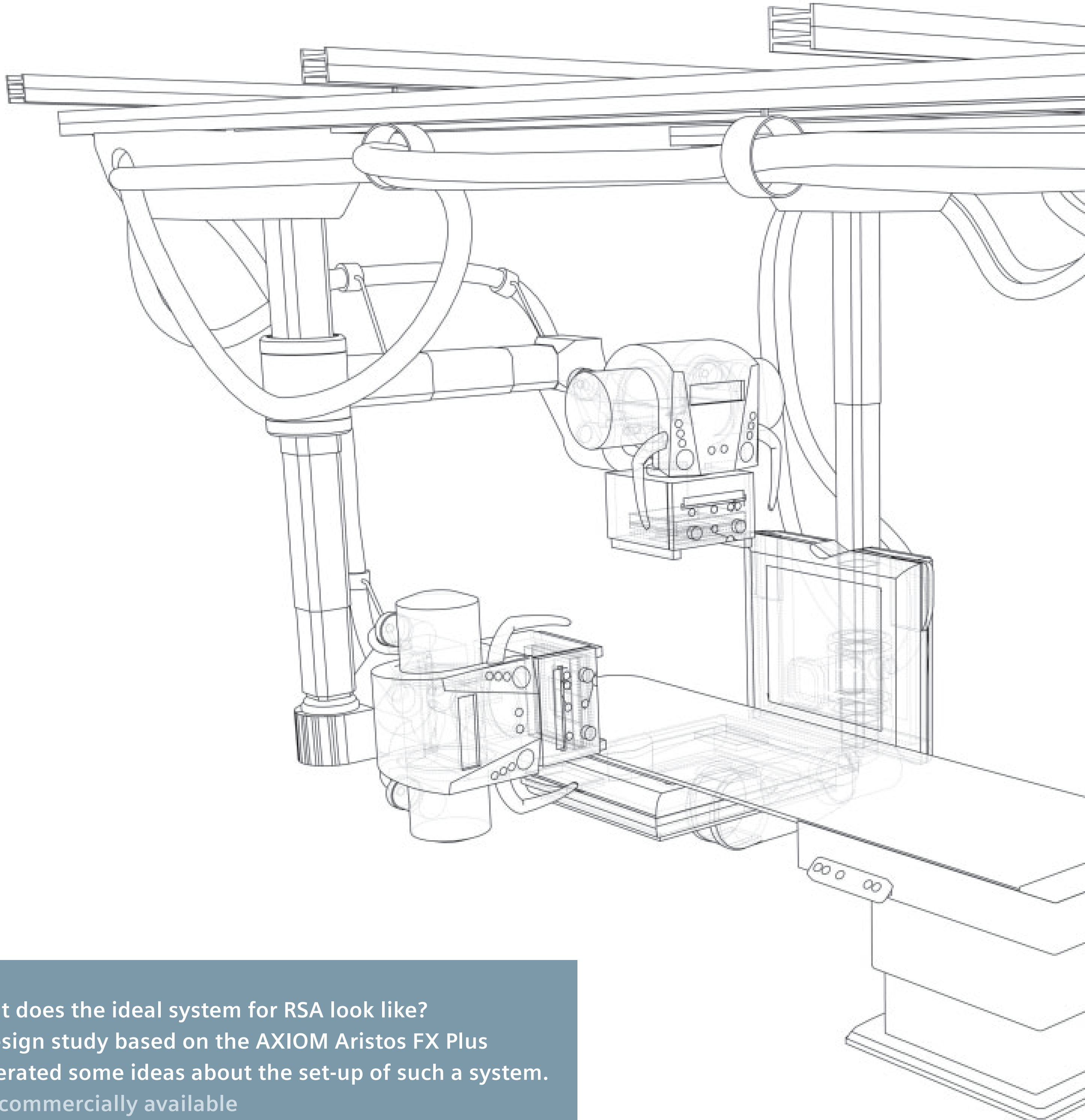
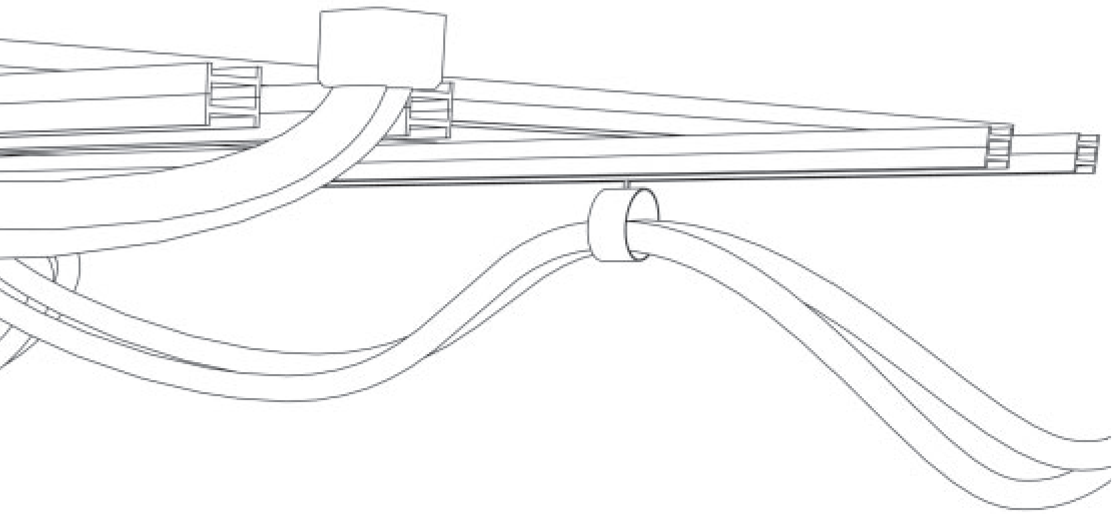
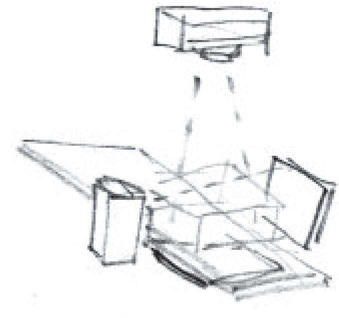


