

Mission Statement and Disclosure Form

A note from Dr. Gross: "I am a specialist in the field of hip and knee replacement. I am in private practice but involved in clinical research, teaching, and orthopaedic implant development. I perform all my surgeries personally, with the assistance of Lee Webb, DNP. No residents or fellows conduct your operation. Visiting surgeons are occasionally present to observe my operations but do not participate in the operations themselves. I have received royalties and research support from various orthopaedic implant companies. I am not paid for the hardware used in your surgery - implants in the Columbia marketplace are excluded from my royalty contract. I will answer any specific questions you have regarding implants to be used in your operation.

It is the standard of care for joint replacement surgeons to provide long-term follow-up evaluations for their patients. Although we do bill for these services, we primarily earn our living from surgery. As a surgeon involved in clinical research, it is particularly important to me to continue a long-term relationship with all patients on whom I operate. I use data gathered in my practice as material for informing patients, improving my outcomes, teaching, scientific presentations, and clinical papers. Patient identity is carefully protected in all mediums. (The only exception is for patients who specifically agree to publicly share a personal testimonials/description of their case.)

Every medical/surgical treatment has potential for complications. I disclose these to you in the consent form provided; a regularly updated list of complications among my patient cohort are posted to my website. If you should have a complication, I will deal with it promptly and directly. Even out of state patients should keep me well informed of any that develop. It is my preference (and in your best interest) for me to deal with all surgical complications personally. Nonsurgical (medical) complications can be dealt with by your local primary care physician or other non-orthopaedic specialist, but please keep me informed/allow me to advise you. Surgical complications may require unexpected trips to Columbia, SC. Many patients have chosen me as their surgeon due to my low rates of complications/revisions. However, equally important is my knowledge in how to deal with postoperative complications. Even after they occur, a good outcome can often be achieved with appropriate, skilled intervention.

I expect to see all patients for follow up evaluations at four- to six- weeks postoperatively and one-year postoperatively. If you are an out of state patient, remote follow up can be arranged (but is not preferred). If your case is routine and stable, long-term follow up (>2 years postoperative) can be done via online questionnaire and digital x-ray. I will provide you with a written reply and will not charge you for reviewing your materials. If a phone consultation is required (after three months post-op) a fee may be assessed. If you do have specific problems that can't be solved by advice given over the telephone, on-site evaluation by me is recommended.

My commitment to you is the highest level of care, both technically and personally. I strive to continue to elevate the level of my expertise by dealing with complications directly and promptly, and by continuing a rigorous and systematic scientific review of my surgical outcomes."



I, (patient name: _____), have read Dr. Gross' "Mission Statement and Disclosure Form" and agree to honor my commitment to provide timely follow up information. I agree to be contacted for follow-up due reminders via the contact info I have provided. I understand that providing this information will benefit not only me, but also Dr. Gross and many future patients of his practice and elsewhere. I

hereby agree to play my part in furthering the practice and science of joint replacement surgery. This contract is not legally enforceable but represents my good faith agreement under which I wish to establish a doctor-patient relationship with Dr. Gross.

Print Patient Name

Patient Signature

Date

Informed Consent for Hip Resurfacing Arthroplasty

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:

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 Tendinitis	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

