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Informed Consent for Hip Resurfacing Arthroplasty

Updated 2/23/2023 TPG.

In my (Dr. Gross') opinion, Hip Resurfacing Arthroplasty (HRA) is the best way to reconstruct a severely arthritic hip. It is more complicated to perform than a standard Total Hip replacement (THR); therefore, few surgeons are willing to offer this procedure. In the major joint registry reports, THR has better implant survivorship in most groups of patients (except in men with osteoarthritis who are under 60 years old).

However, registries measure outcomes for average surgeons. The average surgeon performs less than 2.5 HRA cases/year. This is not adequate to be an expert. In reports by high volume hip resurfacing surgeons, results are much better than the registries suggest.

Dr. Gross has now performed over 6800 Hip Resurfacing Arthroplasty (HRA) procedures over the last 20 years and currently performs nearly 500 cases/year. The proven advantages of HRA are better function, longer implant survivorship, fewer dislocations, no thigh pain (from a THR stem), bone preservation, and longer life expectancy than THR patients.

HRA does not result in a normal hip. But, when done by an expert, it more nearly approaches a normal hip in biomechanics and function and patients are more likely to resume heavy work and impact sports than they could with a THR. Long-distance running is even possible for many (but not all) patients. Also, activities that require extreme range of motion such as full squats, yoga, gymnastics, and ballet are possible because HRA has near normal stability.

There are several other HRA surgeons in the world who have reported similar long-term implant survivorship data. There is no large single-surgeon report of THR that can match the results reported here. Most failures occur during the first two years after surgery, which is why it is critical to severely limit activities in the first 6 months to allow adequate healing. After that, a patient can gradually return to completely unrestricted activity. There remains a slow rate of failure that occurs over time. But this does not seem to be affected by activity.

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 implants; we exclusively use Biomet uncemented implants). Not all complications lead to failure.

Below is a complete list of ALL major complications (not just failures/causes for revision) in the >5500 HRA cases performed using the Biomet uncemented system since 2007.

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I. Failures (requires revision surgery) **TOTAL: 59/5684 (1.0%)**

Cause of Failure/Revision	# cases
1) Femoral neck fracture	17
2) Failure of acetabular ingrowth	11
3) Adverse-wear related failure	4
4) Femoral head collapse (osteonecrosis)	3
5) Late acetabular loosening	5
6) Component Shift	4
7) Late Fracture	5
8) Early Infection	5
9) Unknown cause (revised elsewhere)	4
10) Recurrent Instability	2
11) Unexplained pain	5
12) Late infection	1
13) Psoas Tendonitis	1

II. Complications (requires reoperation*) **TOTAL: 30/5684 (0.5%)**

*implants are not removed during reoperation

Cause of Reoperation	# cases
1) Late Fracture (>6 months)	6
2) Early Fracture (<6 months)	5
3) Deep Infection (cured)	5
4) Hematoma	3
5) Fascia Failure	5
6) Superficial Infection (cured)	3
7) Other	2
8) Dislocation	1
9) Abductor Tear	1
10) Acetabular Cup Shift	1
11) Psoas Tendonitis	1

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III. Other complications (conservative treatment) **TOTAL: 145/5684 (2.6%)**

Complication	# cases
1. Acetabular component shift (nonsymptomatic)	30
2. Dislocation	26
3. Cardiovascular complication	20
4. Nerve Palsy/Injury	11
5. Urinary Retention	8
6. Spinal Headache	9
7. Other	7
8. Hematoma	5
9. Early Fracture (<6 months)	4
10. Late Fracture (>6 months)	4
11. Femoral Component Shift	4
12. Anxiety Attack	3
13. GI Bleed	2
14. Nausea/Vomiting	2
15. Unexplained Pain/Swelling	3
16. Severe Constipation/Diarrhea	2
17. Abductor Tear	2
18. Wound Dehiscence	1
19. Early Infection	1
20. Fascia Failure	2