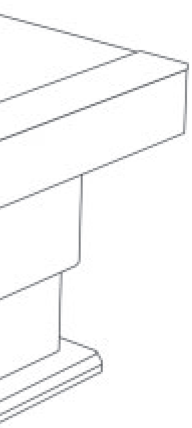
**What does the ideal system for RSA look like?
A design study based on the AXIOM Aristos FX Plus generated some ideas about the set-up of such a system.**
Not commercially available





For over 30 years now, a method known as radiostereometric analysis (RSA) has been used by orthopedists all over the world. Developed in Sweden in the 1970s, it is now considered the benchmark for quantifying micromotions in implants.

How Digital Radiography will revolutionize Radiostereometric Analysis



Joint wear, disease and accident are just a few reasons why the hip or knee might require implant surgery. The first artificial hip implants were developed more than 40 years ago and research is still ongoing. New materials and surgical methods are constantly improving artificial joint implantation and helping patients to live a pain-free life. However, even now the detailed functions of cemented and non-cemented femoral stems are still not entirely understood. Once the implant has been inserted into the femur, there are still some aspects to be considered concerning how the bone-cement-stem construct behaves. For the implant's long-term performance quality, the shape of the materials used and the interfaces are vital. Studies have revealed that the development of clinical loosening is attributed to micromovements, abrasive wear, leakage and even joint fluid pumping out to the cement-bone interface. Radiostereometric analysis (RSA) is the ideal method for observing and assessing this total migration (stem versus bone) correctly and accurately.

RSA What is RadioStereometric

1 Marker insertion

During surgery, small spherical (0.5, 0.8, 1.0 mm) markers made of biocompatible tantalum are inserted into the patient and/or attached to the prothesis.

2 Radiographic examination

The patient is x-rayed from two angles simultaneously together with a reference cage, producing two radiographs. The examination can be performed with a tube angle of 90° or a tube angle of 30°.

3 Measurement

Thanks to the calibration cage, the exact three-dimensional position of the markers can be identified by specially designed software.

