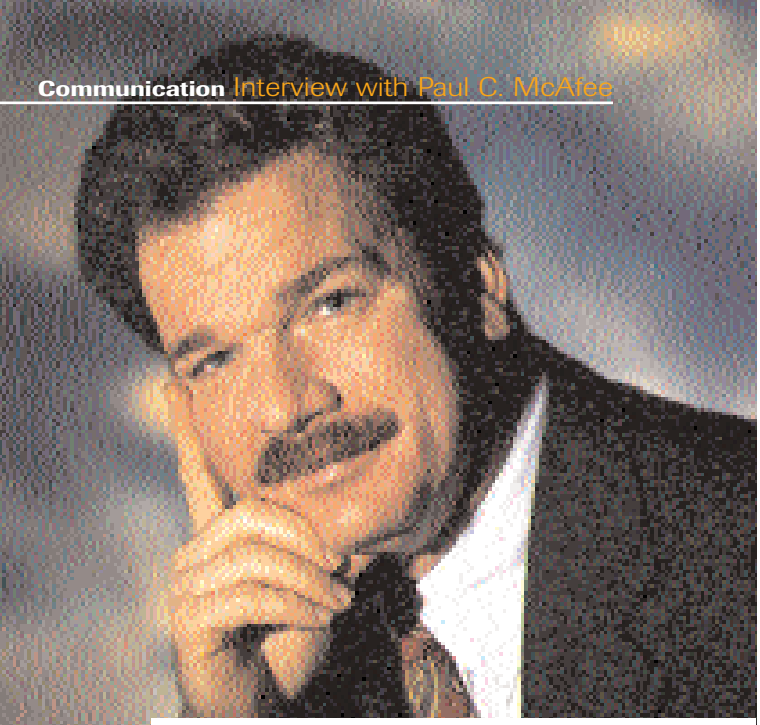

Interview with **Paul C. McAfee, MD**

– Spine surgeon
Orthopaedic Associates
An integrated spine center
Towson, MD, USA

About…

… Paul C. McAfee
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Paul C. McAfee received his B.A. degree from the University of Rochester, and his MD from the State University of New York at Syracuse. He completed his surgery training at the University of Virginia. His post graduate training was completed at Syracuse and Case Western Reserve University. He is fellowship-trained in spine surgery. Dr. McAfee's areas of expertise are in spinal reconstructive surgery and general orthopaedics.

As Chief, Spinal Reconstructive Surgery, St. Joseph Medical Center Towson, Maryland, Dr. McAfee is a respected leader in spinal surgery and is recognized as one of the pioneers in the field of disc replacement, having • • •

ASN : How did you become interested in artificial discs to solve the problem of adjacent segment disease ?

Alan Hilibrand and I did the same spine fellowship with Henry Bohlman. Alan Hilibrand's study shows 3% incidence of adjacent disc disease per year in the cervical spine. He started with 440 of Henry Bohlman's cases, then over 20 years calculated the incidence of how many came back in with adjacent disc space narrowing. But it is not just 3% incidence of X-ray narrowing, it's a 3% incidence of symptomatic degeneration requiring a return to the operating room. So 3% in a year worked out to be about 25% in 10 years. That means that when a patient undergoes a spinal fusion, he or she has 1 in 4 chances of going back in the operating room in the first 10 postoperative years. That's really why I started looking at the Link prosthesis and tried to adapt it to the cervical spine. So I worked with Helmut Link and his company called CerviTech, using conventional biomaterials (cobalt chrome, titanium (TiCaP), and moderately cross-linked UHMWPE), the same as those used for the SB Charité lumbar disc replacement. There were also spinal surgeons that evaluated it as well, and the CE mark should be approved by the end of this month (September 2003). As for the European investigative Team, they are headed by Alan Crockard (n.a. Royal College of Surgery) , we couldn't hope for a better person to work with. The first pilot studies were all done in Brazil, on 64 cases, with Luis Pimenta. They were not just simple, in a one level situation, they were two and three level cases. I think there are 12 double level cases and there are about 20 revision cases in patients who had prior surgery such as cervical cages. The most common indication was adjacent segment disease. So we know now that we can realign the spine normally and we know we can bring the motion back to a normal disc. What we don't know is if we can get an artificial disc adjacent to a fusion to get superphysiologic motion- in other words, the motion has to be better than normal, as it has to compensate for the fusion level.

