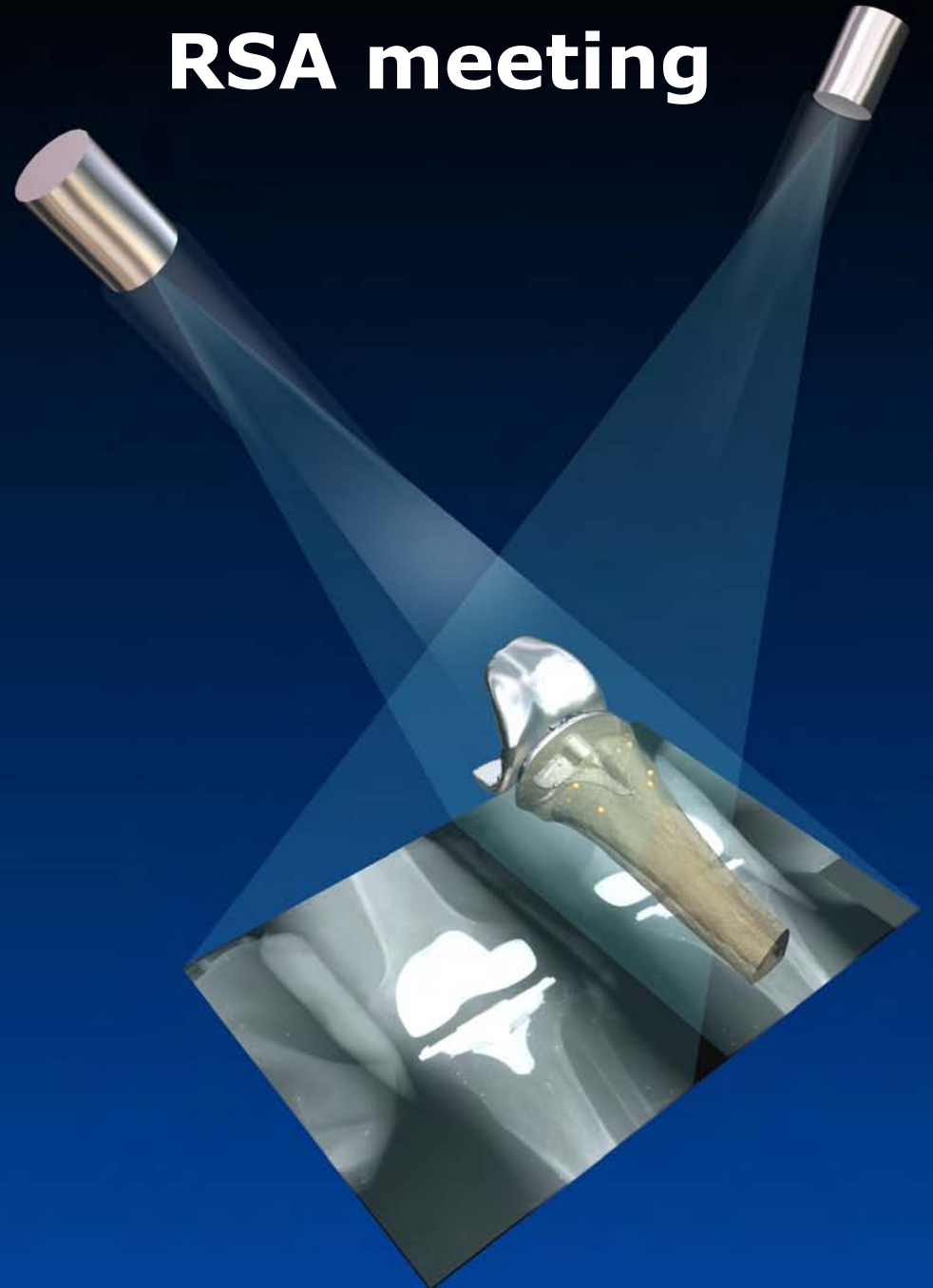


# Second International RSA meeting



LEIDEN UNIVERSITY MEDICAL CENTER

**April 6-8 2011, Leiden, The Netherlands**

## *Welcome to Leiden*

Situated at what has traditionally been an important junction where waterways and roads cross stands a city that will enchant you: Leiden. The city is famous for its almshouses, university, museums and glorious history. The spirit of the Golden Age lives on here, a place where Rembrandt was born and inspired so many other influential painters. But even after this era Leiden continued to attract scientists, artists and industry. The canals, the historical buildings, the alleyways, the treasuries of knowledge, culture and science: Leiden.

We have organised a meeting that combines the state-of-the-art of radiostereometry and the historic atmosphere of Leiden. The programme promises to give you a broad overview of RSA, but will also give you the opportunity to experience the city. The meeting will be held in the historic center of the university, the Academy Building (1581). If the weather is good we will have a canal tour, and dinner will take place at the “Oranjerie” the central building of the Hortus Botanicus which was established in the year 1740.

In the scientific programme, there are several long-term follow-up studies showing the predictive value of RSA for future loosening. There will be a number of basic science studies showing the potential of RSA when used in new fields such as high speed dynamic analyses. But we also have a vast number of papers focussing on early clinical trials of new prosthesis designs. In addition, there is enough room in the programme to network and socialise with your colleagues and partners.

We are looking forward to a fruitful and interesting meeting that might be an historic event in itself!



## *Venue: Academy Building*

Leiden was given its University in 1575. It was located in the chapel of the former Dominican convent on the Rapenburg. The nuns had left the convent after the Reformation, and the building was empty. An extra storey was added to the chapel by creating a new floor, as can be seen from the tall windows which are interrupted halfway. The Academy Building is still in use by the University for lectures and official occasions, such as graduations and doctoral defences. And it is an excellent location for an international conference...



## *Dinner: Hortus Botanicus*

The Hortus Botanicus Leiden, which was founded in 1590, is the oldest botanical garden in the Netherlands and located in the historical centre of Leiden. Behind the academy building of the Leiden University you will discover a green oasis with a large collection of plants native to Southeast and East Asia, Southern Europe and South Africa. The Hortus is a haven within the city centre, a historical monument and a meeting place full of character.



People come here to relax, enjoy the seasons or to learn more about the diversity of the plant kingdom. And it is a perfect spot for having dinner...

