

Current Status of Conserve® Plus Hip Resurfacing

Information for Patients and Others

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In the past 3 years, the report of numerous adverse local tissue reactions (ALTR)¹ has raised doubts over the benefits of metal-on-metal (M/M) implants used for Hip Resurfacing Arthroplasty (HRA) and total hip replacement (THR). The recall of ASR resurfacing device (manufactured by DePuy) and its Big Femoral Head THR system using the same socket has resulted in unprecedented and grossly unbalanced reporting in a media blitz from the New York Times and has led to intense legal litigation, bringing intense scrutiny to all M/M devices. Anxiety has grown among patients and surgeons despite the fact that the vast majority of M/M devices are functioning well with up to 15 years of follow-up.²⁻⁵

It is now clear that it is not the M/M bearing itself that is the problem in hip resurfacing, but how the system is designed and how the components are oriented during surgery. Metal-on-metal bearing systems are quite sensitive to coverage of the ball by the socket in order to maintain lubrication and minimize wear, but this fact was not fully appreciated until after clinical experience. Fortunately, the acetabular component with the largest femoral head coverage is the Conserve® Plus (Wright Medical Technology, Inc.) which has been associated with lowest production of metal ions (wear) and a virtual absence of ALTR as shown by Langton et al⁶. In addition, optimal orientation has been addressed in several studies. Basically, the message is that excellent results can be achieved if you use a **well-designed acetabular component and orient it optimally**.

Since all currently available designs have varying degrees of reduced coverage in the smaller sizes, safe zones for socket orientation should be determined for all systems using an accurate digital measurement method system to determine both socket abduction and anteversion (e.g. Einzel-Bild-Rontgen-Analyse, Innsbruck, Austria) in a large series with long term results. We have done this for the Conserve® Plus by analyzing the component orientation of all of our 1350 hips resurfaced since 1996. We then correlated component orientation and blood serum ions for cobalt and chromium from 341 patients. We have found a safe component orientation zone (i.e. no danger of increased wear) was produced for all sizes when the orientation angles of abduction were 42° +/-10° and anteversion of 15° +/-10°. Unfortunately, in a small number of my patients (mostly in very flexible women who did activities which require a large range of motion such as dancing), the components were oriented to increase motion in certain directions which can lead to increased wear. A handful has been revised between 5 and 10 years after surgery. The type and intensity of activity probably played a role in increasing wear, although we have not been able definitively to confirm that hypothesis. However we have sufficient information now so that, by determining component orientation, we can assure the vast majority of my patients (>95%) that they have no wear issues and will not have any problem with wear in the future.

Because we have studied and analyzed a group of patients who had ions drawn before surgery and serially thereafter up to 12 years postoperatively, we are now able to conclude that once the bearing is functioning well with low wear, it will continue to function well. There has been no statistical change in ion levels after the "wear in period" (6-12 months after surgery). As mentioned above, when properly oriented, the Conserve Plus design has the lowest blood serum cobalt and chromium ions of all of the hip resurfacing systems. Because of the confidence we have in our studies, it is not necessary to test patients for serum ions if they have optimally oriented components. However, if patients remain concerned, ion levels can be obtained. However, you should understand that the range of "normal" laboratory values relate to patients who have no implants. People with implants will inevitably show some increase in ion levels since even the best bearings have some wear.

In summary, the problems associated with M/M devices (such as ALTR), unlike the first generation of resurfacing with polyethylene bearings (circa 1975-1992), are not due to the bearing materials but rather to the device design and surgical technique. Thus, these problems can be prevented by proper component design and optimized socket orientation in both the coronal and sagittal planes.⁶⁻¹² One problem often misunderstood by surgeons, patients, and others is hypersensitivity or allergic reaction to metal. This is a very rare occurrence and can be determined only by an expert in histological analysis. To date, no cases have been identified in patients who have had the Conserve® Plus implanted in the U.S.