Five steps to analysis

RSA was developed by Göran Selvik and his colleagues in Sweden in the 1970s and is now considered a powerful tool for clinically assessing implant migration. It enables accurate three-dimensional measurements to be taken from sequential biplanar radiographs in vivo over time. The three-dimensional kinematics of skeletal or implant movements can be determined between repeated examinations. Later researchers like Kärrholm, Söderkvist, Nyström and Börlin, have improved on Selvik's method. Their main goal was to improve user-friendliness and precision, making them key players in developing software tools like UmRSA® by RSABiomedical™. RSA itself covers a large field of applications including orthopaedics, paediatrics, odontology, plastic surgery, oncology, rheumatology, neuro- and hand surgery. This method's workflow can be described in five main steps: Implantation of markers, radiographic examination of the patient and a calibration cage, identification of markers and measurements of the radiographs, computations of marker coordinates and computation of motions of the implant.

Setting the right marks

During surgery, spherical markers made of biocompatible tantalum are inserted into the anatomic structure of interest, e.g. pelvis and the proximal femur. Normally, three stable markers are sufficient for an accurate evaluation, but, in practice, six to nine markers and even more are used to compensate for possible loosening and to achieve optimum precision. Post-operative radiographic examinations are performed in fixed intervals, usually directly after surgery, then three and six weeks later, and finally after three, six, twelve and 24 months. To perform the radiographic examination, two x-ray tubes are used to simultaneously expose the implant. These kinds of systems are usually designed particularly for RSA examinations. The two tubes are positioned at a 30 degree angle above the patient table. A calibration cage is also needed for containing a certain number of tantalum beads held in fixed, well-defined positions and that permit the formation of a three dimensional coordinate system afterwards. During the examination, the x-rays are guided through this cage before being projected on the image recep-

Analysis (RSA)

RSA was developed by Göran Selvik in the 1970s and 1980s in Sweden and is now considered the benchmark for quantifying implant migration. It enables accurate three-dimensional measurements in vivo over time from sequential biplanar radiographs. The three-dimensional kinematics of skeletal or implant movements can be determined between repeated examinations. RSA serves a large field of applications covering orthopedics, pediatrics, odontology, plastic surgery, oncology, rheumatology, neurosurgery, and hand surgery. The workflow of this method can be largely described in five steps.

4 Analysis

Using the position data from several examinations, three-dimensional motions of the anatomic structures of interest and the prosthesis are calculated.

5 Conclusion

The high precision of the method allows for early and appropriate conclusions even in small studies, making them more cost-effective.

tor system, normally film or CR cassettes. It is also very important to keep radiation doses as low as possible because a series of examinations will follow.

Motion detection

Thanks to the calibration cage, the exact three-dimensional position of the markers can be identified by specifically designed software. Just a few years ago, the radiographs had to be measured manually. Now, the radiographs are measured using a digital method. The images are either scanned using a high-resolution scanner and optimized with regard to contrast and brightness, or the digitized images from the x-ray system are directly uploaded into the measuring software. So far, though, the resolution quality of these images has not been sufficient, especially for large film sizes used for hip examinations. The software then calculates the position of the markers in vivo and can detect micromotions of the implant. The cage coordinate system is reconstructed based on the known coordinates of the cage markers. After the second examination, the positions of the implant markers can be compared. As the markers in each segment, e.g. femur or stem, are modelled as rigid bodies, they can be compared by means of rigidity and stability. The relative motions of the implant are computed by using the femoral stem bone markers as a fixed reference segment. This means that the bone markers maintain the same positions mathematically that they had at the initial post-operative examination. The mathematical determination of the femur's motions between examinations is utilized to "replace" its original position at the time of the first follow-up examination. The most recent observations have revealed a 50% drop in the error rate by using the digital method, which provides a more accurate measurement.

