

Informed Consent for HRA

Dr. Gross has now performed over 4600 Hip Resurfacing Arthroplasty (HRA) procedures over the last 16 years. Most failures occur during the first two years after surgery, which is why it is of the utmost importance to follow your surgeons postoperative care instructions. However, there remains 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. Herein, we report implant survivorship, for all three of our HRA implant groups (we no longer use Corin or Biomet hybrid HRA; we exclusively use Biomet uncemented HRA). Not all complications lead to failure. Below is a complete list of ALL major complications (not just failures/causes for revision) in the first 3500 HRA cases using the Biomet uncemented system:

A. FAILURES REQUIRING REVISION (1-9 YEAR FOLLOW-UP)

1. Femoral neck fracture	9
2. Failure of acetabular ingrowth	9
3. Adverse-wear related failure	3
4. Unknown cause (Revised elsewhere)	2
5. Intertrochanteric femoral fracture	1
6. Subluxation	1
7. Unexplained pain	1
8. Femoral head fracture	1
9. Subtrochanteric femoral fracture	1
10. Femoral component loosening	1
11. Deep infection	0
12. Recurrent dislocation	0

TOTAL: 29 /3500 (0.8% of total cases)

B. COMPLICATIONS REQUIRING REOPERATION*

1. Traumatic intertrochanteric fracture (5-11 months postop)	5
2. Deep infection (cured)	3
3. Superficial infection (cured)	2
4. Fascia failure	2
5. Hematoma	2
6. Frostbite from ice machine	1
7. Suture reaction	1
8. Dislocation	1

***Implants are not removed during reoperation.**

TOTAL: 17 /3500 (0.5% of total cases)

C. OTHER COMPLICATIONS

1. Acetabular component shift (nonsymptomatic)	22
2. Dislocation	10
3. Acute urinary retention	6
4. Deep vein thrombosis	6
5. Fracture (treated without surgery)	6
6. Pulmonary embolus	5
7. Nerve stretch injury (foot drop)	3
8. Spinal headache	3
9. GI bleed	2
10. Embolic stroke	2
11. Femoral component shift	2
12. Esophageal tear	1
13. Implant squeaking	1
14. Arrhythmia	1
15. Urinary tract infection	1
16. Femoral notching	0
17. Vascular injury	0
18. Death due to surgery	0