## *Detailed Programme*

### *Programme Summary*

<b>April 5</b>	<b>RSA Course (extra)</b>	<b>10.30 – 18.00</b>
Tuesday	Medis Headquarters	
<b>April 6</b>	<b>RSA Course</b>	<b>10.30 - 18.00</b>
Wednesday	Medis Headquarters	
<b>April 6</b>	<b>Welcome Drinks</b>	<b>18.00 - 20.00</b>
Wednesday	Faculty Club, Academy Building	
<b>April 7</b>	<b>Day 1 of meeting</b>	<b>08.00 - 17.00</b>
Thursday	Klein Auditorium, Academy Building	
<b>April 7</b>	<b>Canal Boat Tour</b>	<b>17.30 – 19.00</b>
Thursday	Embark in front of Academy Building	
<b>April 7</b>	<b>Conference Dinner</b>	<b>19.00 – 21.30</b>
Thursday	Oranjerie, Hortus Botanicus	
<b>April 8</b>	<b>Day 2 of meeting</b>	<b>08.30 - 18.00</b>
Friday	“Klein Auditorium”, Academy Building	

### **April 6**

**10.30 - 18.00** **RSA course (separate registration via [www.rsaresearch.org](http://www.rsaresearch.org))**

**18.00 - 20.00** **Welcome drinks at Academieggebouw**

### **April 7**

**08.00 - 08.50** **Registration with Coffee**

**08.50 - 09.00** **Welcome**

*Edward Valstar and Rob Nelissen*

*Leiden University Medical Center, The Netherlands*

**09.00 - 09.30** **Opening Keynote: 35 years of RSA (20 min + 10 min discussion)**

*Johan Kärrholm*

*Sahlgren Hospital, Gothenburg, Sweden*

**09.30 - 10.30** **The knee (8 min + 4 min discussion)**

Chair: Johan Kärrholm, Rob Nelissen

**1** Correlations between implant-to-bone fixation and tibial component alignment in unicompartmental knee arthroplasty. A radiographic and radiostereometric study

*Paolo Barbadoro, Francesco Cenni, Andrea Ensini, Alberto Leardini, Claudio Belvedere, Alessandro Feliciangeli, Sandro Giannini*  
*Movement Analysis Laboratory, Istituto Ortopedico Rizzoli, Bologna, Italy*

**2** RSA Evaluation of an Implant System for Above the Knee Amputee Patients

*Audrey Nebergall, Charles Bragdon, Anne Antonellis, Johan Kärrholm, Rickard Branemark, Orjan Berlin, Henrik Malchau*  
*Harris Orthopaedic Laboratory, Massachusetts General Hospital, Boston, MA, USA*

**3** Cemented versus press-fit placed stems in revision total knee replacement: an RCT using model-based RSA

*Petra Heesterbeek, Ate Wymenga, Gijs van Hellemond*  
*Sint Maartenskliniek, Nijmegen, The Netherlands*

**4** Tibial Bone Density is Associated with Total Knee Implant Migration

*David Konadu, Janie Astephen Wilson, Michael Dunbar, Elise Laende, Allan Hennigar, Michael Gross*

Capital District Health Authority and Dalhousie University, Halifax, Canada

- 5 Patient characteristics and preliminary migration results of hydroxyapatite-coated uncemented tibial components in a multi-center RSA study  
*Michael Dunbar, Glen Richardson, Dermot Collopy, Elise Laende, Allan Hennigar*

Capital District Health Authority and Dalhousie University, Halifax, Canada

10.30 - 11.00 **Coffee break**

11.00 - 11.30 **RSA as a clinical assessment tool  
(2 times 12 min + 6 min discussion at end)**

- 1 North-American perspective

*Michael Dunbar*

Dalhousie University & the QEII Health Sciences Centre, Halifax, Canada

- 2 **European perspective**

*Maiken Stilling*

Aarhus University Hospital, Denmark

11.30 - 12.30 **Wear assessment (8 min + 4 min discussion)**

Chair: Charles Bragdon, Bart Kaptein

- 1 RSA Wear Analysis of Oxinium and CoCr Heads Against XLPE and Conventional Polyethylene in THR: A Randomized Controlled Trial  
*Richard W. McCalden, Steven J. MacDonald, Xunhua Yuan, Robert B. Bourne, Douglas D.R. Naudie, David W. Holdsworth, Matthew G. Teeter*  
London Health Sciences Centre, London, Ontario, Canada

- 2 Estimating in vivo wear in hard-on-hard hip bearings using stem-referenced point-transfer

*Per-Erik Johanson, Michael Eriksson, Johan Kärrholm*

Sahlgren University Hospital, Gothenburg, Sweden

- 3 Multi-center RSA Evaluation of In Vivo Wear of Vitamin E Stabilized Highly Cross-linked Polyethylene

*Meridith Greene, Charles Bragdon, Young-Min Kwon, Andrew Freiberg, Harry Rubash, Søren Overgaard, Annie Gam-Pedersen, Henrik Malchau*

Massachusetts General Hospital, Boston, USA

- 4 The Robustness and Accuracy of an in vivo Linear Wear Measurement for Knee Prostheses based on Model-Based RSA

*Emiel van IJsseldijk, Edward Valstar, Berend Stoel, Rob Nelissen, Bart Kaptein*  
LUMC, Leiden, The Netherlands

- 5 How Do CAD Models Compare to Reverse Engineered Polyethylene Components for Use in Wear Analysis?

*Matthew G. Teeter, Douglas D.R. Naudie, Robert B. Bourne, David W. Holdsworth*

London Health Sciences Centre, London, Ontario, Canada

12.30 - 14.00 **Lunch**

14.00- 14.30 **RSA from implant manufacturer's perspective  
(2 times 12 min + 6 min discussion at end)**

- 1 Stryker's perspective

*Eric Garling*

Stryker Europe, Duisburg, Germany

- 2 Biomet's perspective

*Hans van den Berg*

Biomet Europe, Dordrecht, The Netherlands

14.30 - 15.30 **Basic science and validation (8 min + 4 min discussion)**

Chair: Richie Gill, Eric Garling

- 1 In-vitro validation of the Adora RSA direct digital X-ray system

*Martin Richard Downing, George Patrick Ashcroft*

University of Aberdeen, Scotland, UK

- 2 Is a single RE model sufficient for accurately measuring implant migration? An experimental and clinical evaluation

*Frank Seehaus, Andreas Sukau, Bart Kaptein, Gabriela von Lewinski, Thilo Flörkemeier, Henning Windhagen, Christof Hurschler*

Hannover Medical School, Hannover, Germany

- 3 Validation of model-based RSA and the effect of implant orientation with Unicompartmental Knee Replacement

*BJL Kendrick, JS Weston-Simons, BL Kaptein, DW Murray, AJ Price, HS Gill*

- 4 Model-Based RSA of coated hip stems: which contour fits best?  
*Andreas Sukau, Frank Seehaus, Bart L. Kaptein, Gabriela von Lewinski, Thilo Flörkemeier, Christof Hurschler*  
*Hannover Medical School, Hannover, Germany*

