

Corin CEO Paling Responds to *OTW* FDA Panel Story, Fires Salvo at Smith & Nephew

By Walter Eisner

March 2, 2007

In our feature story last week about the FDA Orthopaedic and Rehabilitation Device Panel's vote to recommend that the FDA approve Corin USA's Cormet hip resurfacing device, we noted that Ann Benson-Gyles testified before the panel and told them that she had flown in from England at her own expense to tell them about her Corin hip device.

We reported that she said the device "worked brilliantly at first, but the failure came later." She testified that the implant came loose after five years and that she had been told by her experts that it was due to the double heat process used at the time in manufacturing the device.

Corin testified at the panel meeting that the device she described was no longer being used.

We were very pleased to hear from Corin CEO Ian Paling this past week to give us more information about that testimony.

Ian Paling writes to us that Benson-Gyles had a Corin McMinn resurfacing hip in 1996 that was revised in 2005, thus "lasting nine years, which is not too bad." Paling further tells us that Benson-Gyles' claim that the failure of the device was due to metallosis caused by heat treatment is "a completely unfounded statement. We have demonstrated (and published) many times that heat treatment does not affect wear properties. She admitted at the panel hearing that her expenses were paid for by her surgeon."

Paling points out that Benson-Gyles was "being exhorted to speak by known Smith & Nephew employees, who of course are the owners of the BHR (Birmingham Hip Resurfacing) device."

He said he wouldn't be surprised, although not "100% sure," if "her surgeon" was not D.J.W. McMinn, the inventor of the competitive device.

Thank you, Mr. Paling, for the candid response to our story.

Anyone who has ever watched the British House of Commons in action on C-SPAN will know that this was a pretty mild tiff between competitors.

Birmingham Hip Resurfacing Inventor McMinn Gives Corin and Stryker the “Heat Treatment”

By Walter Eisner

It looks like 2007 is becoming the year of the hip. On February 27 we reported on the FDA’s orthopedics panel’s recommendation to approve Corin’s Cormet hip resurfacing device with conditions (<http://ryortho.com/members/newsletters/volume3/issue7/02-27-07-FDA.htm>).

On March 2nd we heard from Ian Paling, CEO at Corin, who asked us to set the record straight about the testimony given by one of Dr. Derek McMinn’s patients, Anna Benson-Gyles, at the FDA panel hearing (<http://ryortho.com/NEWSSHORTS/volume3/issue8/03-02-07-NS-Corin.htm>).

This week we hear from Dr. McMinn, the inventor of the Birmingham Hip Replacement System, manufactured by Corin competitor Smith & Nephew.

Corin’s Paling told us that the patient who testified at the panel hearing had “had a Corin McMinn resurfacing hip in 1996 that lasted nine years, which is not too bad.” He said claims that the failure of the device was due to metallosis caused by heat treatment was “a completely unfounded statement. We have demonstrated (and published) many

times that heat treatment does not affect wear properties. She [the patient] admitted at the panel hearing that her expenses were paid for by her surgeon.”

Dr. McMinn, Benson-Gyles’ surgeon, vehemently disagrees with Paling. He says that, in vitro, the heat treatments matter and, “Perhaps the marketing people at Stryker Inc. should consult their own in-house experts in the field of biomaterials before rushing to market a carbide depleted metal/metal bearing in the form of the Cormet 2000 and risking catastrophe for many patients.”



We love the way the Brits debate.

The FDA has not made a final decision about approval of the Corin device and the public debate about hip resurfacing continues to generate a lot of heat. We will share Dr. McMinn’s comments with Corin and Stryker and report on any responses they may have in our next edition of *Orthopedics This Week*, which will be published on March 27.

McMinn’s Response

I write in response to Mr. Ian Paling’s comments dated 2nd March 2007.