ASN : Do you think that the latest developments in spine arthroplasty will soon lead to precise indications for disc replacement, or is it still a long way before these indication are well defined ?

We started a prospective study on the SB Charité in the United States in part to see if we could gain some insight into the correct indications for an artificial disc. Now that DePuy AcroMed, a Johnson & Johnson company, owns the SB Charite III, I am very confident that they will replicate their strong commitment to clinical results as they have shown in many areas of spine surgery, most notably in spinal fusion. As we continue to catalog and learn from the 15 year history of the SB Charite III disc clinical experience around the world and following the FDA approval of this device in the United States there is no doubt that DePuy AcroMed will be a leader in the area of spine motion preservation, especially regarding the right indications. Defining those indication will not take a very long time, but it will take a few more years. For example, I saw a patient in my office this week with an isthmic spondylolisthesis at L3-L4 which had developed below a 12 level scoliosis instrumentation and fusion 15 years previously. It might turn out that anterior disc replacement is not appropriate for this difficult a case. This situation might only be correctable with a posterior dynamic stabilization device such as Dynesys. We need to do a critical analysis of staged indications for disc replacement. Right now the US FDA prospective study on disc replacement pertains to only one vertebral level of collapse with no prior attempted thoracolumbar spinal arthrodesis. In addition to drawing scientific conclusions about indications, we also intend to learn more about adjacent level disease in the motion preservation population versus the fusion population. We will use existing data to investigate this important question. The main persons in our lab who are running this study are Brian Cunningham and Anton Dmietriev. They digitized every X-ray in the United States FDA study and the measurements are very detailed. They include the anterior, middle and posterior disc space height and the neuroforaminal height, as well as the flexion extension angles and that's not only on the operated level but also on the adjacent level above. So we have already patients we operated three years ago and we are doing that not only for the SB Charité patients, but also for the control patients that got a stand alone BAK cages. So we will have that information, too.

ASN : Coming back to spinal fusion, which obviously remains the gold standard for the moment, what's your opinion on different types of instrumentation, such us rigid versus semi-dynamic, regarding adjacent level degeneration ?

We had a Volvo Award for the first study which was actually done on device related osteoporosis and we felt that there was some osteoporosis at the vertebral body that occurred with spinal instrumentation. And it turns out that it is very true that if you use an interbody cage there can be bone remodeling and trabecular thinning after two years. We were able to retrieve equine spines an average of 12 years after Bagby performed anterior cervical interbody fusions in thoroughbred racehorses. They demonstrated resolution of cervical spondylitic myelopathy-the device related osteoporosis was an inevitable effect of an arthrodesis but it was clinically insignificant and did not causes symptoms at an average of 12 years post operatively. So you have kind of a balance, you achieve a more successful fusion with a more rigid implant but in the long term you also get osteoporosis in the vertebral body. One of the individuals in our biomechanics lab Yoshihisa Kotani did a great study as well as Masahiro Kanayama, from Dr Kaneda's fellowship program from Haikkado University (Sapporo, Japan), who found that there is some ligamentous atrophy associated with rigid fusion. So not only across the fusion do you get some thinning of the trabeculae and device related osteoporosis but actually the ligaments at the operative area of the fusion get atrophic. This is the only spinal study I know that identified the problem of device-related ligamentous atrophy.

ASN : Intuitively one might think that the ligament atrophy is a natural phenomenon in this case since once you fixed the spinal segment, there is no motion anymore so the ligaments lose their main function, i.e. maintaining movement in physiological limits. Hence the ligaments atrophy. Do you agree with this ?

• • • performed more than 200 motion-preservation procedures in 10 countries and having invented a cervical disc replacement. His early pioneering work on CT scans for burst fractures led to a better understanding of implant behavior first with Harrington rods and, subsequently, with many other devices. He and his lab have set the standard on biomechanical testing of implant and construct performance. More recently, they have done pioneering work on disc endplate interface behavior and the effects of wear debris around the spine.