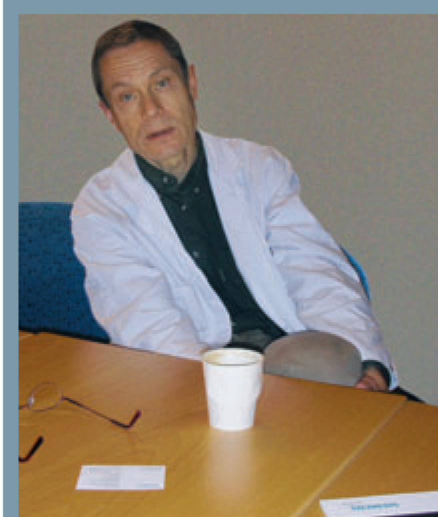
Digital brings advantages

Digital has clear advantages over analog. Many applications and mathematical algorithms have been developed and advancements in computer programs and digital radiography continue to expand its capabilities. Compared to the analogue method, digital evaluation has a few important advantages. First of all, the digital method can be made more accurate and it supports the use of model-based

Interview

radiostereometry that is not based on implanted markers. Secondly, digital radiography is advantageous in terms of contrast and brightness. This is especially applicable to some new types of digital detectors. Lastly, it is less labour intensive and contributes greatly to an improved workflow.

Improved technology to monitor implants could become interesting as we face the problem of a constantly aging society. The number of hip implants is growing, which is why RSA is becoming increasingly important. Recent developments, such as full digital radiography imaging, show great potential for the further development of RSA. However, the question should be: What can be done to improve RSA even further? What is the ideal system for such an application? What are the challenges and requirements of ideal RSA? To answer some of these questions, AXIOM Innovations visited Professor Johan Kärrholm at Sahlgrenska University Hospital in Göteborg, Sweden. He is a leading international scientist and practitioner of radiostereometric analysis (RSA) and one of its early users. He discussed with us the future of this method, his vision of an ideal system for this kind of examination and the future role of digital radiography.

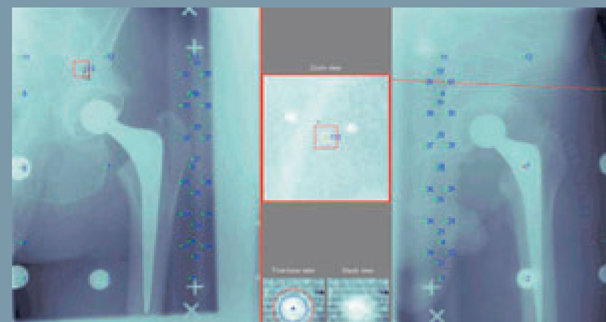


Prof. Kärrholm, the RSA method has been established for some decades now. Could you tell us how long you have been using this method in your hospital and for which post-operative examinations RSA is used?

I have used RSA since 1978. Today, we use this method to follow up total hip and knee prostheses. We use it to study implant fixation and wear. In some studies, dynamic investigations are performed to evaluate the kinematics of different implant designs. We also record the three-dimensional kinematics of the knee in patients before and after surgical repair of the anterior cruciate ligament. These patients are operated on using various methods. At present, we are focusing on early reconstructions of the ligament. We have studied the kinematics of the shoulder joint in patients with impingement syndrome. These patients have been evaluated before and after randomisation of three different types of treatments. There are also some ongoing studies on the follow-up of spine implants in which we are evaluating new devices inserted into the cervical spine and plan on studying lumbar disc replacements.

What methods were traditionally used before the RSA method?

Joint, implant and fracture motions were basically measured using conventional radiography and sometimes improved by correction for magnification and different types of adjustments for geometrical deviations. Other methods used were goniometry, photogrammetry based on markers placed on the skin, and in smaller studies of selected patients, pins drilled into the bones were used as markers.



An example of digital images of hip implant with tantalum markers.

How would you describe your experiences with RSA? Are you satisfied?

Yes and no. I have been working with this method for almost 30 years, so it is quite obvious that I consider it an excellent method, even if we are always in the process of improving it. Due to continuous development efforts, the accuracy of this method has been improved and the evaluation time decreased by more than 80%. The introduction of fast digital detectors enables the imaging systems to generate high-resolution exposures at a rate of 20 frames/sec. Real-time recordings or close to real-time recordings with a short delay until final evaluation will probably be possible in the near future. Such evaluation possibilities would have a huge impact on the user-friendliness and applicability of RSA.