- 5 Marker instability in long-term follow-up studies  
*Bart Kaptein, Bart Pijls, Marc Nieuwenhuijse, Edward Valstar, Rob Nelissen*  
*LUMC, Leiden, The Netherlands*

15.30 - 16.00 **Coffee break**

16.00 - 17.00 **Long-term follow-up (8 min + 4 min discussion)**

Chair: Michiel Mulier, Edward Valstar

- 1 Fixation of a Trabecular Metal Knee Arthroplasty Component: Five Year Results of a Prospective Randomized Study  
*David Wilson, Michael Dunbar, Allan Hennigar, Glen Richardson*  
*Dalhousie University & the QEII Health Sciences Centre, Halifax, Canada*
- 2 Migration of Souter Strathclyde elbow prosthesis: 10-year follow up  
*Joris van der Lugt, Edward Valstar, Sietske Witvoet-Braam, Rob Nelissen*  
*LUMC, Leiden, The Netherlands*
- 3 Long term migration is different in HA coated, uncoated and cemented total knee arthroplasty  
*Bart Pijls, Edward Valstar, Bart Kaptein, Martha Fiocco, Rob Nelissen*  
*LUMC, Leiden, The Netherlands*
- 4 The importance of adequate stem anteversion for rotational stability in THA. An RSA-study with 10 years follow up.  
*Sverrir Kiernan, Kirstine Hermann, Leif Ryd, Gunnar Flivik*  
*University Hospital, Lund, Sweden*
- 5 Short term excessive migration associated with long term failure of the all-polyethylene acetabular component of the Exeter total hip arthroplasty: 10 to 12 year follow-up  
*Marc Nieuwenhuijse, Edward Valstar, Bart Kaptein, Rob Nelissen*  
*LUMC, Leiden, The Netherlands*

17.30 - 19.00 **Canal tour of Leiden**

19.30 - **Conference dinner**

**April 8**

08.30-09.00 **Coffee**

09.00-09.30 **Keynote: The role of RSA for rapid implant assessment (20 min + 10 min discussion)**

*Leif Ryd*

*Karolinska University Hospital, Stockholm, Sweden*

09.30-10.30 **New applications (8 min + 4 min discussion)**

Chair: Christof Hurschler, Leif Ryd

- 1 Radiostereometric analysis: method validation for evaluation of sternal instability in a phantom  
*Rikke Falsig Vestergaard, John Michael Hasenkam, Kjeld Søballe, Maiken Stilling*  
*Aarhus University Hospital, Denmark*
- 2 Evaluation of One-Level Lumbar Fusions with Pedicle Screw Instrumentation and the Trabecular Metal Intervertebral Cage Using Radiostereometric Analysis  
*Elise Laende, William Oxner, Leanna MacLean, James Edwards, Allan Hennigar, Michael Dunbar*  
*Capital District Health Authority & Dalhousie University, Halifax, Canada*
- 3 Optimizing RSA for spinal fusion assessment  
*Richard van der Put, Andreas Burger, Hadi Boustani, Antonius Rohlmann, Allan Hennigar, Michael Dunbar*  
*Halifax Biomedical Inc, Mabou, Canada*
- 4 Component Stability in Primary Total Shoulder Arthroplasty: a Radiostereometric Analysis  
*Chris Lenarz, Meredith Greene, Yousef Shishani, JP Wanner, Charles Bragdon, Henrik Malchau, Reuben Gobezie*  
*Massachusetts General Hospital, Boston, USA*

- 5 Longitudinal Migration and Inducible Displacement of a Mobile Bearing Total Ankle Arthroplasty System  
*Mark Glazebrook, Jason Fong, David Wilson, Allan Hennigar, Patricia Francis, Michael Dunbar*  
*Dalhousie University & the QEII Health Sciences Centre, Halifax, Canada*
- 10.30 - 11.00 **Coffee break**
- 11.00 - 11.30 **Keynote: Towards an evidence based clinical introduction in TKA (20 min + 10 min discussion)**  
*Bart Pijls*  
*LUMC, Leiden, The Netherlands*
- 11.30 - 12.30 **Dynamic RSA and fluoroscopy (8 min + 4 min discussion)**  
Chair: Allan Hennigar, Bart Kaptein
- 1 Linking fluoroscopy to RSA: clinical evaluation of the ROCC and Triathlon total knee prostheses  
*Nienke Wolterbeek, Eric Garling, Rob Nelissen, Edward Valstar*  
*LUMC, Leiden, The Netherlands*
- 2 Rotational instability following tibia plateau levelling osteotomy in the canine cranial cruciate ligament deficient stifle: first in-vivo results.  
*Peter Böttcher, Janna Rey, Gerhard Oechtering*  
*University of Leipzig, Germany*
- 3 Fluoroscopy-based motion analysis of the replaced joint in total ankle replacement  
*Francesco Cenni, Alberto Leardini, Claudio Belvedere, Matteo Romagnoli, Maria Teresa Miscione, Sandro Giannini*  
*Movement Analysis Laboratory, Istituto Ortopedico Rizzoli, Bologna, Italy*
- 4 A Study on Validation of a New Digital roentgen Stereophotogrammetric Analysis Technique for Measuring Three-Dimensional, In Vivo Joint Kinematics  
*Jinwu Wang, Guangshan Liao, You Wang, Zhenan Zhu, Kerong Dai*  
*Jiao Tong University, Sjanghai, China*
- 5 Semi-automatic segmentation method for dynamic roentgen fluoroscopic stereophotogrammetric analysis  
*Arnaud Barré, Jean-Philippe Thiran, Nicolas Theumann, Brigitte Jolles-Haeberli, Kamiar Aminian*  
*Ecole Polytechnique Fédérale de Lausanne, Lausanne, Switzerland*

- 12.30 - 14.00 **Lunch (Parallel meeting of RSA network board)**
- 14.00 - 14.30 **Keynote: RSA Evaluation of THR Stems: Can it Predict Outcome? (20 min + 10 min discussion)**  
*Richie Gill*  
*Botnar Research Centre, University of Oxford, UK*
- 14.30 - 15.15 **The hip Part I (8 min + 4 min discussion)**  
Chair: Rob Nelissen, Edward Valstar
- 1 Five year migration results of four cemented femoral stem designs in a randomised trial  
*Martin Richard Downing, George Patrick Ashcroft*  
*University of Aberdeen, Scotland, UK*
- 2 Proof of concept of long term (5 year) follow up with Model Based Roentgen Stereophotogrammetric Analysis (MBRSA) of metal on metal arthroplasty of the hip.  
*Michiel Mulier, Ruben Wauthlé*  
*University Hospital, Leuven, Belgium*
- 3 Measuring joint surface proximity using a biplanar X-ray system, with application to the hip  
*Katharine Wilson, Angela Kedgley, David Wilson*  
*University of British Columbia, Vancouver, Canada*
- 15.15 - 15.30 **Short Coffee Break**
- 14.30 - 15.15 **The hip Part II (8 min + 4 min discussion)**  
Chair: Rob Nelissen, Edward Valstar
- 4 The effect of adding tobramycin to Simplex P cement on femoral stem micromotion as measured by radiostereometric analysis - A two year randomized controlled trial  
*Martin Petrak, Eric Bohm, Trevor Gascoyne, Thomas Turgeon*  
*Concordia Hip and Knee Institute, Winnipeg, Canada*
- 5 Two-year Results of an RCT Using RSA to Compare Minimally Invasive Surgery (MIS) to Standard Exposure in Primary Uncemented Ceramic Modular THA