TOTAL: **71/3500** **(2.0% of total cases)**

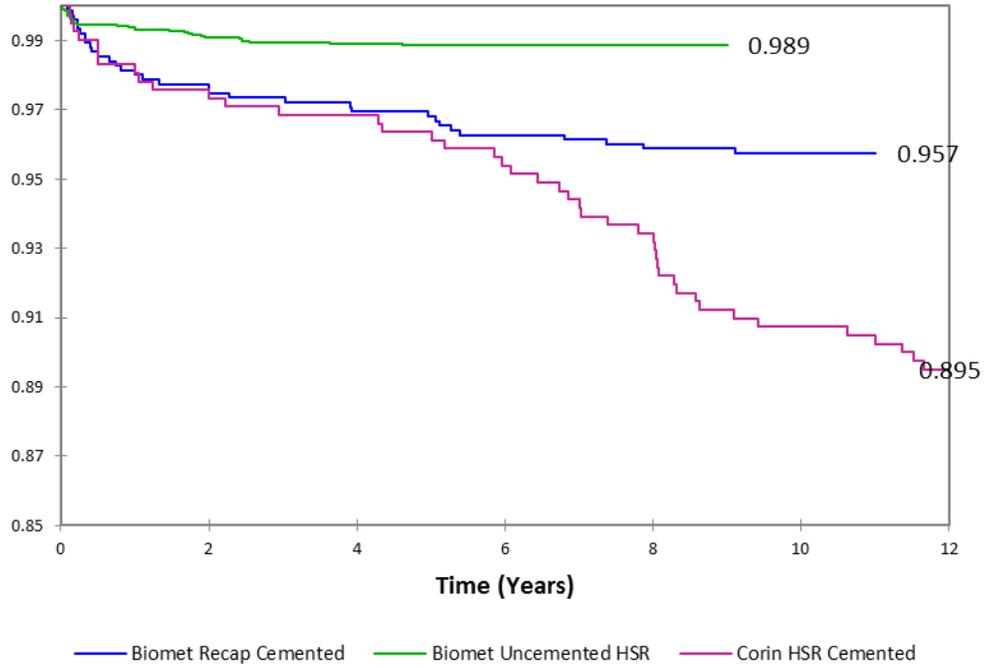
D. RESURFACING SURVIVORSHIP

Includes ALL implant types*: 4635 cases over 16 years

**unless noted otherwise in each graph*

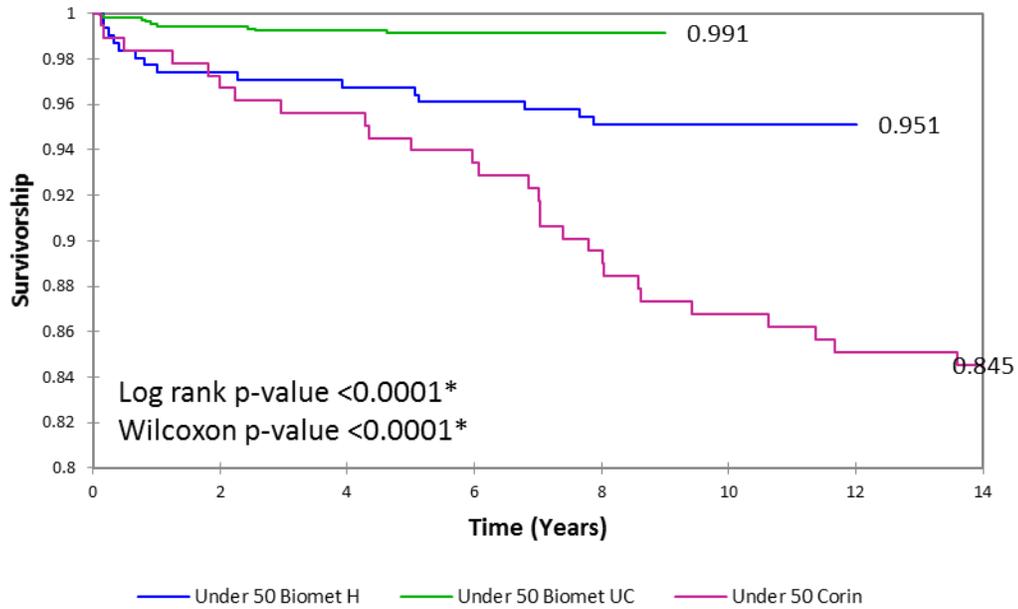
Survivorship of hip resurfacing continues to improve as we gain more experience and find measures to prevent failures. These survivorship curves give the reader an opportunity to see what the odds are that their implant will still be functioning at some time point after implantation. We have used three implant systems in the last 16 years. Unless specified the results include unselected consecutive patients (includes both genders, all ages and all diagnoses). We present four Kaplan-Meier survivorship curves: all implant groups, all implants for patients under 50 at time of surgery, all implants for patients over 50 at time of surgery, Biomet implants grouped by gender.

Kaplan Meier Survivorship of All Implants (2001-2016)