What about the acceptance of RSA by orthopedic specialists? Most RSA examinations are performed in Sweden. Why so many in Sweden? And how do you see the development of RSA in other countries?

Radiostereometry was developed in Sweden by Hallert and Selvik. It was used early on in clinical research. This is why the predictive value of radiostereometric measurements in clinical practice was also recognized early on here and is the reason for its international success. Today, radiostereometric software and equipment are developed in Sweden and Holland and used in Europe, the United States and Australia.

What about the costs of the RSA method?

Any medical method comes at a cost. In Sweden, radiostereometry has been used to study a number of implants and bone cements. The results from these studies ensured that some poor-performing products never entered the Swedish market on a large scale. Thus, RSA studies have resulted in a reduced revision rate of both total hip and total knee prostheses. In Sweden, the costs for such revisions vary between € 10,000 – € 20,000 which means that this research has been cost effective.

Where do you see the most potential for improvements in the future?

Radiostereometry can be improved in many ways. A more standard method of inserting tantalum markers into bone should be developed. Markerless RSA for orthopaedic implants is another rapidly developing field. Such a method means that you do not have to mark the implant itself. Even if this procedure does become routine, there is a potential risk of implant fracture. It is also expensive. Further development of dynamic RSA based on digital detectors is another potential for improvement. If such recordings were combined with CT or MRI imaging to delineate the anatomy of the bone, we would be able to gain a great deal of understanding about contact surfaces, joint motion and ligament function. Further types of measurements can be performed, such as the height of the cartilage and evaluation of wear of total knee prostheses.

Many hospitals are currently shifting from conventional film-based radiography to digital radiography. What do you think about digital radiography for RSA?

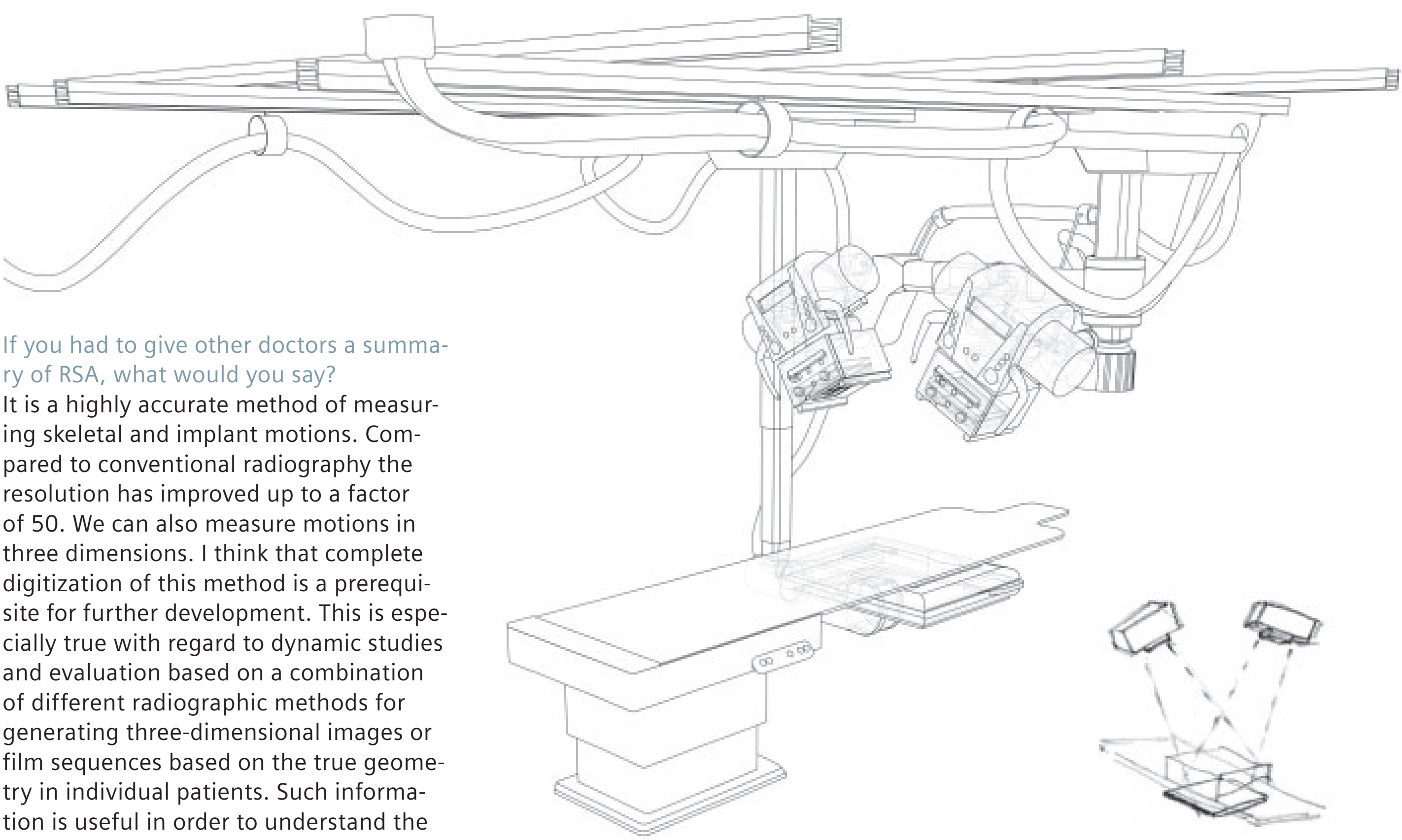
In Sweden, most radiographic centres are completely digitalized. We do all our measurements on DICOM images. As pointed out above, digital radiography facilitates quicker evaluation, more sophisticated studies and the evaluation of new fields in orthopaedics, especially related to joint kinematics.