*Michael Dunbar, **Allan Hennigar**, Elise Laende, Michael Gross, David Amirault  
Dalhousie University & the QEII Health Sciences Centre, Halifax, Canada*

- 6** Low BMD increases stem migration in cementless total hip arthroplasty  
*Hannu T Aro, Jessica J Alm, Niko Moritz, Petteri Lankinen, Tatu J Mäkinen  
Turku University Hospital, Turku, Finland*

**16.15 - 16.45**     **Panel discussion and wrapping up**

**16.45 - 18.00**     **Drinks**

**18.00-**             **Adjourn**

*Abstracts*

## *Session: The knee*

### **Correlations between implant-to-bone fixation and tibial component alignment in unicompartmental knee arthroplasty. A radiographic and radiostereometric study**

Paolo Barbadoro, Francesco Cenni, Andrea Ensini, Alberto Leardini, Claudio Belvedere, Alessandro Feliciangeli, Sandro Giannini

*Movement Analysis Laboratory, Istituto Ortopedico Rizzoli, Bologna, Italy*

The surgical keys to unicompartmental knee arthroplasty (UKA) success are: correct prosthesis component alignment, soft tissue integrity, and durable implant component fixation. After UKA, complications include arthrosis progression in the contralateral compartment, peri-prosthetic fractures, polyethylene wear and aseptic loosening. The latter can be accurately investigated by using radiostereometric analysis (RSA). Particularly, tibial component mobilization represents one of the main UKA revision causes. Tibial cut execution is another critical factor: a bone over-resection results in a high tibial fracture risk; an excessive varism of the tibial cut is related to a high compressive stresses at bone-implant interface resulting in tibial component loosening.

The aim of the present study is to investigate in UKA patients, and by RSA, about possible tibial component migration, by reporting eventual significant correlation between implant-to-bone fixation and prosthetic alignment.

Tibial component migration was measured in twenty-three patient with primary cemented UKAs with all-poly tibial component by RSA at 3, 6, 12, 24 months. Clinical/radiological evaluations were performed in order to quantify tibial component alignment, including natural and implanted slope. Varus alignment of the tibial component was found to be significantly correlated to the maximum total point motion, anterior tibial sinking, varus knee rotation, anterior and medial knee translation. Tibial component posterior slope was found to be correlated to the external rotation alignment of the tibial component.

Data suggest not to exceed 5° varus in tibial cut. Good clinical results and long-term fixation seem possible in case of correct surgical indications and by using an accurate implant technique.

### **RSA Evaluation of an Implant System for Above the Knee Amputee Patients**

Audrey Nebergall, Charles Bragdon, Anne Antonellis, Johan Kärrholm, Rickard Branemark, Orjan Berlin, Henrik Malchau

*Harris Orthopaedic Laboratory, Massachusetts General Hospital, Boston, MA, USA*

Introduction: Treatment of high, above the knee amputees is complicated by the difficulty or inability to properly use conventional socket prosthesis. This study reports on the outcome of a transdermal, femoral implant system for the treatment of these difficult cases.

Methods: Fifty one patients with high above the knee amputations were enrolled into an RSA study. RSA and plain radiographs were obtained at 6 months, 1, 2, 5, and 7 years after surgery. RSA films were analyzed using UmRSA software (RSA Biomedical, Umea, Sweden). Plain radiographs were graded for bone resorption, cancellization, cortical thinning, and trabecular streaming or buttressing in defined zones around the implant.

Results: Analysis from the UmRSA software showed that the median  $\pm$  standard error of the proximal/distal migration of the implant was  $-0.01 \pm 0.01$  mm at 1 year;  $-0.02 \pm 0.02$  mm at 2 years,  $-0.03 \pm 0.06$  at 5 years, and  $-0.02 \pm 0.05$  mm at 7 years. The median  $\pm$  standard error of the rotational movement was  $-0.09 \pm 0.16$  degrees at 1 year;  $-0.07 \pm 0.16$  degrees at 2 years;  $0.42 \pm 0.34$  degrees at 5 years; and  $0.38 \pm 0.34$  degrees at 7 years. A Mann-Whitney test showed no significant difference in the median rotations or migrations at any follow up time.

Plain radiographic grading between the Stage 1 Post-op and 2 year films showed that the greatest incidence was cancellization as it appeared in 58% of patients primarily in the medial and posterior zones; 34% of patients showed cortical thinning primarily in the anterior and lateral zones; 22% of patients showed trabecular streaming in the proximal zones.

Discussion: The OPRA system is a promising new technique for addressing the difficult prosthetic challenges faced by patients with high, above the knee amputations.



## **Cemented versus press-fit placed stems in revision total knee replacement: an RCT using model-based RSA**

Petra Heesterbeek, Ate Wymenga, Gijs van Hellemond

*Sint Maartenskliniek, Nijmegen, The Netherlands*

**INTRODUCTION** The number of revision of total knee replacements (TKR) increases annually. Because of reduced bone stock stable fixation of the implant is important. So far, there is no consensus on the fixation technique. Goal was to assess the primary stability of cemented versus press-fit placed stems.

**PATIENTS AND METHODS** In this randomised controlled trial 32 patients needing revision TKR were included and received cemented or press-fit placed stems by randomisation. Migration of the femoral and tibial implants was measured with model-based (MB-RSA). During the first 5 postoperative days the baseline RSA radiograph was obtained. Patients were followed up at 6 weeks, 3-6-12-24 months. Migration (translation and rotation) of the tibial and femoral implant in 3 dimensions was calculated at each follow-up moment compared to baseline measurement. At 6 weeks double RSA radiographs were obtained to assess the reproducibility of the measurement method.

**RESULTS** Reproducibility of the MB-RSA was excellent. Tibia translation could be calculated with at least 0.69mm accuracy, tibia rotation with at least 0.88 degrees. For the femur, posterior-anterior translation was less precise (1.11mm), as was anterior-posterior tilt (1.42°). Six month follow-up was available of 28 patients, 12 months for 17 patients. So far, no difference in migration was found between cemented and press-fit placed stems for both femoral and tibial components.