FDA Advisory Panel meetings have two sessions where the public can address the Panel. When Anna Benson-Gyles decided to appear before the Panel, I was happy to fund her trip. This is no secret. In her written evidence she states that I was her surgeon and in her oral evidence in her financial disclosure she stated that her surgeon funded her trip. For the record, it makes no financial difference to me whether Smith & Nephew sell 1 or 1 million Birmingham Hip Resurfacing in the next year nor does it make any financial difference to me whether Stryker Inc. sell 1 or 1 million Cormet 2000 resurfacing[s] in the next year. For the record, Smith & Nephew had no part in influencing Ms. Benson-Gyles and were not even aware of her decision to appear before the FDA Panel.

Ms. Benson-Gyles’s written evidence can be seen in the News section and her oral evidence can be seen in the Case Studies section on the following web site: www.mcminncentre.com.

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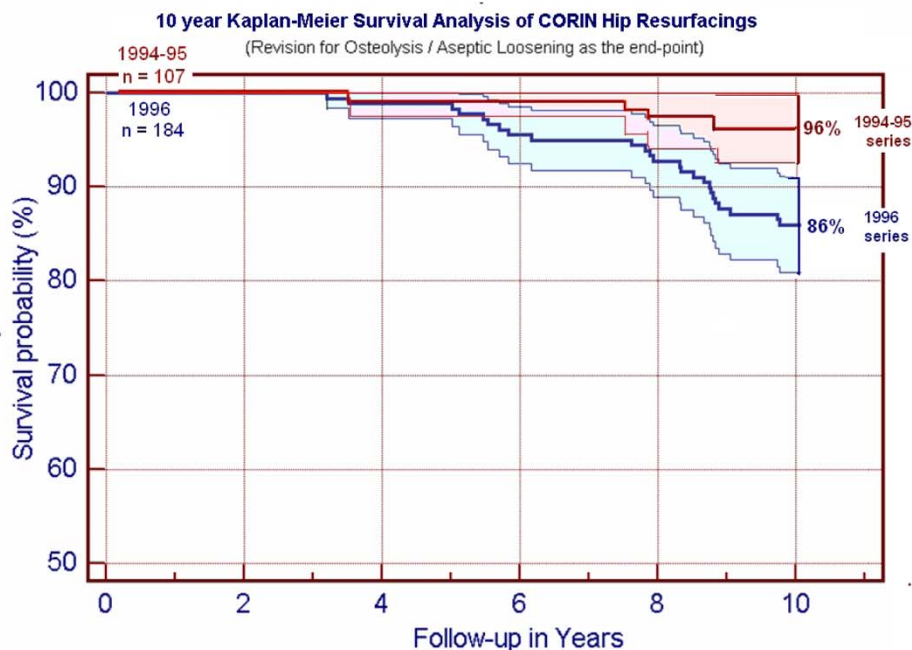
The McMinn/Corin Experience

Ms. Benson-Gyles had her left hip resurfaced by me with a McMinn Resurfacing manufactured by Corin Medical Ltd. on 1st August 1996. She did very well initially but by the time of her right hip resurfacing in 2002 she had x-ray evidence of osteolysis around her left hip resurfacing. On 1st February 2005, 8½ years after implantation, she required revision surgery to a total hip replacement with acetabular bone grafting to augment her deficient acetabulum damaged by osteolysis. In her own words to the FDA Panel “You are the experts and I’m confident that you will make the right decision in the interest of health and safety of the American people, I would not want anyone to go through what I went through.”

It is disappointing that Mr. Paling feels that this outcome is “not too bad.”

In my total series of patients operated on with Corin’s resurfacing in 1996, 14% of the group of 184 patients have been revised at the 10 year follow-up stage with all but one patient suffering bearing related failure and osteolysis. It is even more disappointing that of the patients who have not been revised in this group and who have had x-rays at the 10 year stage, one third of the group have impending failure with osteolysis and/or loosening. Disappointing too is the fact that with the same implant (apart from one detail) performed during 1994 and 1995, only 4% of this group have had revision of their implant at the 10 year stage—hardly improvement with experience of manufacture.