Dr. McAfee has been an investigator and international leader for minimally-invasive surgical techniques. He has led the way in understanding approach-related morbidity from conventional and minimally-invasive strategies. He has the most personal experience with lumbar artificial disc replacement of any surgeon in the United States. A member of the Committee on the Spine - American Academy of Orthopaedic Surgeons, Dr. McAfee also serves on the editorial boards of Spine, Journal of Spinal Disorders, and The Spine Journal. He has published extensively throughout his career. ●

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That's absolutely true. It's an effect of the instrumentation and of the fusion. Now you may get a more reliable fusion if you use instrumentation, but the more rigid the construct, the more dramatic the atrophy. So you get atrophy of the ligaments and bone osteoporosis in the area of the fusion. But what we also found is ligaments hypertrophy at the adjacent level, because the ligaments have to absorb the excessive stresses, for example the ligamentum flavum and the posterior longitudinal ligament got thicker in the adjacent levels.

ASN : What do you think about the Dynesys system ?

I am in the study group for CenterPulse and I think that the indications now are central spinal stenosis and grade 1 degenerative spondylolisthesis. I talked to Rudy Bertagnoli who is experienced in this technique in Europe and I think that there is a real place for motion preservation. The main reason is that right now if a patient has leg pain we have to exclude him from the SB Charité protocol. If a patient comes to me with radiculopathy from the lumbar spine, if you do a disc replacement, that means two operations-a posterior nerve root decompression and an anterior disc replacement. But if you do a case with Dynesys , you can address the issue of nerve root compression from the back during the same motion preserving procedure. In addition I don't think there is a place for disc replacement with isthmic spondylolisthesis, but this is a great indication for the Dynesys. If I can just clarify further, I have a statement about Dynesys . We did very extensive studies with Steve Griffith from CenterPulse, the director of research at CenterPulse. What we did is a study in 12 baboons with two-level Dynesys procedure and we proved that with time the flexibility increased with the Dynesys system. In other words, the central "shock cord" stretches out a little bit and that's actually advantageous. This device and what we have studied about it raises some interesting questions. For example, what is the optimum tightness of the construct for each particular patient ? And one of the questions I asked myself is "Do you tighten the construct with the hips extended or do you tighten it with the hips flexed because this changes the interspinous distances ?". Believe it or not, if you simply use the self retaining retractor and stretch the paraspinal muscles, it actually brings the spinal processes closer to each other. So you do not only have to watch the hip position during surgery but you have to watch the amount of distraction in the paraspinal muscles that the retractors are causing. So my approach is that we try to reproduce the standing physiologic position with the Dynesys procedure but the fact is that we do not really know the optimum tightness and tension of the motion preserving posterior instrumentation systems at the current time

ASN : As a Biomechanics specialist, do you think that in the future Biomechanics evaluation of patients will become mandatory in order to better predict the surgery outcome, for example how much lordosis should the surgeon correct, how tight the construct should be and so on ?

> Left to right : L. Pimenta, MD A. Cappuccino, MD & P. McAfee, MD

That's a great question. I really think it will absolutely be mandatory. I am not sure of the exact mechanism yet but Mekanika is a company we are working very closely with. The have about 50 spinal stiffness gauges they are distributing across the United States and we already have them not only in the laboratory but in patients. During the Dynesys procedure, after you have the pedicle screws in, you can measure stresses for distraction and compression and rotation. So it is one thing to test it in the lab, but I think it is also important to know what the baseline is in the patient. We have an idea of the normal range of stiffness between the adjacent pedicles after intraoperative insertion of pedicle screws, but we also have an idea of what the definition of stable and unstable is. But I absolutely agree that there has to be a biomechanical way to quantify instability, whether we try a repair with Dynesys, or a posterior motion preserving procedure.

ASN : This is all about local analysis. But don't you think that global posture plays a major role in the final outcome, mainly regarding the patient's re-adaptability after restabilization ?

That's a good point. We should talk about the adjacent level. Well, we do not measure only one adjacent level, but we have to look at the entire adjacent spinal segmental balance. Is it in a physiologic position or is the plumline anterior or posterior to the L5-S1 disc space ? This is where X-ray spinal parameters assisted by clinical computer analysis will be very useful. There is another interesting project Johnson & Johnson DePuy AcroMed is working on. The De Puy AcroMed Motion Preservation Team has been working on a system that at the last instrumented level, say in a scoliosis construct, would allow some motion at the limit of a long construct, that would make a transition from the stiff area of the spine to the mobile segments. I am very excited about these developments.