**DISCUSSION AND CONCLUSION** Model-based RSA was feasible for assessing migration of revision TKR. So far, there was no difference in primary stability at 6 and 12 months between cemented and press-fit placed stems. However, this is a very preliminary conclusion, since not all patients had completed the follow-up.

## **Tibial Bone Density is Associated with Total Knee Implant Migration**

David Konadu, Janie Astephen Wilson, Michael Dunbar, Elise Laende, Allan Hennigar, Michael Gross

*Capital District Health Authority and Dalhousie University, Halifax, Canada*

**Purpose.** Aseptic loosening of the tibial component of total knee prosthesis is a common cause of revision surgery. While micromotion at the bone-implant interface can now be accurately measured with Radiostereometric Analysis (RSA), mechanisms responsible for loosening remain poorly understood. The purpose of this study was to investigate the association between bone density in the proximal tibia and post-operative knee implant migration.

**Methods.** Fifty-one subjects who received total knee arthroplasty surgery with the Wright Medical Advance Biofoam (uncemented) implant were recruited. Bone density of seven regions of the proximal tibia (medial, lateral, anterior, posterior, and three regions below implant tip) was measured with DEXA post operatively at two, six, 12 and 24 weeks. RSA exams were also taken immediately post-operatively, and at six, 12 and 24 weeks. Correlations between bone mineral density and RSA migration were examined at 24 weeks post-operatively.

**Results.** There was no significant correlation between bone density and maximum total point motion (MTPM) of the tibial implant component. There were, however, significant correlations between the medial region under the tibial tray density and the distal ( $r^2 = 0.341$ ,  $P = 0.003$ ) and anterior ( $r^2 = 0.230$ ,  $P = 0.018$ ) translation of the implant; and between the region under the tip of the implant and lateral translation ( $r^2 = 0.176$ ,  $P = 0.042$ ).

**Conclusions.** These results support that a portion of the variability in post-operative implant migration can be attributed to the quality of the subchondral bone, which has important implications for post-operative treatment strategies to remove implant micromotion and prevent aseptic loosening.

## **Patient characteristics and preliminary migration results of hydroxyapatite-coated uncemented tibial components in a multi-center RSA study**

Michael Dunbar, Glen Richardson, Dermot Collopy, Elise Laende, Allan Hennigar

*Capital District Health Authority and Dalhousie University, Halifax, Canada*

**Purpose.** Determining the success of total knee arthroplasty in an objective manner remains a challenge for orthopaedic surgeons. Radiostereometric analysis (RSA) can measure the migration of an implant within the bone with a high degree of accuracy. The purpose of this multi-centre study is to use RSA to evaluate the fixation of uncemented tibial components with a surface coating of hydroxyapatite applied in a proprietary manner.

**Methods.** Thirty-one patients were recruited in a consecutive sample survey of patients undergoing total knee arthroplasty in Halifax, Canada (n=16) and Perth, Australia (n=15) using the same inclusion/exclusion criteria and receiving the same uncemented implants with the same surgical approach. During surgery, eight tantalum markers, one millimetre in diameter, were inserted into the proximal tibia. Using a calibration box, stereo RSA radiographs were taken post-operatively and then again at six weeks and three, six, 12 and 24 months following surgery. Health status and functional outcome measures were recorded to quantify functional status of subjects before surgery and at each follow-up interval.

**Results.** The patients recruited at the two centers were of the same age group (66±6.2 years) and weight (88±15 kg), but differed in height (Halifax: 168±9.2 cm, Perth: 178±8.3 cm; p value = 0.004), BMI (Halifax: 31±4.7 kg/m<sup>2</sup>, Perth: 27±2.9 kg/m<sup>2</sup>; p value = 0.005), and tibial component size (Halifax: mean size 4, Perth: mean size 6). The Oxford Knee functional score differed for the two centers pre-operatively (Halifax: 41±7.7, Perth: 31±7.6; p value = 0.003).

The migration results at six months, calculated as maximum total point motion (MTPM) were 0.56±0.55 mm for Halifax and 0.59±0.26 mm for Perth (p value =0.877). The clinical precision of the MTPM metric is 0.12 mm, calculated as the standard deviation of measurements made from double exams of all patients.

**Conclusions.** The initial low migrations suggest good initial fixation, but long-term monitoring of migration will continue. Multi-center recruitment is valuable for obtaining a diverse patient population and ensuring the success of an implant design across a more representative global group.

## *Session: Wear assessment*

### **RSA Wear Analysis of Oxinium and CoCr Heads Against XLPE and Conventional Polyethylene in THR: A Randomized Controlled Trial**

Richard W. M, Calden, Steven J. MacDonald, Xunhua Yuan, Robert B. Bourne, Douglas D.R. Naudie, David W. Holdsworth, Matthew G. Teeter

*London Health Sciences Centre, London, Ontario, Canada*

This study reports on the early clinical performance and wear (measured with RSA) of a randomized controlled trial (RCT) comparing Oxinium and CoCr heads on XLPE and conventional polyethylene (CPE). Forty patients were enrolled in a RCT and stratified to receive either an Oxinium (Ox) or CoCr head against either XLPE or CPE (ie 10 patients in each group). A

ll patients had otherwise identical THRs and had tantalum beads inserted in the pelvis and polyethylene for wear analysis. RSA wear analysis was performed immediately post-op, at six weeks, three and six months and then at one and two years. All patients are a minimum of four years post-op (average 4.6, range 4 – 5.8).

Total 3D femoral head penetration at two years for each group were the following: CoCrXLPE (0.068±0.029mm); OxXLPE (0.115±0.038mm); CoCrCPE (0.187±0.079mm); and OxCPE (0.242±0.088mm). Thus, OxCPE was significantly higher than OxXLPE and CoCrXLPE but not CoCrCPE (p=0.001, p>0.0001 and p=0.094!, respectively).

In other words, head penetration was higher with CPE compared to XLPE but there was no significant difference between Ox and CoCr heads. Similarly, regardless of head type (ie combining similar poly types), there was a significant difference in 3D head penetration at two years between CPE and XLPE (CPE 0.213±0.086; XLPE 0.093±0.041, p>0.0001).

The early results of this RCT, using RSA as the wear analysis tool, indicate a significant improvement in wear with XLPE compared to CPE. However, it failed to show a clear advantage to the use of Oxinium over CoCr against either polyethylene.

