hip

Hip Resurfacing

- Unlike total hip replacement (THR), hip resurfacing does not involve the removal of the femoral head and neck or removal of bone from the femur.
- Rather, the head, neck and femur bone is preserved in an effort to facilitate future surgery should it be necessary
- Hip resurfacing is anatomically and biomechanically more similar to the natural hip joint

Hip Resurfacing

- Purported Benefits
  - increased stability, flexibility and range of motion
  - risk of dislocation lower and higher activity level possible with less risk than THR
  - younger patients needing full joint replacement that are expected to out-live the full replacement may benefit from symptom relief and more bone preservation to tolerate a subsequent replacement surgery later

Key Concerns for Prioritization

- Questions remain about
  - unknown longevity and durability of the procedure
  - reported higher failure rates
  - appropriate patient selection criteria (e.g., age, gender, tried and failed therapies)
  - impact on long term health outcome
  - health system impacts of a surgery designed to delay but not eliminate need for later surgery

Key Concerns for Prioritization

- Efficacy Concern: Medium
  - Compared to total hip replacement (THR)
  - Compared to conservative management
- Safety Concern: Medium
  - Requirement for re-operation near-term and/or longer-term
- Cost Concern: Medium-High
  - Demographics suggest high and rising potential demand
  - Considered a delay tactic against anticipated future THR

Current Coverage Policy in State Agencies

- No Specific coverage policy established by UMP, L&I, or Medicaid
- Newer procedure code is being used and paid

Utilization Trends in UMP, L&I, and Medicaid

ICD-9 Procedure Codes	2005	2006	2007	2008	Total
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Cost Trends in UMP, L&I, and Medicaid

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Total	**$6,903,663**	**$7,408,447**	**$7,787,107**	**$10,797,626**	**$32,896,844**

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Procedure Cost Trends in UMP, L&I, and Medicaid

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Agency Conclusions

- Agencies only reimburse for FDA approved devices
- Should include FDA indications and contraindications
- Consider criteria based on population studied
  - Patients with arthritis
  - Failed conservative management and candidate for total hip replacement
  - Age less than 55
- Monitor utilization and cost trends

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Hip Resurfacing Technology Assessment

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WS Health Technology Assessment Program
Seattle, Washington
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Scope of Report

This report evaluates relevant published research describing the use of hip resurfacing (HR)

HR refers to modern commercially available devices designed for hybrid fixation and not non-hybrid or hemi resurfacing devices.

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Background

Hip arthroplasty in younger patients

- **Total hip arthroplasty (THA) was originally designed for older, relatively inactive patients**

  Historically, 60 to 80 years of age

- **The need for hip prostheses in younger patients is increasing**

  By 2011, more than half of all THAs are estimated to be <65 years

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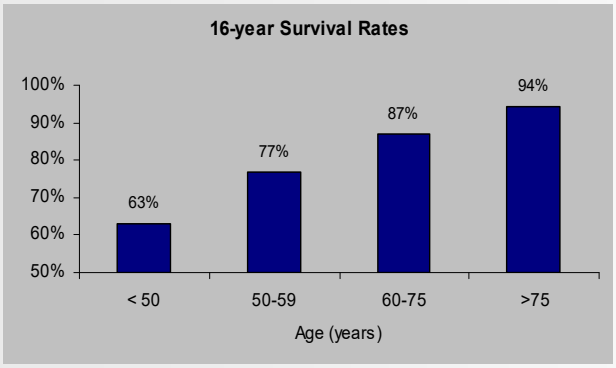
Background

Hip arthroplasty in younger patients

- Younger, more active patients are more likely to need revision THA surgery than older patients:



* Estimated from Swedish Total Hip Replacement Register Annual report 2007

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Background

History of hip resurfacing (HR)

- Initial design (1970-80s) abandoned due to high failure rates caused by metal-on-polyethylene design
- New design (1990s) include high-carbide cobalt chrome metal-on-metal bearings and hybrid fixation (cemented femoral component, uncemented acetabular component)

