

Informed consent for HRA

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Dr. Gross has now performed over 3500 Hip Resurfacing Arthroplasty (HRA) procedures over the last 13 years. Most failures occur during the first year of the healing period. However, there is a slow rate of failure that occurs over time. Therefore the overall failure rate increases for a group of patients as the length of follow-up increases. In the Journal of Arthroplasty 2011, we reported that our Corin Hybrid HRA achieved a 93% survivorship at 11 years follow-up. Longer-term data is not available. The first 1000 Biomet uncemented HRA were reported in the Journal of Arthroplasty achieving an overall 6-year survivorship of 98% (99% for men and 96% for women)

Not all complications lead to failure. Below is a complete list of major complications (not just failures) in the first 2000 uncemented HRA using the Biomet uncemented system:

A.) Failures Requiring Revision Surgery (2000 cases 1-7 year follow-up):

1.	Femoral neck fracture:	9	
2.	Early femoral collapse (osteonecrosis):	2	
3.	Failure of acetabular ingrowth:	7	
4.	Adverse wear related failure:	3	
5.	Acetabular component loosening	1	
6.	Intertrochanteric femur fracture	1	
7.	Subluxation	1	
8.	Unexplained pain	1	
9.	Femoral head fracture	1	
10.	Subtrochanteric femur fracture (related to hardware removal)	1	
11.	Unknown cause (revised elsewhere)	2	
12.	Deep infection with loss of implant:	0	
13.	Recurrent dislocations requiring revision:	0	
14.	Femoral component loosening:	0	
	TOTAL:	29	1.5%

B.) Cases Requiring Significant Repeat Surgery (2000 cases):

1.	Traumatic intertrochanteric fracture (5 and 11 months postop):	2	
2.	Deep infection (cured):	2	
3.	Significant superficial infection (cured):	2	
4.	Abductor tear	1	
5.	Frostbite from ice machine:	1	
6.	Suture reaction	1	
	TOTAL:	9	0.5%

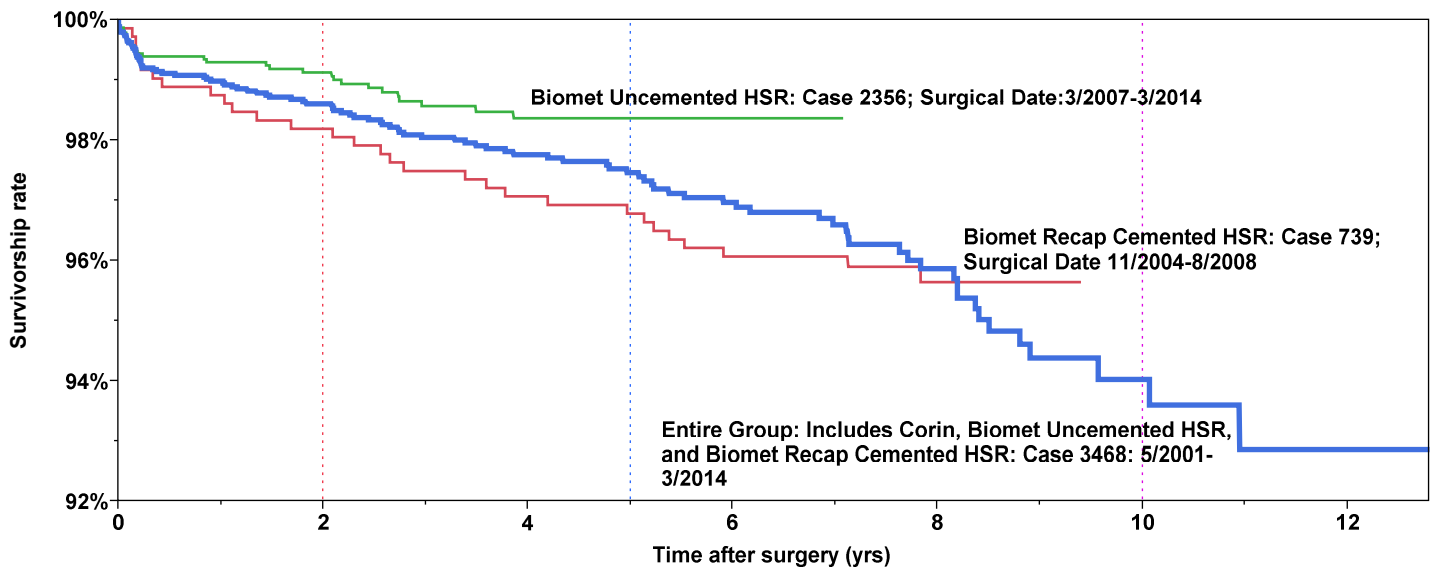
C) Other Complications (2000 cases):