## Estimating in vivo wear in hard-on-hard hip bearings using stem-referenced point-transfer

Per-Erik Johanson, Michael Eriksson, Johan Kärrholm

*Sahlgren University Hospital, Gothenburg, Sweden*

Background: RSA wear analysis requires clear visibility of the articular components. This is a frequent problem in hard-on-hard bearings. We investigated indirect measure of wear by using fictive caput center positions calculated from the femoral stem position.

Method: 23 patients participating in a randomized trial received an uncemented metal-on-polyethylene (MOP, control group) hip arthroplasty (ABG-2, Stryker). The femoral stem and cup liner were marked with tantalum balls. The configuration of visible stem markers was vertically oriented with condition number 280. We measured femoral head penetration up to five years postoperatively on cup-centered films using marker based RSA and the UmRSA software (RSA Biomedical, Umea, Sweden) as reference. In addition, we also calculated the same parameters on stem-centered films using a hemispherical cup algorithm and approximating the femoral head position by performing a point-transfer procedure with the center of the cup as postoperative starting position of the head center and the femoral markers as reference segment for definition of the head center at the subsequent examinations. We also used this method to evaluate 26 hips in the study group with ceramic-on-ceramic (COC) bearings. !

Precision was estimated by double examinations.

Results: 99% precision estimate for proximal penetration in the marker-based analysis was 0.06 mm (n=15) and 0.27 mm in the point-transfer evaluation (n=30). Point-transfer proximal penetration accuracy using marker-based analysis as reference was -0.03 (SEM 0.03) mm. Five year point-transfer proximal penetration in the COC group was 0.06 (SEM 0.03) mm compared to 0.48 (SEM 0.08) mm in the MOP group (p<0.001, t-test).

Conclusion: In vivo proximal wear assessment in a ceramic-on-ceramic hip articulation can be done with reasonable precision using this method, even with seemingly inappropriate stem marker configuration.

## Multi-center RSA Evaluation of In Vivo Wear of Vitamin E Stabilized Highly Cross-linked Polyethylene

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Vitamin E doped highly cross-linked polyethylene (E1TM) was introduced as a low-wear bearing with improved mechanical properties. The purpose of this study is to evaluate the early in vivo E1TM wear and implant stability of Regenerex™ cups using Radiostereometric Analysis (RSA) and to evaluate stability of a porous titanium hemispherical acetabular cup.

Forty-six of fifty patients were recruited into a 5 year RSA study. Tantalum beads placed into the pelvis, femur, and the E1TM liner at surgery to allow for measurement of femoral head displacement and acetabular and femoral component stability. Bi-planer RSA radiographs were obtained immediately post-operatively, at 6 months, 1, 2, 3 and 5 years post-operatively.

Thirty-five patients (38 hips) were followed for 6 months, 27 patients (31 hips) for 1 year, and 13 patients (14 hips) for 2 years. At two years, median superior femoral head penetration was 0.03±0.02mm, acetabular cup migration was 0.13±0.06mm, and stem subsidence was -0.11±0.16mm.

This study provides the first in vivo wear measurement of E1TM polyethylene using the RSA method. The results of this on-going study demonstrate that the small amount of penetration into the liner during the early period, likely due to creep of the material, is low relative to that reported for non-vitamin E stabilized highly cross-linked polyethylene (0.1mm). Acetabular and femoral components were stable.

## The Robustness and Accuracy of an in vivo Linear Wear Measurement for Knee Prostheses based on Model-Based RSA

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**Introduction** Accurate in vivo measurements methods of wear in total knee arthroplasty are required to assess new implant designs. Measurements based on model-based roentgen stereophotogrammetric analysis(RSA), in which 3-dimensional reconstruction methods are used, have shown promising results, yet the robustness of this measurement is unknown. In this study, the accuracy and robustness of this measurement for clinical usage was assessed.

**Methods** The validation experiments were conducted in an RSA set up with a phantom set-up of a knee in a vertical orientation. 72 RSA images were created using different variables for knee orientations, two prosthesis types (Fixed bearing Duracon knee and fixed-bearing Triathlon knee) and accuracies of the reconstruction models. The measurement error was determined for absolute and relative MJGW measurements and the effect of knee positioning, true MJGW was determined was determined.

**Results** The measurement method overestimated the MJSW with 0.1mm on average. The precision of the method was 0.05mm ( $2 \times SD$ ) for the Duracon prosthesis and 0.10mm for the Triathlon prosthesis. A slight difference in error was found between the measurements with  $0^\circ$  and  $10^\circ$  anterior tilt. (difference = 0.08mm,  $p = 0.04$ ).

**Discussion** The accuracy and precision of 0.1mm can be achieved for linear wear measurements based on model-based RSA, which is more than adequate for the applications in clinical studies. The measurement is robust in clinical settings. Although anterior tilt seems to influence the measurement, the size of this influence is low and clinically irrelevant.

## How Do CAD Models Compare to Reverse Engineered Polyethylene Components for Use in Wear Analysis?

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To accurately quantify wear, the original geometry of the component must be estimated accurately using a reference geometry, such as a computer-aided design (CAD) model or a scan of a never-implanted component.

We sought to quantify the deviations between CAD models and unworn manufactured inserts, assess the effects of rescaling the models on the observed deviations, and determine how these deviations compared to those in other reference geometries. Five cruciate-retaining (CR) and five posterior-stabilizing (PS) Genesis II tibial inserts (Smith & Nephew, Memphis, TN) and their CAD models were obtained.

The inserts were scanned and reconstructed using micro-computed tomography. Surface deviations were quantified between the individual inserts, and between the inserts and a CAD model, a scaled CAD model, and multiple inserts averaged together. Mean articular deviations between the individual scanned CR inserts and the CAD model, scaled CAD model, and averaged geometry were  $-25.7$ ,  $-14.4$ , and  $1.4 \mu\text{m}$ , respectively.

Mean articular deviations between the individual scanned PS inserts and the CAD model, scaled CAD model, and averaged geometry were  $-36.8$ ,  $-36.1$ , and  $-0.4 \mu\text{m}$ , respectively. Baseline deviation between CR inserts was  $-10.4 \mu\text{m}$  and between PS inserts was  $9.7 \mu\text{m}$ . For wear studies, using a reference geometry constructed from multiple scanned inserts will provide a better estimation of the pre-implantation geometry than that obtained from a single insert or a CAD model.

Knowledge of the errors resulting from various reference geometries will ensure accurate quantification of wear occurring in clinically implanted devices.

## *Session: Basic science and validation*

### **In-vitro validation of the Adora RSA direct digital X-ray system**

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The Adora RSA (NRT, Denmark) is a new stereo X-ray system custom built for Radiostereometry. Images are acquired using CXDI50C digital detectors (Canon, Netherlands). Analysis software was written locally to detect both Tantalum markers and the spherical head of the hip implant, and for RSA reconstruction and kinematic analysis.