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Background

Design of HR versus THA

- THA: femoral head removed and replaced with a metal prosthetic ball
- HR: surface of the femoral head is removed and replaced with a metal cap inserted into the femoral shaft
- Both HR and THA replace the acetabulum with a metal cup

Images from Corin (Cormet) and Smith & Nephews (Birmingham)

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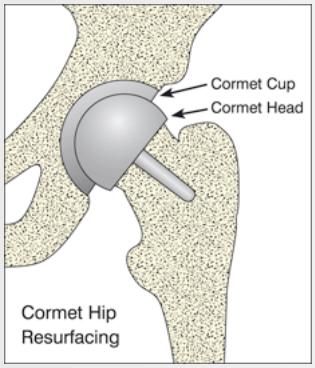
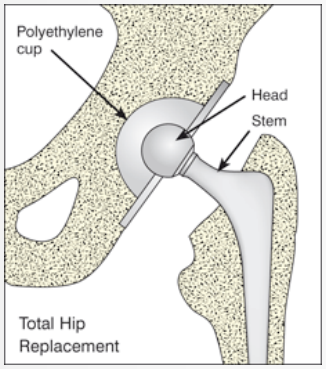
Background

Theoretical advantages of HR versus THA

- Preservation of femoral bone stock





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Images from Corin (www.keepmeactive.com)

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Background

Theoretical advantages of HR versus THA

- Reduction in stress-shielding as more normal femoral loads are maintained
- Improved function due to preservation of femoral head
- Lower morbidity at time of revision surgery than that which occurs in THA patients
- Lower risk of dislocation
- Better replication of normal anatomy
- Greater range of motion

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Background

Indications for HR (FDA)

Adults who may not be suitable for THA due to increased risk of ipsilateral hip joint revision as a result of their younger age and/or increased activity level, and who have pain due to:

- Non-inflammatory degenerative arthritis (eg., osteoarthritis, traumatic arthritis, avascular necrosis with < 50% involvement of the femoral head, or developmental hip dysplasia), or
- Inflammatory arthritis (eg., rheumatoid arthritis)

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Background

Contraindications for HR (FDA)

- Infection or sepsis
- Skeletal immaturity
- Conditions that could compromise implant stability or postoperative recovery (ie., vascular insufficiency, muscular atrophy, neuromuscular disease)
- Inadequate bone stock to support the device, including:
  - Severe osteopenia or osteoporosis
  - Severe avascular necrosis (> 50% of the femoral head)
  - Multiple femoral neck cysts (>1 cm in diameter)

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Background

Contraindications for HR (FDA) (cont…)

- Females of child-bearing age
- BMI > 35
- Known or suspected metal sensitivity
- Moderate or severe renal insufficiency
- Immunosuppression (ie., AIDS, those receiving high doses of corticosteroids)

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Background

Common current HR devices

Device name	Company
Birmingham*	Smith and Nephew
Cormet*	Styker/Corin Medical
Conserve Plus*	Wright Medical Technology
ASR	Depuy (J & J)
Durom	Zimmer

*FDA cleared

We included all HR devices because:

- total HR devices are similar
- the results for one device can be reasonably generalized to the others
- including all HR devices provides more data
- registries included several brands together – difficult to tease apart

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Key Questions

When used as an alternative in patients where total hip arthroplasty (THA) is indicated:

1. What is the evidence of efficacy and effectiveness of HR?
2. What is the evidence about the safety profile for HR?
3. Is there evidence of differential efficacy or safety issues with the use of HR?
4. What is the evidence of cost implications and cost effectiveness of HR?