1.	Dislocations:	8	
2.	Pulmonary emboli:	5	
3.	Deep vein thrombosis:	5	
4.	GI bleed requiring transfusion:	2	
5.	Embolic stroke:	2	
6.	Arrhythmia	1	
7.	Esophageal tear	1	
8.	Frostbite from ice machine:	1	
9.	Nerve injuries:	0	
10.	Postoperative transfusions:	0	
11.	Femoral notches:	0	
12.	Vascular injuries:	0	
13.	Deaths:	0	
	TOTAL:	25	1.3%

D.) Hip Resurfacing Survivorship

3468 cases over 13 years

Survivorship of hip resurfacing continues to improve as we gain more experience and find measures to prevent failures. These survivorship curves give the reader an opportunity to see what the odds are that their implant will still be functioning at some time point after implantation. We have used three implant systems in the last 13 years. We present three Kaplan-Meier Survivorship curves: the best are uncemented Biomet devices (Green), the second are all of my hip resurfacing combined (blue), and finally hybrid fixation Biomet devices (Red). The earliest Corin Hybrid group is not listed separately.



7 years

9 years

10 years

Overall survivorship:	96.6%	94.4%	94.0%
Biomet Hybrid:	96%	95.7%	
Biomet Uncemented:	98.5%		

E.) Reducing Failures in HRA:

In the last 10 years we have learned what patients with particular characteristics are at higher risk for failure. The strategy of many experts is patient selection. If they avoid performing hip resurfacing on higher risk patients, their overall results will improve. I disagree with this defeatist strategy...and no one has demonstrated that these high-risk patients will fare better with a THR.

My improving results are **not** achieved by patient selection. I have always practiced minimal patient selection and my criteria have not changed much over the last 13 years. Instead, my goal is to find treatment modifications to improve the results in patients that are traditionally identified as higher risk. In some cases, we have already accumulated scientific evidence of improved results; in other cases, we still need more time to gather data to be certain that our treatment modifications have improved results. Examples of our innovations include:

1. Femoral neck fracture: stratifying risk of femoral neck fracture by bone density and BMI and treating higher risk patients with slower weight bearing and bisphosphonate drugs. We have demonstrated that this substantially reduces risk. Fracture risk now less than 0.07%.
2. Failure of acetabular implant attachment: dysplasia patients are at higher risk because of socket deformities. Use of Trispike acetabular components in severely deficient sockets has eliminated these failures in this high-risk group since 2007.
3. Femoral cysts: Bone grafting cysts instead of filling them with cement has resulted in eliminating femoral cysts as a risk factor for failure in our patients.
4. Femoral Loosening: The major source of late failure in my cemented femoral components. We have demonstrated that uncemented femoral components are at least as good as cemented ones at up to seven years follow-up. We have not yet had one

case of femoral loosening after 1 year in over 2500 cases. We have had no femoral failures in high-risk osteonecrosis cases (others avoid resurfacing these).

5. Adverse wear related failure (AWRF): We have determined that this is caused by faulty implant design and certain acetabular component positions, particularly high acetabular inclination angles (AIA). We have published a robust guideline for component positioning and an intraoperative XR technique that allows us to achieve this goal in over 99% of cases. The last AWRF case was created in 6/2009 and has been revised with an excellent final outcome.
6. We have published a report demonstrating that revision of failed HRA can be performed with a high success rate (96% 6-year survivorship) nearly as good as primary surgery. Unlike other reports, our success rate for revising for AWRF has been 100% without major complications. The strategy used was repositioning a new metal bearing in the correct position **not** using the failed strategy of changing to small plastic bearings.

Past results do not guarantee future complication rates. Although the above represent the most common complications associated with this procedure, others could also occur. We continue to strive to make improvements, and hope that these complication rates can be further decreased as we gain even more experience.

- Dr. Gross is the operating surgeon (No trainee will perform your operation).
- Dr. Gross developed the Biomet implants but no longer receives royalties for these implants.
- Biomet Recap and Magnum components are FDA approved. Use as a total hip resurfacing is however considered off-label.
- Information from your treatment is used for research purposes, but you will not be identified.

If you have any questions about the above information, please don't hesitate to ask.

I have reviewed the above and understand the risks involved with this operation. I would like Dr. Thomas Gross to perform hip resurfacing on me.

Patient signature

Date

Witness

Date