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IV. Implant Survivorship

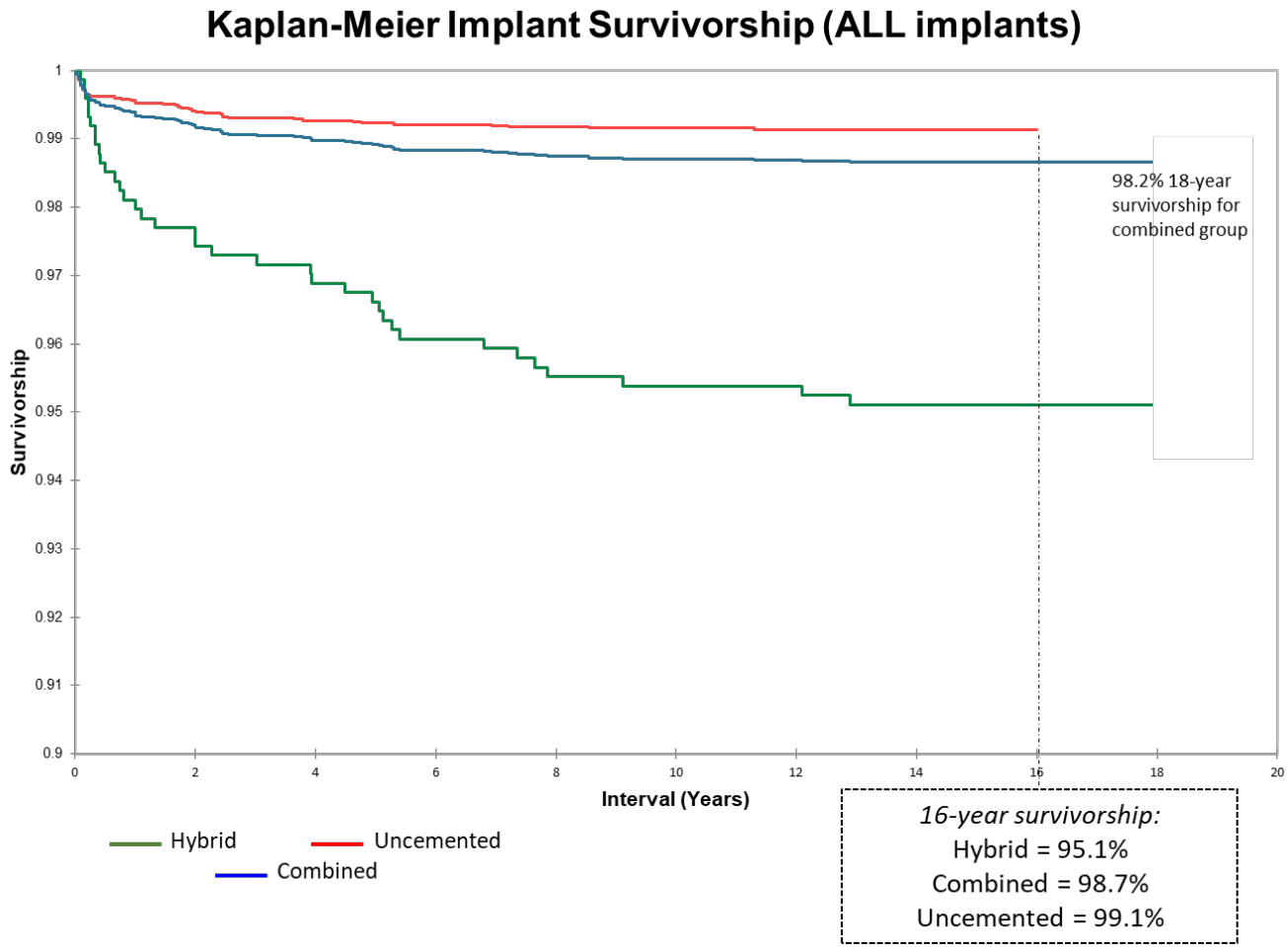
Includes ALL implant types*: 6800 cases over 20 years (**unless noted otherwise in each graph)*

Survivorship of hip resurfacing continues to improve as we gain more experience and identify 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 present three Kaplan-Meier survivorship curves: all implant groups, Biomet uncemented implants for patients under 50 at time of surgery, and Biomet uncemented implants grouped by sex. Unlike for THR, HRA survivorship does not vary by age or sex (overall 99.1% 16-year implant for both age groups, and 99% 13-year implant survivorship for both sexes)

Most failures occur in the first 1-2 years. If you make it to one year, your implant survivorship at 13 years is 99.6%. If you make it to 2 years, it is 99.8%. Dr. Gross' uncemented resurfacing implant survivorship beats all registry benchmarks for THR regardless of age or sex.