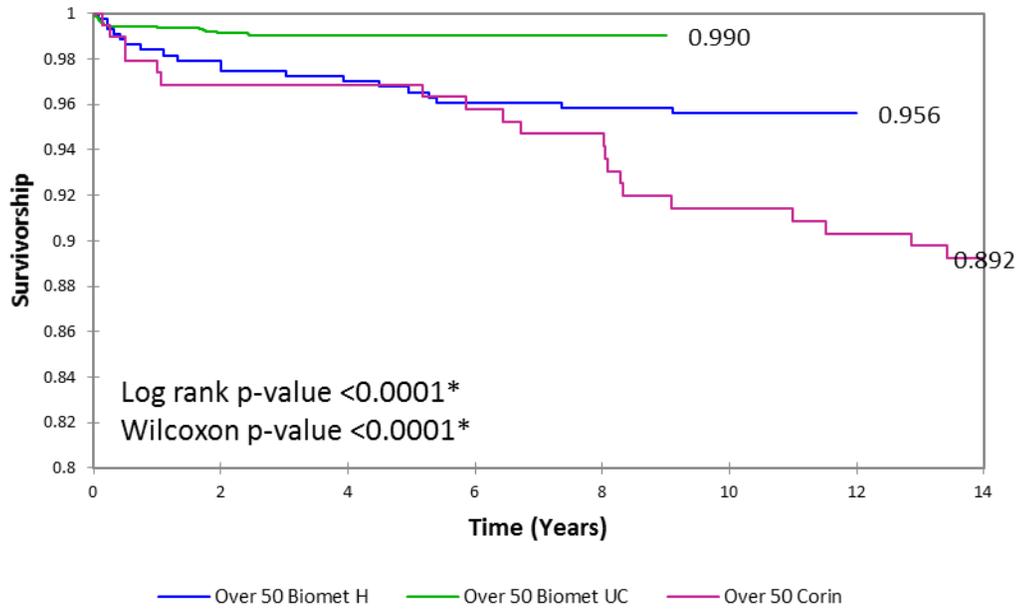
Notice that patient follow-up is longer for the Corin and Hybrid Biomet groups. All Biomet hybrid implants (n=794) are now a minimum of 10 years old, all Corin Hybrid implants (n=373) are at least 12 years old. Results are steadily improving with improvements in implants, knowledge about resurfacing and surgeon experience. Current 9-year implant survivorship with the Biomet uncemented implants (n= 3468) is 99%.

Kaplan Meier Implant Survivorship - Under 50 (Grouped by Implant)



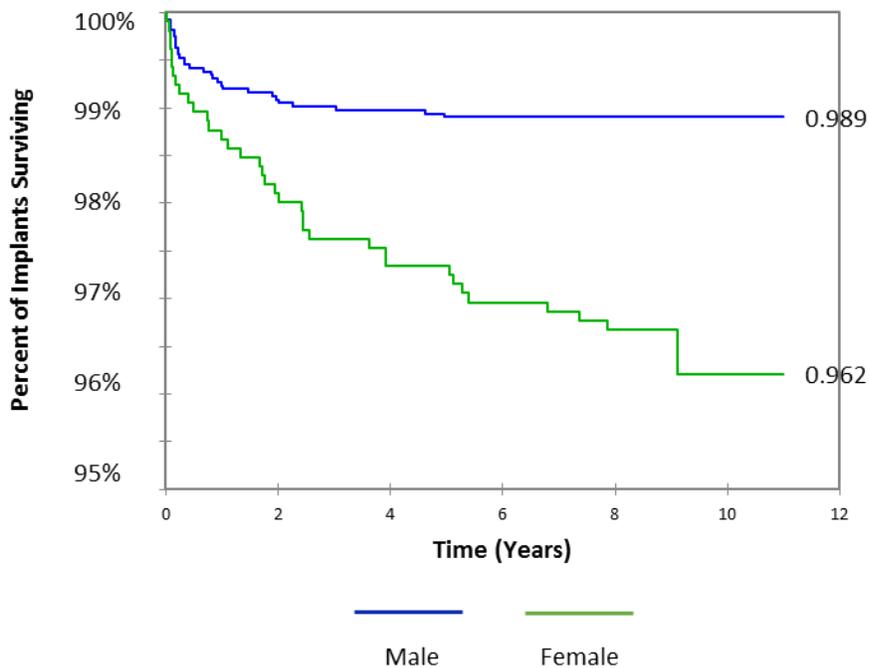
Survivorship continues to improve with experience. The standard for “excellent survivorship” in Total Hip Replacement (THR) is 95%+ 10-year implant survivorship. However, reported registry results for THR in patients under 50 is only 80% 10-year implant survivorship. It can be seen here that 9-year survivorship for our current implant, the uncemented (UC) Biomet ReCap, is at 99%. Implant survivorship does not drop off in our younger patients with HRA as it does for reported results on THR. THR lasts reasonably well in older folks for whom golf and walking are considered an “active” lifestyle, but this is not adequate for younger patients with greater range-of-motion.