An acetabular PE cup was cemented into a Sawbone pelvis. Ten 1.0mm tantalum markers were inserted into the pelvis, four into cement, and ten 0.8mm markers into the cup into which a 28mm metal head was fixed.

The phantom was imaged repeatedly without movement, then moved in translation (up to 100 mm) and rotation (all axes, up to 45 degrees), and with full X-ray repositioning. Precision errors were calculated on the assumption of no relative movement between components.

Results are given for repositioning movement categorised as none, small (less than 25mm or 15 degrees), medium (less than 50mm or 30 degrees), and large.

For the head, the mean total point motion error was 4, 10, 14 and 24 micrometers. Mean error of segment fitting was less than 60 microns with no markers rejected from the composite segment of 24 markers.

For cup migration total translation error was 10, 16, 24, and 35 microns with rotation errors less than 0.05 degrees.

Observed errors were small, but increased significantly with movement, consistent with our detector tests which demonstrated microscopic geometric non-uniformity. X-ray exposure and tissue thickness were also identified as factors in precision.

We conclude this system has excellent precision for Radiostereometry.

### **Is a single RE model sufficient for accurately measuring implant migration? An experimental and clinical evaluation**

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One possible source for migration detection by model-based RSA presented models from reverse engineering (RE). In a clinical situation, one RE-model of a prosthetic component would be applied to all implanted prostheses of the same type and size. Aim of this study is thus to investigate sufficiency of a single RE-model of one prosthetic component for prosthesis migration.

For five short stem hip prosthesis components (Metha, Aesculap AG, Germany) the RE-models were generated. Within a phantom model set-up each short stem was examined in two protocols. Protocol one (single implant) simulated migration with one short stem in 6 DOFs under application of the original a randomized RE-model. The second protocol (single model) simulated migration for five different short stems in 2 DOFs with a randomized model. In protocol three (clinical set-up), migration of three patients (follow-up 3 month) was calculated under application of five models respectively.

Single implant analysis of the implant-specific RE-model reports a maximum bias and SD of -0.024mm (0.075) for out-of-plane translation. Using non-specific RE-models, maximum bias in out-of-plane direction is -0.038mm (0.056). Protocol two indicates a maximum bias (SD) of -0.044mm (0.054). For protocol three the SD for out-of-plane translations is 0.221mm.

In conclusion, the high accuracy of model-based RSA can be attained using representative RE-models. However, the variation in translational out-of-plane migration of clinical data was somewhat high compared to results of the phantom study. More patients must be investigated to assure that all implants may be represented by a single surface model.

## Validation of model-based RSA and the effect of implant orientation with Unicompartmental Knee Replacement

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**Introduction** Validation of model-based RSA with the Oxford Unicompartmental Knee Replacement (OUKR) is required as the components are considerably smaller, with different geometry. Out of plane, (*z*-axis), movement was identified as a potential source of inaccuracy and investigated.

**Methods** A phantom was produced, providing a rigid body with condition number < 10. A micromanipulator allowed movements along each of the three axes. Measurement of migration, using the model-based RSA system, was compared to the known applied movement.

Six gross movements within the calibration frame were performed to test repeatability (maximum total point movement, MTPM). In three axes, five macro movements of 1mm and five micro movements of 100µm were performed sequentially.

The femoral component was inverted and translations repeated.

**Results** The MTPM of the femoral component was 0.631 mm (SD 0.524 mm). Accuracies (mm) for the tibial component for micro and macro translations were *x*: -0.050 (SD 0.014), *y*: 0.021 (0.011), *z*: -0.003 (0.033) and *x*: 0.040 (0.053), *y*: 0.037 (0.015), *z*: -0.144 (0.218), respectively. Accuracies (mm) for the femoral component for micro and macro translations were *x*: -0.044 (SD: 0.038), *y*: -0.018 (0.020), *z*: -0.121 (0.110) and *x*: 0.040 (0.092), *y*: 0.018 (0.022), *z*: -0.201 (0.190), respectively

Mean pose estimation error for the correctly orientated implant was 0.221mm (SD 0.003). Mann Whitney U test showed a significant difference, ( $p < 0.001$ ), from the inverted mean implant pose estimation error (0.294mm (0.006)). Mean micro *z*-axis migration error was -0.121 (SD 0.110) for the normally positioned component and -0.176 (0.110) when inverted.

**Discussion** Model-based RSA can be used for the assessment of migration in the OUKR. Pose estimation is sensitive to implant orientation and differences also affect the accuracy of migration measurement.

## Model-Based RSA of coated hip stems: which contour fits best?

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Recent investigations have provided evidence which supports the use of model-based RSA in clinical studies for detecting implant migration. However one source of variability is the choice of the projected implant contour selected for model registration, depending on the type (different geometries, surface coatings). Aim of this study was to investigate the effect of contour reduction on the accuracy of migration results.

Implant migration was simulated in a relative motion protocol using an experimental phantom model set up. A plasma-coated short-stem femoral hip component was investigated. In a clinical setting, a single surface model would be applied to multiple patients regardless of the implant CCD-angle. For this to be possible, the contour of the most proximal part of the prosthesis needs to be excluded from registration calculations. Two contour registration protocols, differing within the proximal part of the prosthesis were thus compared in this analysis (full & reduced). The plasma-coated parts of the prostheses were completely excluded from contour selection in the reduced contour protocol. For both protocols, the neck contour was considered unavailable for registration due to geometrical differences.

Worst case bias is reported of 0.022 mm for in-plane and -0.024 mm for out-of-plane translation, and 0.315 deg for in plane and -0.075 deg for out of plane rotations. However, no significant difference was observed between both protocols.

Exclusion of projected implant regions is often inevitable for practical reasons. In the context of the present study, we have seen that contour reduction does not result in reduction of accuracy.

## Marker instability in long-term follow-up studies

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Roentgen Stereophotogrammetric Analysis (RSA) is based on measuring relative displacement of a prosthesis, with respect to the bone over time. In order to measure with sub-millimeter accuracy, about five tantalum beads are implanted in the bone during surgery, that act as reference points. It is assumed that these markers form a rigid body, allowing for measuring the migration of the prosthesis with six degrees of freedom. For this, a rigid body error (RBE) criterion has been defined, that states that the average displacement of these markers with respect to each other should be less than 0.35mm in clinical RSA studies. In this study, the rigid body assumption and the effect of the RBE criterion on the migration results in long term clinical RSA studies are investigated.