Also, in a recent multicenter international study (27 HRA centers in 13 countries), over 11,000 cases in patients under age 50 with multiple different metal-on-metal HRA brands showed a 90% 20-year implant survivorship (93% in men and 81% in women). For comparison, THA registries show approximately 80% implant survivorship at 10 years and 50% at 20 years in this age group.



Note that the survivorship y-axis begins at 90%.
There have been no instances of adverse metal wear from any surgeries performed after 2009.

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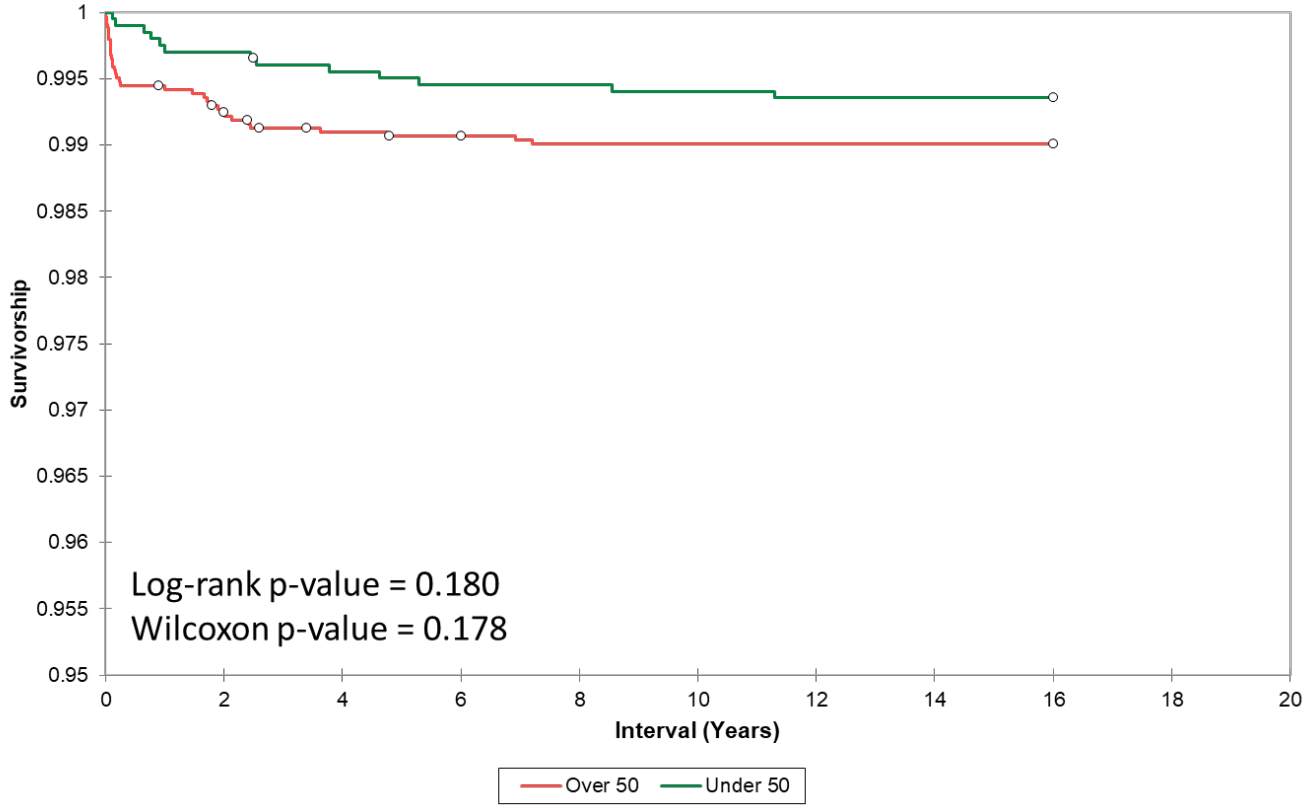
Kaplan-Meier Implant (Uncemented ReCap) Survivorship by Age at Time of Surgery