ASN : Will this procedure, in your opinion, improve the long term outcome for the adjacent levels ?

I think it will, because this transition will make forces more physiological. I personally believe that it will help against the adjacent level diseases. You should not only look at the 25% incidence of symptomatic patients that go back to the operating room, you have to look at probably 40% incidence of radiographic change. I think you can know more about forces when you look at the X-rays to see whether there is some

osteophyte formation, disc end plate irregularity, or vacuum disc sign.

ASN : We can roughly say that the three last decades were fully dedicated to fusion techniques in spine surgery. We are facing today an evolution towards a new generation of procedures, such as disc replacement, in order to preserve spinal motion. Given your experience in spine surgery and biomechanics, what do you think about spine surgery academic training ? Did you notice this evolution in young surgeon's training ? Is the training also more specialized ?

I have my opinion on this, but it is not necessarily the right one. What I see is that orthopaedic spine surgeons and neurosurgeons are complementary and are almost indistinguishable now in their expertise. I think that neurosurgeons can be just as good as the orthopaedic surgeons in spinal fusion instrumentation whereas orthopaedic surgeons have to be as good as neurosurgeons in decompressions and in their respect of the nerve roots and spinal cord. Right now the oldest spine organization, the Scoliosis Research Society is changing our bylaws to include membership to neurosurgeons with specialty interest in spine - with equal membership privileges to orthopedic surgeons. But maybe in the future there will be specialists in disc replacement and that's because this is such an isolated area. I would expect that the revision of failed disc replacements will be a subspecialty in itself. I think that so far you have groups like the Scoliosis Research Society and Cervical Spine Research Society and North America Spine Society. They are all extremely encouraging and accommodating in their own programs to include courses on disc replacement. They are not necessarily accepting the fact that this is the treatment of choice but I think they are open minded and allow analysis of the new technologies. That's really the important thing. You cannot expect a scientifically well-renowned group like the Scoliosis Research Society to jump in feet first in every new trend, but they have been very scientific about allowing an analysis. For example, at the International Meeting of Advanced Spine Technologies (IMAST) there is always a morning session on disc replacement and it is very interesting to get the comments from the more conventional fusion surgeons. But I think that training will evolve beyond didactic lectures, and it will happen when surgeons will pick their fellowships, based on whether they want to do 80% of their work in spinal arthroplasty or if they want it to be 10%. Right now you have the possibility to choose whether or not you want to do primarily scoliosis deformities in paediatrics, or do you want to do adult surgery, or do you want to go to a fellowship program devoted to cervical spine exclusively ? So, I think that in the future training will be more individualized. There is no question that this is good for spine surgery in the long run throughout the entire world.

INTERVIEW BY A. MITULESCU & A. TEMPLIER

Non-fusion technology

"A State of The Art Debate" Live Surgery-via Satellite Zürich & New York, December 12-13, 2003.

The Swiss Spine Institute has for some time been introducing innovative symposiums to Spine Surgeons around the world. We now believe there is an urgent need for the scientific exchange of information between the United States of America and Europe concerning the latest technology and the most clinically advanced techniques of spine arthroplasty. This live surgery, live-via satellite symposium between Zürich and New York will feature :

- Six live surgeries transmitted live via satellite Real-time audience interaction from both continents with the operating surgeons
- Audience polling, "What would you do?" with results projected on screen
- Video conferencing between the two audience groups and faculty

Speakers and Moderators

Opinion leaders in the field of Non-Fusion Technology, as well as guest surgeons of the Swiss Spine Institute and the Texas Back Institute will be announced shortly.

Symposium Venues

- Dolder Grand Hotel, Zürich Switzerland
- Marriott East Side Hotel, New York USA

Registration Deadline & Fees

Full registration is $951.00. We have a limited number of seats available so registration should be made as soon as possible to guarantee your place. Registration deadline is November 15, 2003. Full registration includes single symposium admission, meeting guide, final program, two buffet lunches, coffee breaks and welcome cocktail. For this event only, full registration also includes one year's complimentary registration as an Associate Member of the Swiss Spine Institute, valued at $385.00.

Registration

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This will be an event not to miss.
Christian R. Etter, MD (Switzerland)
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