What would such a digital system for RSA look like in your opinion?

I think that a modern RSA laboratory should be based on digital flat detectors. They make it possible to generate test exposures easily in order to initially locate tantalum markers before definitive exposure. There are now systems which can capture more than 20 frames/sec. Even if you do not need that high a speed for some kinds of dynamic studies, it is, of course, very useful. Data processing has become much faster and I think it will soon be possible to obtain an almost instantaneous evaluation of data, at least for simpler images. Today, we have a high degree of flexibility in our laboratories. If we get the opportunity to change over completely to digitized evaluation, we of course need to maintain this flexibility to be able to study almost any joint in the body.

"If we get the opportunity to change over completely to digitized evaluation, we of course need to maintain this flexibility to be able to study almost any joint in the body."

Prof. Dr. Johan Kärrholm, Head of Radiography Department, Sahlgrenska University Hospital, Göteborg, Sweden



If you had to give other doctors a summary of RSA, what would you say?

It is a highly accurate method of measuring skeletal and implant motions. Compared to conventional radiography the resolution has improved up to a factor of 50. We can also measure motions in three dimensions. I think that complete digitization of this method is a prerequisite for further development. This is especially true with regard to dynamic studies and evaluation based on a combination of different radiographic methods for generating three-dimensional images or film sequences based on the true geometry in individual patients. Such information is useful in order to understand the pathophysiology of injuries and degenerative diseases and will facilitate prediction of outcome and treatment.

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Sahlgrenska University Hospital (SU) provides emergency and basic care for the Göteborg region and its 1.7 million inhabitants, including highly specialized care for West Sweden. SU is also the country's centre for specialized care, with an excellent reputation in pediatrics (pediatric heart surgery, incubation for premature babies, as well as treatment in pediatric endocrinology), successful transplant procedures, treatment of cardio-vascular diseases, immunology (research into rejection mechanisms) and vaccine research. SU was founded in 1772 following a donation by Niclas Sahlgren. The current hospital was formed in 1997 by merging the three hospitals Sahlgrenska Sjukhuset, Östra Sjukhuset and Mölndals Sjukhus.
SU has been operated by the Västra Götaland Regional Council since its formation in 1999. SU is one of six teaching hospitals for medical training in Sweden. The hospital provides the infrastructure necessary for teaching and research in cooperation with the Sahlgrenska Academy at Göteborg University.