The Prognosis for your Conserve® Plus hip resurfacing:

We recently published our long-term Conserve Plus survivorship of 99.7% at 10 years in patients who had good bone quality and femoral components 46mm or larger (mostly males). These are arguably the best results for any hip replacement, and the numbers are holding at 12 years. For those patients who had risk factors (femoral components smaller than 46mm or large cysts), the survivorship of our second generation implantation technique is now 94.3% at ten years, up from 88% with the first generation technique (used in the first 300 patients performed between 1996-3/2000). I anticipate further improvement in

the results for patients with risk factors as our technique continues to improve. We now use a thinner shell socket to save bone, too. We intend to follow as many patients as possible from more recent surgeries. Doing so allows us to optimally advise you and other patients about the future. What has been the most impressive about our results has been the virtual elimination of neck fractures and femoral loosening despite resurfacing hips in young and older patients with serious cystic defects. Although we have had a few cases of long term socket loosening, we now know that, as with wear prevention, the risk can be minimized by proper component orientation.

I am truly surprised by the quality of results we have achieved and the activities our patients enjoy in their professional or recreational sports. My initial goals for survivorship have been exceeded, but there is always room for improvement, especially in predicting lifetime durability in young patients. My own indications for hip resurfacing have greatly expanded to include all ages and conditions. Contrary to what most surgeons believe, gender is definitely not a contraindication! Our results in the over 65 year age group are comparable as well, with 98.9% survivorship at five years and 95.6% at ten years. In a comparison study in this age group, hip resurfacing outperformed our THR's.

The advantages of hip resurfacing are clearly important: stability without dislocation and minimally bone invasive. It just makes sense to save the head and neck so that conversion to a THR, if ever necessary, could be performed easily. This enables patients seeking to restore their previous lifestyle to be highly active more safely than with a THR. Numerous authors have reported high levels of physical activity in patients after hip resurfacing¹³⁻¹⁶. Further, we believe that resurfacing is biomechanically and physiologically superior, and there some evidence to support that opinion.

To improve initial socket stability socket stability at surgery and promote long term fixation, we have recently developed (in association with Wright Medical Technology) a new method of socket fixation using a porous titanium material mimicking trabecular bone¹⁷. In addition, we have a promising method to promote porous ingrowth for the femoral component for patients who desire to participate in high-impact activities. We currently have 2.5 years of promising experience with this device.

The problem now is getting these innovations approved by the US FDA. Unfortunately, the negative media blitz questioning the very basis of what makes our resurfacings so successful, the Metal/Metal bearing, has adversely affected the approval of improvements specifically addressing areas of concern. Primarily because of the ASR tragedy and recall, the FDA and others now question the FDA's previously well-established methods for the approval of device improvements. The vast majority of these 5-10K approvals have ultimately enhanced safety and efficacy (i.e. performance, durability) of literally thousands of devices.

It is also has become apparent that one of the problems today is that there are not enough surgeons trained to perform hip resurfacing successfully due to the increased difficulty of performing resurfacing compared to THR. Increasing the number of well-trained surgeons is a future goal.

The manufacturing quality of M/M bearings is excellent, particularly the control of clearance and roundness of the components, and it is certainly sufficient to produce safe and successful hip arthroplasty devices as long as conservative guidelines for cup implantation are followed. However, there will undoubtedly be further improvements and reduction in the wear properties of M/M bearings in the future. Metal-on-metal hip resurfacing is not a new technology anymore and the devices that have been approved by the FDA after sufficient clinical trials have been available for well over a decade. It is important to understand that the devices that were recalled or withdrawn were in the experimental phase. This means they did not have satisfactory five year results, the minimum amount of time to compare their safety and efficacy to the established, well-functioning devices such as the Conserve[®] Plus.

It is clear to us now that metal-on-metal implants can be extremely successful when a well-designed component is oriented properly. In these patients, wear is not a problem, and the survivorship is excellent. Our technique is improving, and there have been improvements in component design as well. Although we are facing challenges from the media and the FDA, I am convinced that hip resurfacing, particularly with the Conserve[®] Plus, remains an excellent procedure.

References are posted on our website: www.jri-docs.com