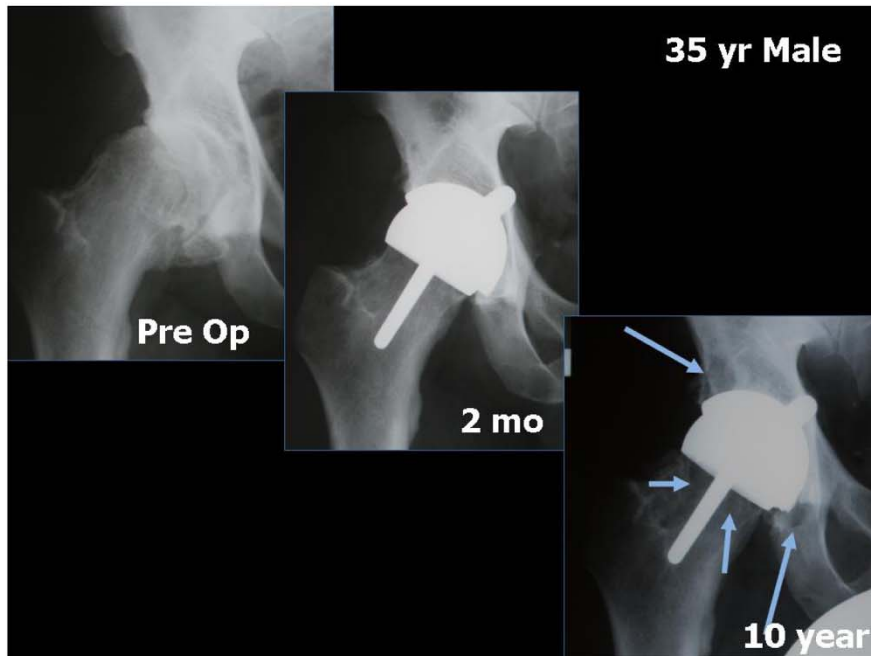
Shown below are the survivorship curves of these two series showing significantly worse results in the 1996 series.



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Shown below is an example of a 35 year old man's hip x-rays resurfaced with a Corin implant in 1996 and his 10 year x-ray shows osteolysis in the pelvis and in the femoral neck. Currently he has minor symptoms and is unrevised at this stage.



McMinn and Corin Split Over Heat Treatment Process

What changed in Corin's manufacture of the 1994/1995 group of implants and the 1996 group of implants?

The answer is that Corin, without any reference to me [as] the inventor surgeon, changed the heat treatment process of the metal castings on this implant. During 1994 and 1995 the implants were single heat treated in the main. During 1996 the implants were double heat treated in the main. These heat treatments of 'solution heat treatment' (SHT) and 'hot isostatic pressing' (HIP) were introduced to get rid of factory discovered microporosity and reduce factory scrap rates. HIP had not been discovered during the historic metal/metal era and the combination of HIP and SHT in 1996 was the first time ever that these heat treatments had been used in combination with metal/metal bearings. These double heat treated bearings, therefore, have no historic precedence and the good results from historic metal/metal bearings cannot be relied upon.

When I became aware of this at the end of 1996, Corin refused to return to as-cast bearings (i.e. the same metallurgy as the historic era metal/metal bearings) so I severed my links with Corin Medical Ltd and Corin re-launched the McMinn Resurfacing with some minor changes as the Cormet 2000. Importantly, according to the sponsor's submission to FDA, the Cormet 2000 has exactly the same heat treatments applied as the McMinn Resurfacing from the 1996 cohort.

There are seven published papers which interested parties can read on the McMinn Centre web site showing that heat treatments deteriorate the wear of metal/metal bearings. There are two categories of laboratory tests for pre-clinical

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testing of bearings; there are tests like pin on disc tests which test the material, then there are hip simulator tests which attempt to test the whole system. In general, the category of tests which show that heat treatment of cobalt chrome is damaging to a metal/metal bearing are the tests of material. The tests of the system in general have shown that heat treatment does not show up as a problem.

However, there is an important catch.