Above is the survivorship curve separated by age for our uncemented ReCap group. 16-year implant survivorship is better than 99% for both groups and there is no difference in survivorship based on age, unlike the typical pattern found in standard stemmed Total Hip Replacement, where implant survivorship worsens in younger patients.

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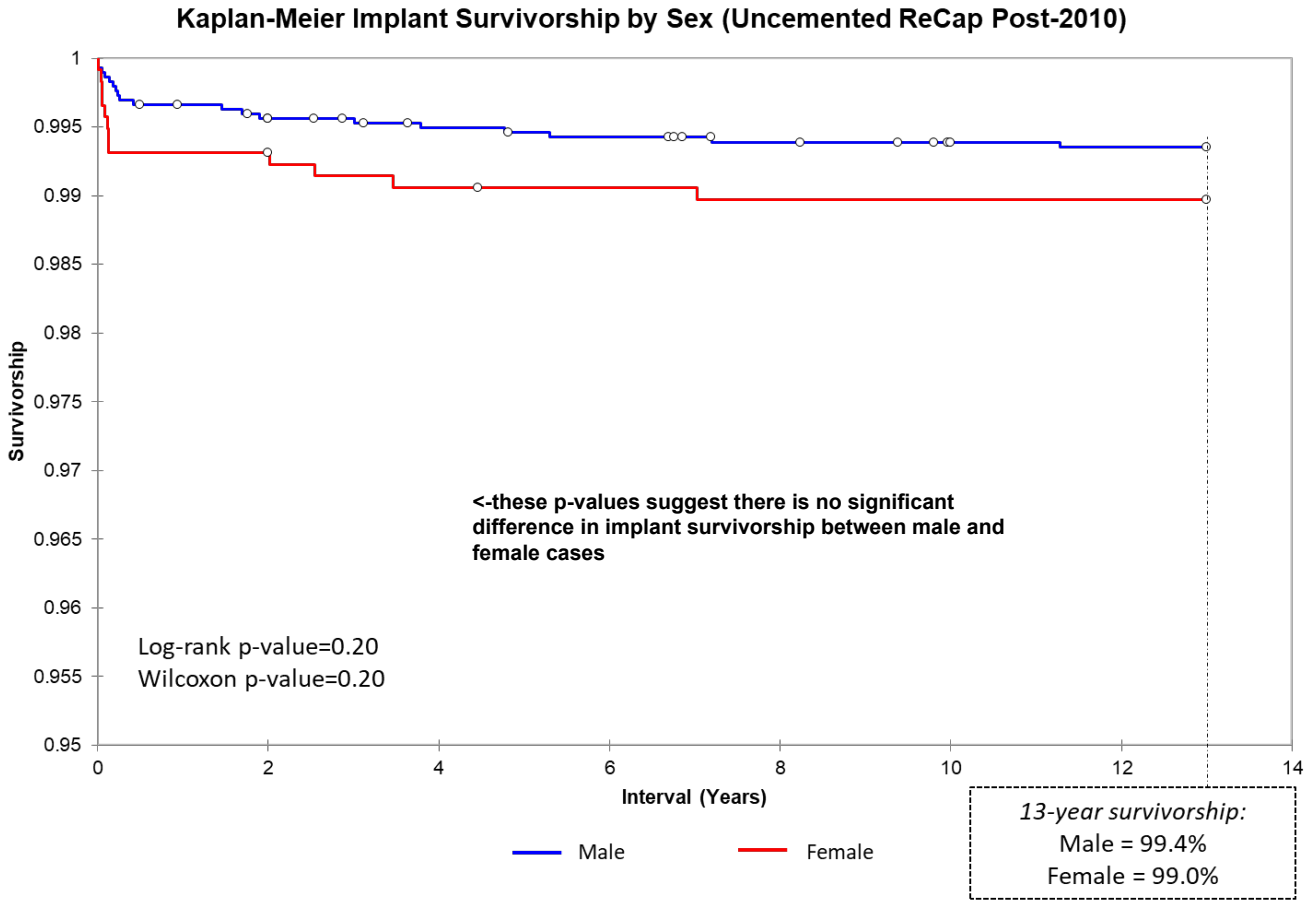