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Inclusion Criteria

Study design

- Key Question 1 - RCTs and comparative studies with concurrent controls
- Key Questions 2 & 3 – RCTs and comparative studies with concurrent controls, registry studies; case-series with >5 years follow-up
- Key Question 4 - economic analyses and cost data from other HTAs or other published articles

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Inclusion Criteria

Study parameters for key questions 1-3

- Population: primary total HR for arthritis, developmental dysplasia, or osteonecrosis
- Intervention: modern commercially available hybrid HR device
  - FDA-approved and un-approved devices with at least one year of follow-up data available in peer-reviewed journals were included
- Comparator: primary THA

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Outcomes

- **Efficacy / effectiveness**
  Physical function/disability (clinical success, pain, activity, or motion), QoL
- **Safety**
  Revision, complications

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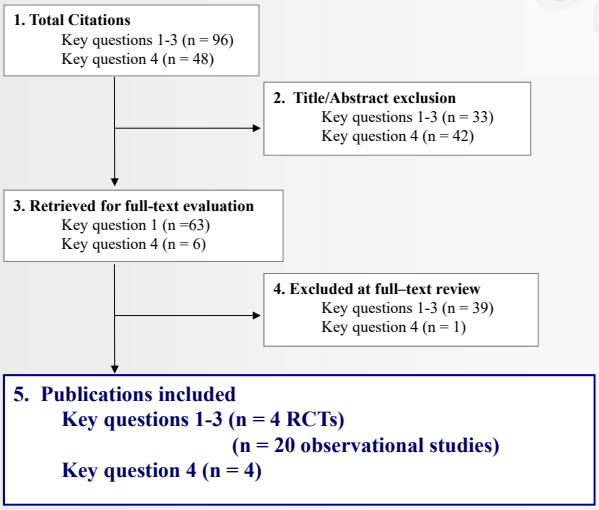
Literature Search



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RCTs comparing HR with THA

Study	Demographics	HR	THA	Follow-up	FDA status (HR device)	LoE	Industry sponsored?
Garbuz (2009)	mean age: 52 89% male	n = 48	n = 56	Efficacy: 1 year Safety: 1–2 years	Not approved (Durom)	II	yes
Lavigne (2009)	mean age: 50 60% male	n = 24	n = 24	1–1.5 years	Not approved (Durom)	II	yes
Vendittoli (2006)/ Rama (2009)	mean age: 50 65% male	n = 24	n = 24	1 year	Not approved (Durom)	II	no

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Internal Validity: RCTs

Methodological principle	Garbuz (2009)	Lavigne (2009)	Rama (2009)	Vendittoli (2006)
Study design Randomized controlled trial	✓	✓	✓	
Statement of concealed allocation		✓		
Intention to treat*		✓		
Independent or blind assessment	✓	✓		
Co-interventions applied equally	✓	✓	✓	
Complete follow-up of ≥ 85%		✓	✓	
Adequate sample size	✓		✓	
Controlling for possible confounding	✓	✓		
Evidence class	II	II	II	

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Generalizability: RCTs

- Patients: Average age 49–52 years, 60–89% males
- Most patients had only one hip treated, but some had both (as reported by two studies)
- Surgical indication (reported for two studies):
  - Osteoarthritis (76–77%)
  - Developmental dysplasia (6–8%)
  - Osteonecrosis (2–6%)
  - Other

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Cohort studies

- 1 prospective cohort study
- 8 retrospective cohort studies
- N (range) = 42 – 603 patients
- Follow-up:
  - Short-term (<5 years): 8 studies
  - Mid-term (5–10 years): 1 study (5.9 years)
  - Long-term (10+ years): none
- LoE: III (all)

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Cohort studies

- **FDA-status of HR device:**
  - Cleared: 7 studies (Birmingham (2), Cormet (1), Conserve Plus (4))
  - Not cleared: 2 studies (Durom)
- **Industry sponsored:**
  - Yes: 5 studies
  - No: 3 studies
  - Unknown: 1 study

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Generalizability: Cohort Studies

- Patients: Average age 31–55 years, 29–81% males
- Most patients had only one hip treated, but some had both (as reported by two studies)
- Surgical indications:
  - Osteoarthritis (majority of cases in six studies)
  - Developmental dysplasia (100% of patients in one study)
  - Osteonecrosis
  - Ankylosing spondylitis (100% of patients in one study)
  - Other
  - NR by one study