In Vivo vs In Vitro

In these hip simulator studies, synovial fluid substitute is used to lubricate the bearings and it has been demonstrated that fluid film lubrication of these metal/metal bearings does occur in vitro. This means that in hip simulator tests, the ball 'water skis' on the socket with a fluid layer separating the metal parts under test. In this idealized regime of a hip simulator, defective material can escape detection as the surfaces are protected by fluid film lubrication.

Experience with these metal/metal bearings shows an important mismatch between in-vivo and in-vitro usage.

We now know that during the normal working day there are periods where fluid film lubrication does not occur and metal/metal contact does occur with wear of the bearing parts. The bearing parts therefore must be capable of resisting wear. Double heat treatment is known to deplete cobalt chrome of its carbides, ceramic-like hard particles embedded in the material which confer wear resistance.

Which of the two categories of test is most clinically relevant? The answer is none of them, when we have 10 year clinical and x-ray results from a 'first of a kind' bearing showing awful results. What we should be doing is abandoning that material and not relying on simplified pre-clinical tests. This would not be the first time that hip simulator studies have lead us up the garden path. Hylamer, an 'improved' plastic for use in hip replacement, passed all its pre-clinical tests but when introduced into clinical practice was a failure with many patients being damaged. Anna Benson-Gyles expressed surprise that her group of patients from 1996 were not included in the sponsor's submission to FDA. It is disappointing that this does not seem to have been addressed during the FDA hearing.

Advice to Stryker

I am very surprised that a huge company with massive research resources like Stryker Inc. are prepared to distribute the Cormet 2000 for use in the USA. I draw attention to the following publication by Wang, Wang and Gustavson showing clearly that heat treatment deteriorates the wear properties of cobalt chrome when used as a metal/metal articulation. These authors were all employees of Howmedica and the research on which this publication was based was performed in Howmedica's research laboratories. Howmedica, of course, has been acquired by Stryker Inc.

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Kathy K. Wang,¹ Aiguo Wang,¹ and Larry J. Gustavson¹

Metal-on-Metal Wear Testing of Co-Cr Alloys

Reference: Wang, K. K., Wang, A., and Gustavson, L. J., “**Metal-on-Metal Wear Testing of Co-Cr Alloys,**” Cobalt-Base Alloys for Biomedical Applications, ASTM STP 1365, J. A. Disegi, R. L. Kennedy, and R. Pilliar, Eds., American Society for Testing and Materials, West Conshohocken, PA, 1999.

Summary

The wear characteristics of eight different Co-Cr alloy metal-on-metal bearing combinations were studied using a reciprocating wear machine. Wear specimens were made from three different Co-Cr alloys, cast Co-Cr (as-cast and solution treated Conditions), low carbon wrought Co-Cr and high carbon wrought Co-Cr alloys. It was found that the as-cast on as-cast couple was superior to the solution treated on solution treated couple or the as-cast on the solution treated couple. Study also showed that as-cast on as-cast couple was superior to the high carbon wrought alloy. The low carbon wrought alloy was found to be the worst alloy for a metal-on-metal wear application.

The as-cast on as-cast head/cup components were also tested using the hip simulator wear machine. Results showed that the as-cast on as-cast couple was comparable if not superior to the new-generation metal-on-metal component which was made of the high carbon wrought Co-Cr alloy.

Another employee of Stryker Inc. is Dr Robert Streicher, PhD, who has a fine history in developing the Metasul metal/metal bearing when he worked at Sulzer Medical. Dr. Streicher has published extensively on the high carbon/high carbide containing metal/metal hip arthroplasty he helped develop.

Perhaps the marketing people at Stryker Inc. should consult their own in-house experts in the field of biomaterials before rushing to market a carbide depleted metal/metal bearing in the form of the Cormet 2000 and risking catastrophe for many patients.

I applaud Anna Benson-Gyles for having the courage to appear before a very intimidating public hearing of the FDA Advisory Panel. It is to be hoped that her evidence to FDA will prevent further harm to patients.

Derek McMinn FRCS
Consultant Orthopaedic Surgeon