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

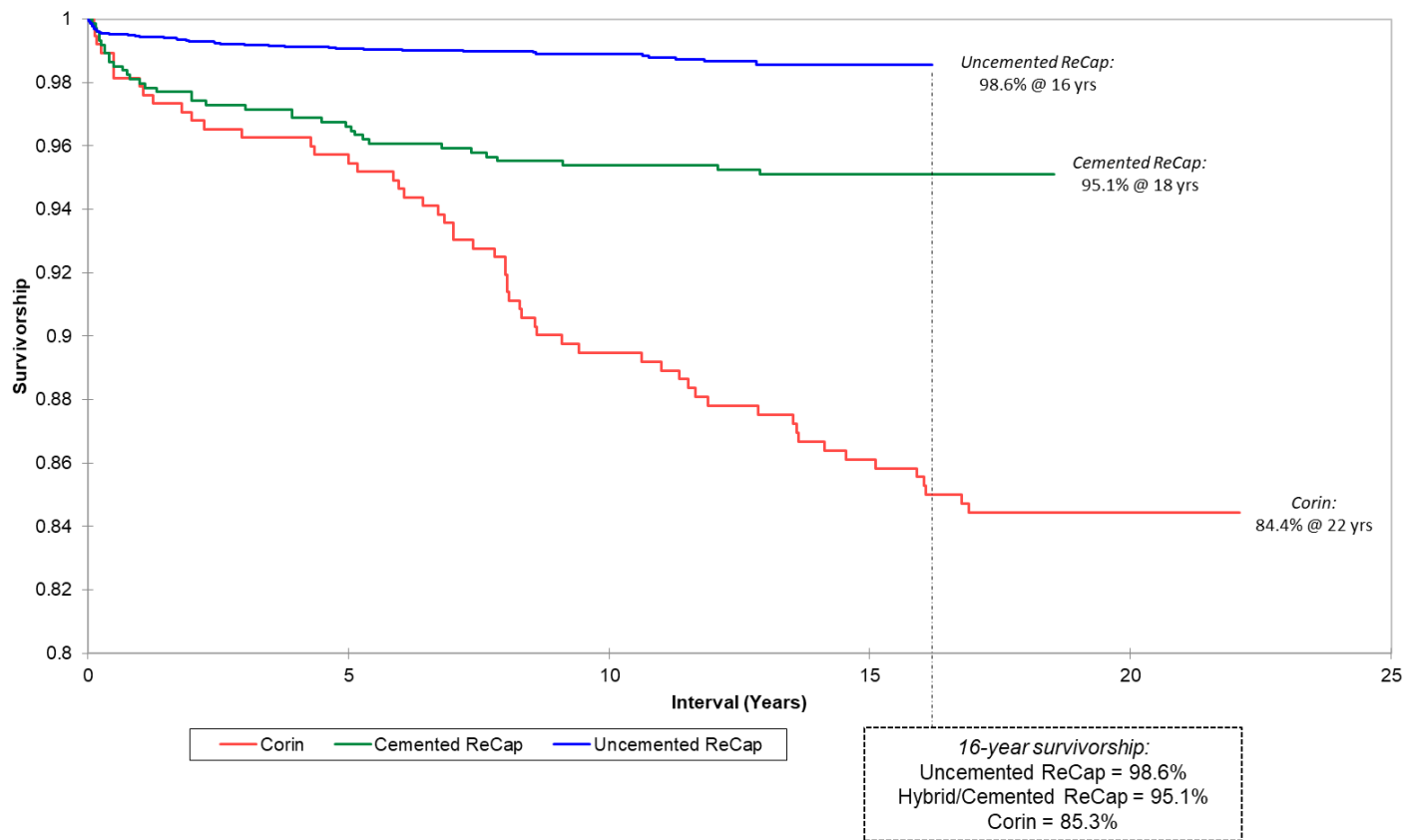
IV. Implant Survivorship

Includes ALL implant types*: 6800 cases over 20 years

**unless noted otherwise in each graph*

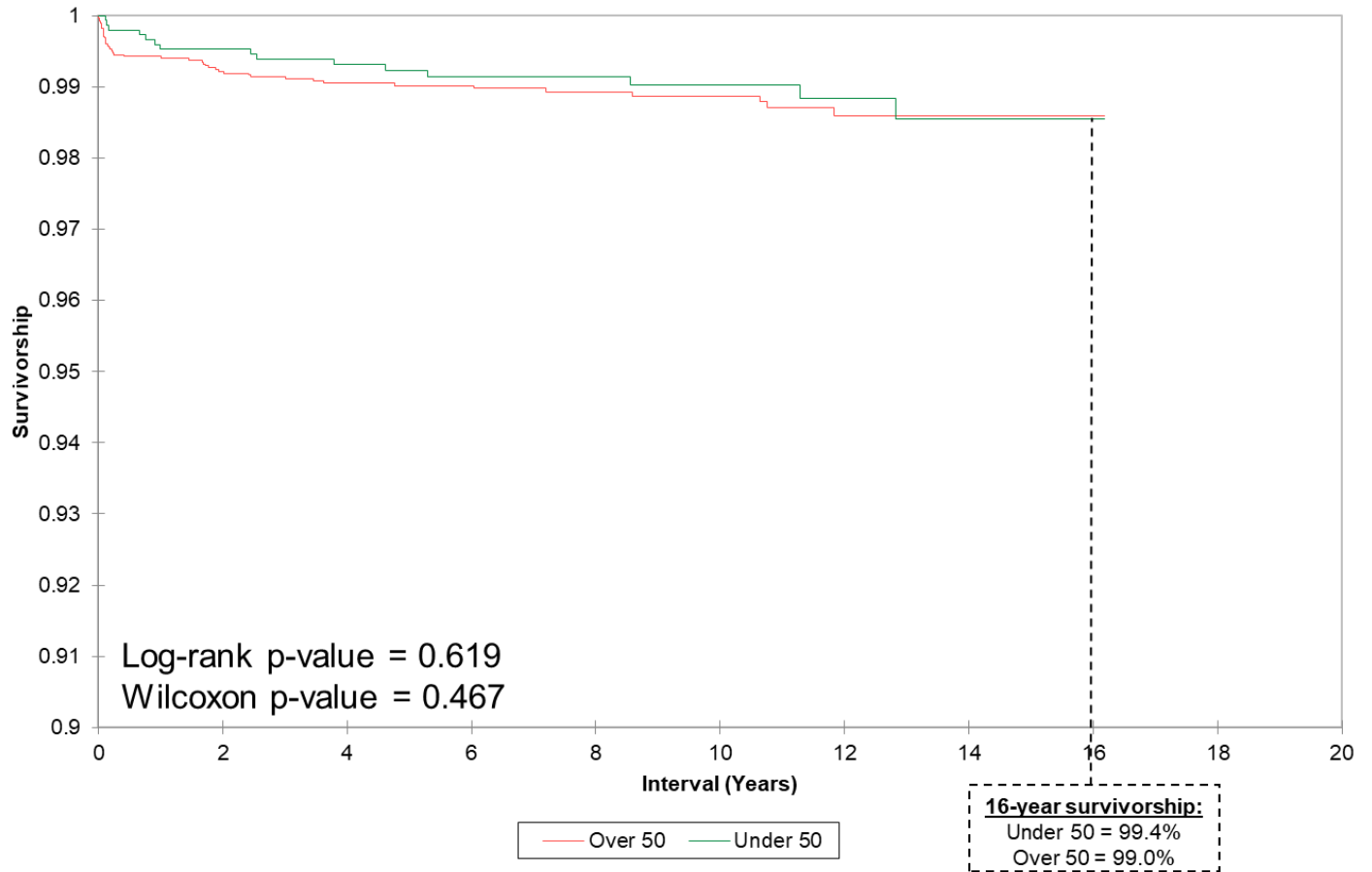
Survivorship of hip resurfacing continues to improve as we gain more experience and identify measures to prevent failures. These survivorship curves give the reader an opportunity to see what the odds are that their implant will still be functioning at some time point after implantation. We present three Kaplan-Meier survivorship curves: all implant groups, all implants for patients under 50 at time of surgery, and Biomet implants grouped by sex. Unlike for THR, HRA survivorship does not vary by age (overall 99.1% 16-year implant for both age groups). 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. In our 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.

Kaplan-Meier Implant Survivorship (ALL implants)