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Registry studies comparing HR with THA

3 international registry studies:

- **Australian Joint Replacement Registry (2008)**
  - Data from ~292 hospitals
  - THA: 125,004 - HR: 10,623
  - Primary outcome: time to revision
- **National Joint Registry for England and Wales (2008)**
  - Data from National Health Service and private providers
  - THA: 152,337 - HR: 14,235
  - Primary outcome: time to revision
- **Swedish Hip Arthroplasty Register (2007)**
  - Data from 79 public and private hospitals
  - THA: 283,089 - HR: 1041
  - Survival, complications

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Key Question 1

What is the evidence of efficacy and effectiveness of total HR compared with THA?

Outcomes efficacy / effectiveness

1. Functional outcome measures (WOMAC, HHS, Oxford; Merle D'Aubigné scores)
2. Quality of life (SF-36, SF-12, EQ-5D)
3. Activity (UCLA, Mont's scoring system)
4. Pain

Details for outcome measures are on page 18 of the HTA report

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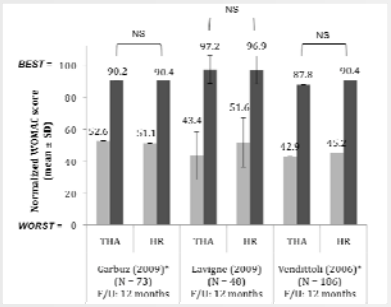
Results – Short Term Efficacy

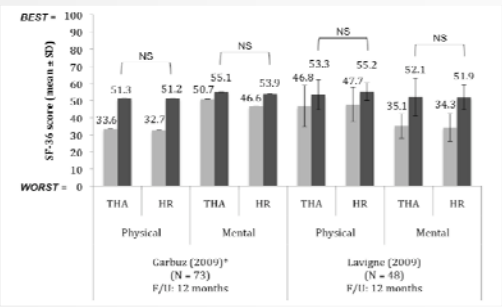
From 3 RCTs: HR is similar to THA with respect to functional, QoL and activity outcomes

Strength of evidence = moderate

WOMAC scores



SF-36 scores



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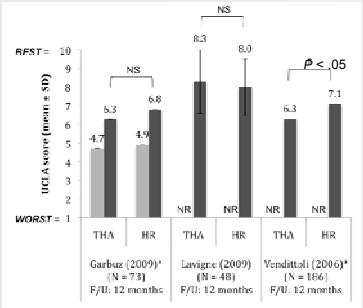
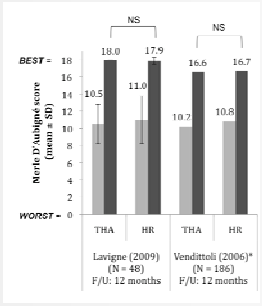
Results – Short Term Efficacy

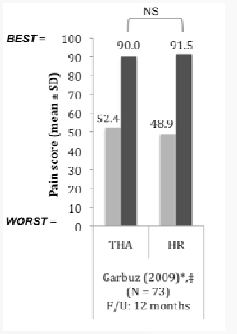
UCLA activity scores



Merle D'Aubigné scores



Pain scores



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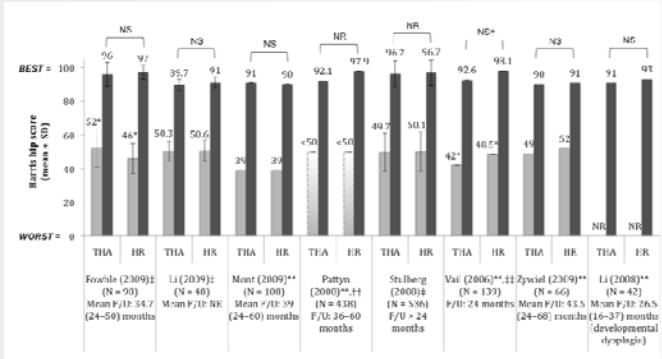
Results – Short Term Effectiveness