Many orthopedic surgeons exclude women from HRA because of poor published results. We, however, elected to investigate WHY implants in women were underperforming and to adjust implant design + surgical technique rather than exclude women from surgery. After implementation of new protocols from 2007-2009, implant survivorship between men and women is not significantly different.

The implant survivorship data reported here far surpasses joint implant registry data from Britain, Sweden and Australia (for both THR and HRA) where these types of data are kept. These are publicly available, and you can get access them online for free. Registry data can be thought of as average surgeon implant survivorship for purposes of a benchmark. But the most important factor in the outcome of any operation is individual surgeon skill. It is hard to know at which level a surgeon you are considering can perform. Anecdotal reports from a few patients or reputation are a poor substitute for data. Few surgeons provide written data such as I do.

Remember, implant survivorship is not the only factor that needs to be considered in deciding between THR and HRA. Other proven advantages of HRA are better functional outcome, less residual thigh pain, fewer dislocations, bone preservation, and longer life expectancy.

After all revisions, reoperations, and complications are accounted for there are still approximately 2% of patients who experience moderate unexplained residual pain after HRA. The risk of moderate residual unexplained pain in THR is 20%. This means we cannot determine a specific reason why they are not satisfied. Some may have referred pain from their back or soft tissue problems we are unable to diagnose.

In a THR thigh pain from the stem is a common cause of residual pain. Residual pain may just represent the fact that HRA does not result in a normal hip. Because we can't diagnose a cause, we don't recommend revision surgery. If a revision is still performed, sometimes a patient improves, but most often they subject themselves to the risk of revision surgery and do not improve. There is no measurable difference in the speed of recovery between THR and HRA.

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Since 2007 Dr. Gross has used primarily the Biomet Recap / Magnum uncemented metal-on-metal hip resurfacing system. The majority of the data presented here is for this system. The FDA has approved these implants for sale in the US. They are however NOT approved for use as a total hip resurfacing combination. Dr. Gross uses them for this “off-label” purpose.

The FDA regulates implant companies. The FDA does not regulate doctors. Once an implant is approved for sale, it can be used for any purpose that a doctor feels is best. When an implant company gets FDA approval for an implant, it may only market and promote this implant for the “indication” that they have received from the FDA.

This is true even if there are scientific papers that demonstrate it is safe and effective when used in a different fashion. Basically, the FDA regulates drug and implant companies conduct, but has no jurisdiction over doctors. We have the education, training, and experience to use an implant or drug for whatever purpose we think is best.

This is a perfectly legal and common practice. I am not even required to disclose off-label use to patients. I chose to do so because metal-metal resurfacing is a highly controversial practice. I use the Biomet Recap/Magnum in an off-label fashion and have the best implant survivorship in the published literature.

If you prefer a device that is FDA “indicated” for metal-metal resurfacing, I recommend seeking a surgeon who uses the Birmingham brand implant, it also has excellent published outcomes.

Thomas P. Gross M.D.

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Patient Acknowledgement

I, (patient name: _____), have reviewed the "Informed Consent for Hip Resurfacing Arthroplasty" information above and understand the risks involved with this operation. I would like Dr. Thomas Gross to perform hip resurfacing on me.

I also understand that all data from my case will be collected and used for research purposes mainly to continue to improve the quality of Dr. Gross' work and to inform future patients and the world about hip resurfacing. My privacy will be protected by anonymizing the data before any publication.

_____

Patient Signature Date

_____

Witness Signature Date