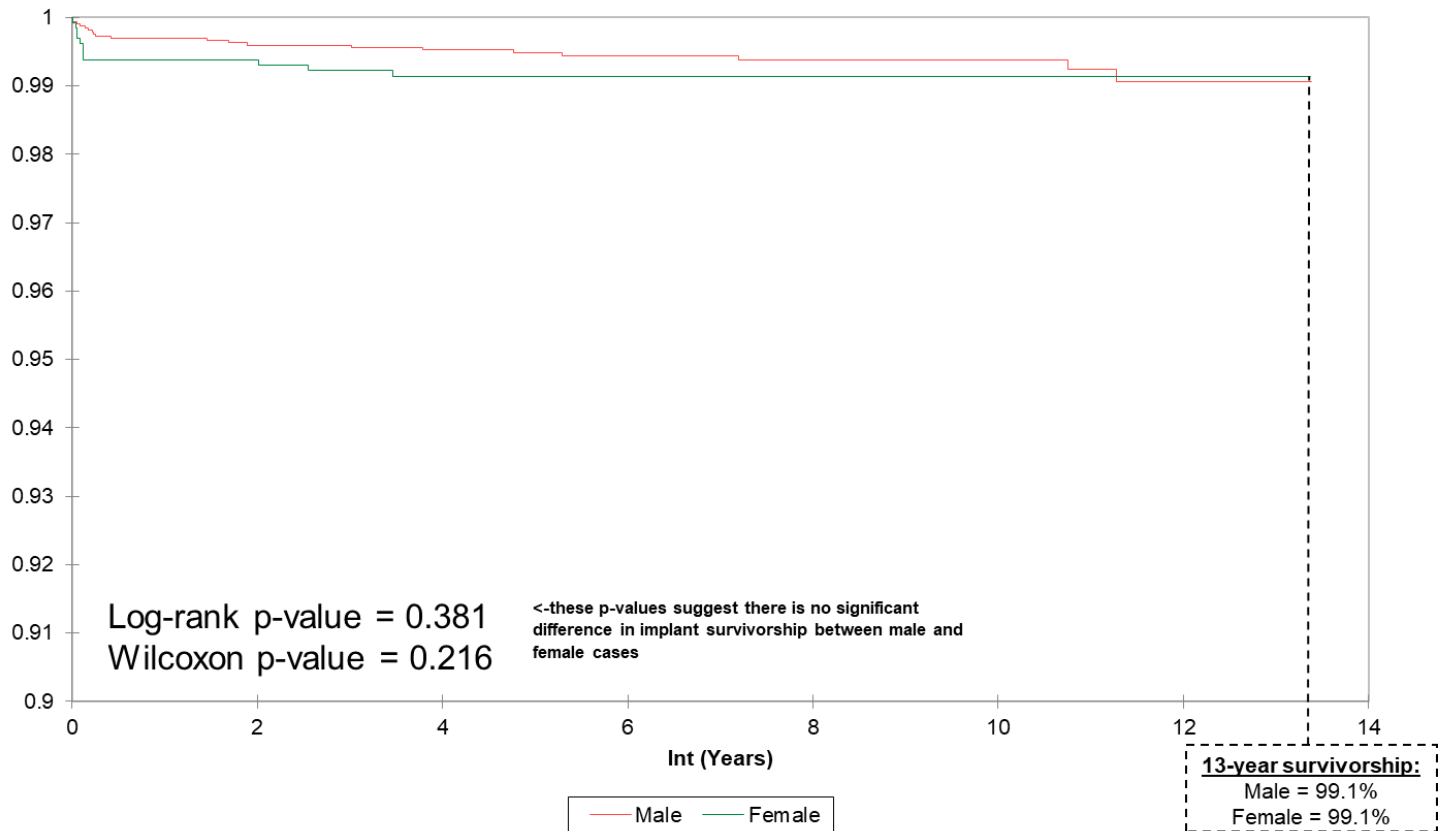
Note that the survivorship y-axis begins at 80%. There have been no instances of adverse metal wear from any surgeries performed after 2009.

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



Above is the survivorship curve separate by age group for our uncemented ReCap group. Note the y-axis start at 90%. There is no difference in survivorship or raw failure rate based on age, unlike the typical pattern found at many other surgery centers.

Kaplan-Meier Implant Survivorship by Sex (Uncemented ReCap – Date of Surgery >2010)



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 include better functional outcome, less residual thigh pain, fewer dislocations, bone preservation, and longer life expectancy.

Among, Dr. Gross' patient cohort, 98.7% report being satisfied with their surgery at 2 years postoperative. After all revisions, reoperations, and complications are accounted for, there are still approximately 3.4% 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.

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.

Thomas P. Gross MD

Patient to complete this section:

I (patient name: _____) have reviewed the 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