From 9 cohort studies: HR is similar to THA with respect to functional and QoL outcomes; activity scores slightly higher in HR patients

Strength of evidence = low

Harris Hip scores



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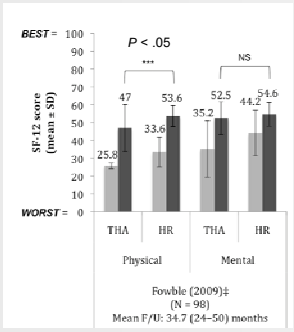
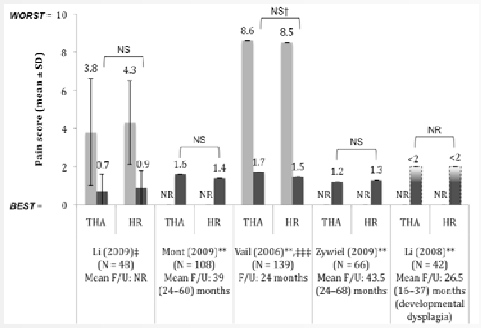
Results – Short Term Effectiveness

SF-12 scores



Pain scores



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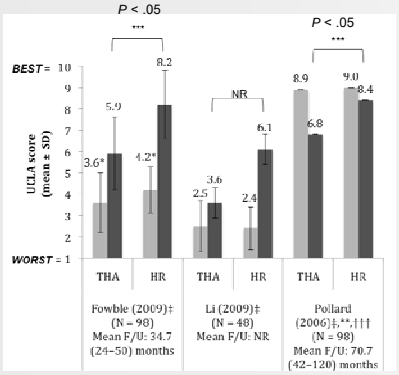
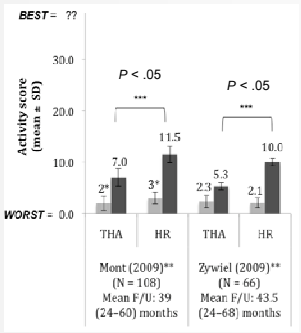
Results – Short Term Effectiveness

UCLA Activity Score



Mont's scoring system



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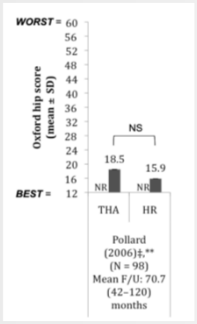
Results – Mid Term Efficacy/Effectiveness

Efficacy: no evidence

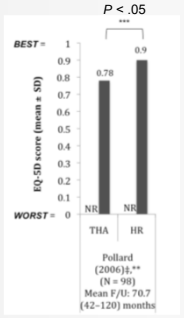
Effectiveness: From 1 cohort study: HR patients have higher QoL scores after 6 years follow-up and similar functional scores

Strength of evidence = very low

Oxford scores



EQ-5D scores



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Key Question 2

What is the evidence of safety of HR?

Safety outcomes:

1. Revision
2. Complications

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Results – Short Term Safety

Short term revision rates are slightly higher in patients treated with HR compared with THA in the majority of studies

Strength of evidence = moderate

RCTs and Cohort Studies

	# studies	N	THA (range)	HR (range)
RCT	1	205	1%	1.9%
Cohort studies	7	1474	0 – 4.3	0 – 8.5

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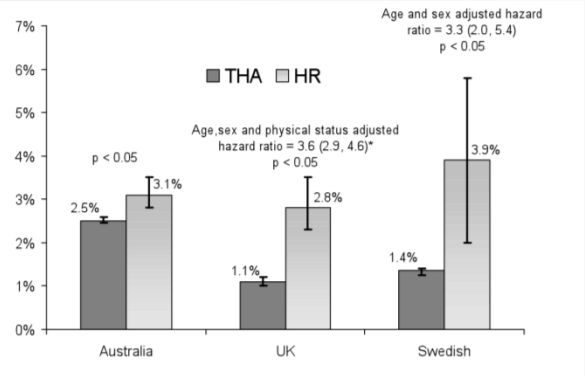
Results – Short Term Safety