Kaplan Meier Implant Survivorship – Over 50 (Grouped by Implant)



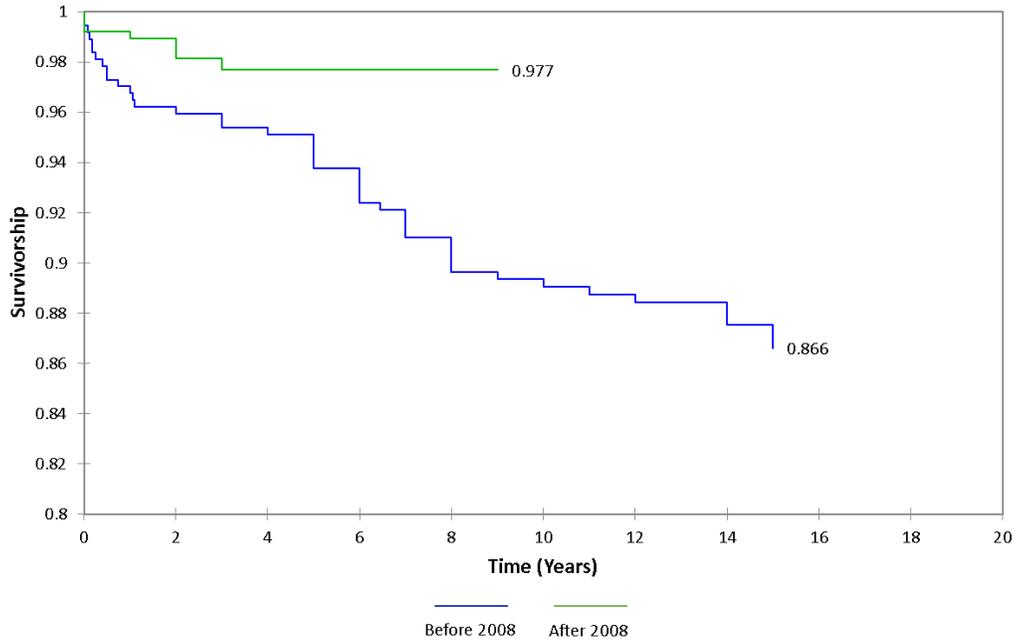
When comparing this graph with that of under 50 (see above), it can be seen that implant survivorship does not depend on age for HRA at our practice. The NICE standard for “excellent survivorship” (95%+ at 10 years) has been achieved in our Biomet hybrid (H) group. With 99% 9-year survivorship, the current Biomet uncemented (UC) device is also on track to achieve this standard.

Kaplan Meier Survivorship of Biomet Implants ONLY – Grouped by Gender (2001-2016)



Women have had higher implant failure rate with HRA than men. This is primarily due to two factors. Dysplasia is more common in women, which carries higher failure rate with hip replacement in general. Also, women usually require smaller bearing sizes, which are more prone to wear failure from edge loading resulting in metallosis. **Both of these problems have now been solved at our practice and are reflected in our improved results in women.** The last wear failure was from a procedure performed in August 2009; the last acetabular failure due to dysplasia was from a procedure performed in December 2007. Currently, 10-year implant survivorship in men is 99% and women 96%, which is far better than the reported registry value of 80% 10-year survivorship for young women with THR.

**Kaplan-Meier Implant Survivorship for Two Female Cohorts
All Implants (2001-2016)**



Several perioperative interventions were established at our practice between 2007-2008 to address common failure modes in women. It can be seen here that these interventions have significantly improved implant survivorship in women. Overall 9-year survivorship for women with the uncemented (UC) Biomet device is 98%.

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 Signature	Date