Registry Studies

3-year rates



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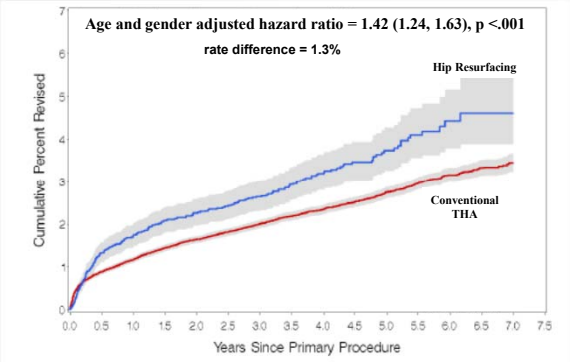
Results – Mid Term Safety

From 1 registry study: cumulative revision rates are higher after 7 years among those with HR vs. THA

Strength of evidence = low

Australian registry



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Complications

Complication rates are low following HR in the short- and mid-term

Strength of evidence = low

Complication	HR (range)
Femoral neck fracture	0.4 – 2.6%
Avascular necrosis	0.4 – 2.0%
Femoral component loosening	0 – 3.6%
Acetabular component loosening	0 – 1.8%
Acetabular component migration	0 – 1.9%
Femoral component migration	0%
Heterotopic ossification	0 – 42.7%

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Metal ion safety concerns

details on pages 68–77 of HTA report

- Elevated Co and Cr serum levels are likely to occur following metal-on-metal HR and THA.
- Concerns over safety of and risks associated with prolonged exposure to metal ions
- No association has been found with current lengths of follow-up between metal-on-metal prostheses and cancer or metabolic disorders.
- Metal ions are known to cross the placenta, thus metal-on-metal prostheses are not indicated for females of child-bearing age.

Strength of evidence = very low

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Key Question 3

Is there evidence of differential efficacy or safety issues with use of hip resurfacing?

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Differential Effectiveness

1. HR in dysplasia vs. other arthritic conditions

From 1 registry study and one small prognostic study:

Short-term revision rates are higher following HR for patients with dysplasia vs. other arthritic conditions:

- Registry study: 12% vs. 3% (5-year cumulative rate)
- Prognostic study: 5.2% vs. 0%

Strength of evidence = low

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Differential Effectiveness

2. HR in osteonecrosis (AVN) vs. other arthritic conditions:

From 1 registry study and 1 small prognostic study:

- Short-term revision rates are higher following HR for patients with osteonecrosis vs. other arthritic conditions (6% vs. 3%).

Strength of evidence = low

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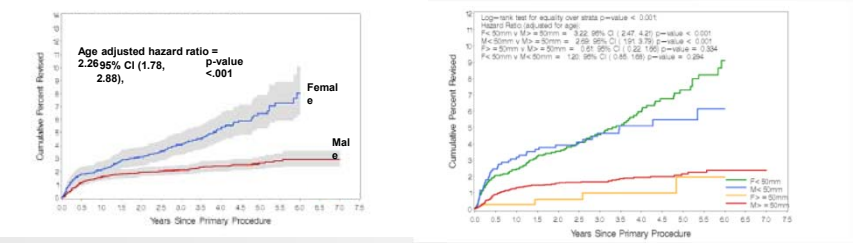
Differential Effectiveness

3. HR in females vs. males:

From 3 registry studies:

- **Short-term revision rates are higher for females than males (hazard ratio range: 1.57 – 2.5)**
- **Difference in rates between sexes was not significant when controlling for femoral component size; smaller femoral heads are correlated with higher failure rates**



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Strength of evidence = moderate

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Differential Effectiveness

4. Obesity:

From two low quality studies: 1 reported lower revision risk and 1 reported higher revision risk with increasing obesity

Strength of evidence = very low

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Key Question 4

What is the evidence of cost implications and cost effectiveness of hip resurfacing?

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Economic conclusions

From two published studies and one HTA, results mixed:

		Revision assumption	Cost per patient	Results
McKenzie	cost utility	HR: 1.52% THA: 1.36%	HR: £5396 THA: £4075	HR slightly more costly throughout 20 yr F/U
Vale (HTA)	cost utility	HR: 0.5% THA: 1.0%	HR: £5515 THA: £4195	HR more costly than waiting followed by THa
Buckland	cost consequence	unknown	HR: $14,900 THA: $11,100	HR less costly than waiting followed by THA

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Economic conclusions

From two published studies and one HTA:

- **Limited evidence is available on the cost-effectiveness of HR versus THA or waiting followed by THA in patients under the age of 65**
- **More current revision rates following HR are needed to fully understand whether HR is cost-effective**

Strength of evidence = very low

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HTA Report interpretation: What we know

1. The short-term (< 5 years) efficacy/effectiveness of HR is similar to THA *although there is low evidence that HR may lead to improved activity scores* (moderate/low evidence)
2. Short- and mid-term revision rates are higher following HR compared to THA (moderate and low evidence)
3. Short- and mid-term complication rates (other than revision) are relatively low following HR (low evidence)

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HTA Report interpretation: What we know

4. Patients with dysplasia or osteonecrosis have a higher revision rate than those with other arthritic conditions following HR (low evidence)
5. Females may have a higher revision rate following HR than males (moderate evidence)

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HTA Report interpretation: What we don't know

1. The mid- or long-term efficacy/effectiveness of HR (very low to no evidence)
2. Long-term revision rates following HR compared to THA (no evidence)
3. Whether obese patients have a higher risk of revision than patients with a BMI < 30 following HR (very low evidence)
4. The economic implications of HR; updated revision rates are needed for better prediction models (very low evidence)

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Questions?

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards. [2]

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.[3]

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Centers for Medicare and Medicaid Services	2008	No national coverage policy. HR on list of potential review topics		
Guidelines – WA HTA p. 31 *National Guideline Clearinghouse*		No clinical guidelines related to hip resurfacing procedures were found when the NGC database was searched. Additional searching of the American Academy of Orthopaedic Surgeon's (AAOS) web site did not yield any guidelines specific to hip resurfacing.		
Guidelines – WA HTA p. 31 *National Institute for Health and Clinical Excellence*		The National Institute for Health and Clinical Excellence (NICE), (which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales) concluded in 2005 that "metal-on-metal (MoM) hip resurfacing arthroplasty is recommended as one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement." Although there is sufficient short-term evidence to conclude that MoM hip resurfacing can be as effective as total hip replacement (THR) in patients less than 55 years, NICE acknowledges that there are no randomized controlled trials comparing MoM hip resurfacing arthroplasty with conventional THA. There are also no long-term (>10 years) observational data on the outcomes associated with MoM hip resurfacing devices.		

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

	Total Hip Arthroplasty (THA)	Hip Replacement (HR)
Safety Outcomes	**Safety Evidence**	
Mortality -- Revision Rates -- Complications --Metal-on-metal ions		
Morbidity		
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**	
Pain Reduction		
Improves Function. - Range of motion		
Patient Satisfaction/Quality of life		
Dislocation		
Durability / length of delay to THA		
Other		
Other		
Special Population / Considerations Outcomes	**Special Population Evidence**	
Age		
Gender		
Obesity		
Osteoarthritis		
Developmental Dysplasia		
Osteonecrosis		
Ankylosing Spondylitis		
Other		
Cost	**Cost Evidence**	

Clinical Committee Evidence Votes

First voting question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered. _____ Covered Unconditionally. _____ Covered Under Certain Conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?