From a clinical TKA RSA study with 10 year follow-up, 20, mostly RA patients with more than 5 bone markers are selected. Markers that move more than 1 mm with respect to each other are not included in the analysis, to make sure that correct rigid body matching is performed by the Model-based RSA software. The results show that the average RBE of the bone markers increased from 0.15mm at six weeks post-op to 0.29mm at 1 year post-op. From 1 to 10 years, the average RBE remains relative constant. For some patients though, the RBE increases from 0.06mm at 3 weeks to 0.50mm at 10 years follow-up.

Although the RBE criterion is important to maintain the high accuracy of RSA, this study shows that the rigid body assumption of bone markers is not valid on a sub-millimeter scale. The results of these instable markers on the migration results of individual patients can be relatively large when the RBE criterion is strictly maintained. A solution for this problem is subject of further investigations.

## *Session: Long-term follow-up*

### **Fixation of a Trabecular Metal Knee Arthroplasty Component: Five Year Results of a Prospective Randomized Study**

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**Purpose:** To evaluate the five year Radiostereometric Analysis (RSA) results of the NexGen LPS Trabecular Metal Tibial Monoblock component (TM) and the NexGen Option Stemmed cemented component (Cemented).

**Method:** 70 patients with osteoarthritis were included in a randomized series to receive either the TM implant or the cemented NG component. RSA exams were obtained postoperatively, at six months, one year, two years and five years.

**Results:** At the five year follow-up, 43 patients were able to be reached and were willing to participate in the follow-up exam. Compared to the cemented components, the TM components had significantly higher subsidence than the cemented components ( $p=0.001$ ). There were no other significant differences.

The proportion of 'at risk' components at five years was 2 of 16 (0.11, 95% CI, 0.03-0.33) in the cemented group and was 0 of 25 (0.0, 95% CI, 0.0-0.13) in the TM group ( $p=0.17$ ).

**Conclusion:** In the two year report on this cohort of patients, we indicated our uncertainty concerning the long term stability of the TM implant due to the high initial migration seen in some cases. In this report we have seen stability of this implant out to five years and migrations in this period below the level of detection of our system in all cases. Given these results it is with increased confidence that we can state that this implant appears to achieve solid fixation despite high initial levels of migration.

## Migration of Souter Strathclyde elbow prosthesis: 10-year follow up

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Mechanical loosening which begins with early-onset migration of the prosthesis is the major reason for failure of the Souter-Strathclyde elbow replacement. In a prospective study of 18 Souter-Strathclyde replacements we evaluated the patterns of migration using roentgen stereophotogrammetric analysis. We had previously reported the short-term results after a follow-up of two years which we have now extended to a mean follow-up of 8.2 years (1 to 11.3).

Migration was assessed along the co-ordinal axes and overall micromovement was expressed as the maximum total point movement. The alignment of the prosthesis and the presence of radiolucent lines were examined on conventional standardised radiographs. All the humeral components showed increased and variable patterns of migration at the extended follow-up and four humeral components were revised.

The maximum total point movement at two years in the revised prostheses was 1.8 mm (sd 1.0) and in the non-revised 0.7 mm (sd 0.5,  $p = 0.01$ ). Most humeral components migrated into external rotation resulting in an anterior and varus tilt. The ulnar components remained stable.

## Long term migration is different in HA coated, uncoated and cemented total knee arthroplasty

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Introduction Failed or suboptimal fixation of total knee arthroplasty (TKA) causes continuous migration, subsequent loosening and eventually prosthesis revision. Contrary to early migration, the long term migration of hydroxyapatite (HA) coated tibial components in TKA remains unknown, due to uncertainty on prosthesis fixation of the HA coating. This randomized controlled trial investigates the long term migration measured by radiostereometric analysis (RSA) of HA-coated, uncoated and cemented tibial components in TKA.

Materials and Methods 68 knees were randomized to HA-coated, uncoated and cemented components. All knees have been prospectively followed for a mean 9 years (range 3 months to 16 years). RSA is used to evaluate migration at yearly intervals. Clinical and radiological evaluation was according to the Knee Society System. A generalized linear mixed model (GLMM) has been used to take into account the repeated measurement design.

Results The mean migration at 10 years is 1.66mm for HA, 2.25mm for uncoated and 0.79mm for the cemented group;  $p < 0.001$  GLMM adjusted for age, gender, diagnosis, revisions and BMI. Consequently, HA significantly reduces migration compared with the uncoated components, which is most pronounced for subsidence and external rotation. For the uncoated group there are 20% [95%CI= 2% to 38%] more revisions for loosening compared to the HA group. Accordingly, for every 5 [95%CI = 2.6 to 50] TKA implanted with HA, one revision for loosening is prevented compared to uncoated components. There are no significant differences between the fixation groups regarding clinical or radiological scores.

Conclusion In conclusion, HA significantly reduces migration of uncemented tibial components and is associated with decreased revision rate. The beneficial effect of HA endures beyond 10 years and there is no evidence for delamination of the HA layer. Cemented components showed the lowest migration throughout the follow-up. Most migration occurs in the first post-operative years emphasizing the early predictive properties for late loosening of RSA.



## The importance of adequate stem anteversion for rotational stability in THA. An RSA-study with 10 years follow up

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Progressive retroversion of the stem within the femur has been suggested to be an important initial mode of hip prosthesis failure. In 60 cemented THAs we have assessed the relationship between direct postoperative stem anteversion angle, measured with 3-D CT, and the rotational stability as measured with repeated RSA examinations during 10 years follow up. The prostheses had matt surface, collar and a rounded stem shape. The patients were divided into three groups depending on the measured anteversion angle:  $\leq 10^\circ$ ,  $11^\circ$ - $25^\circ$  and  $\geq 25^\circ$ .

At 10 years, all except one stem had rotated into retroversion. There was a strong correlation between postoperative anteversion angle and later stem rotation into retroversion. The group with  $\leq 10^\circ$  of stem anteversion rotated significantly more into retroversion, seen as early as 3 months, and continuously significant during the follow up period. At 10 years the  $\leq 10^\circ$  group had a mean retroversion of  $13,5^\circ$  compared to  $5,1^\circ$  in the  $11^\circ$ - $25^\circ$  group and  $5,2^\circ$  in the  $\geq 25^\circ$  group. The distal stem migration were accordant with significantly more subsidence at 10 years for the  $\leq 10^\circ$  group (2,4 mm compared to 0.5 and 0.4 mm respectively). Within 10 years 4 of the 13 stems in the  $\leq 10^\circ$  group have been revised because of aseptic loosening.

Our results strongly suggest that the initial rotational position of the femoral component during surgery is decisive for the degree of later retroversion, subsidence and eventual loosening. The degree of retroversion may be prosthesis design sensitive but less than  $10^\circ$  of anteversion appears deleterious.

## Short term excessive migration associated with long term failure of the all-polyethylene acetabular component of the Exeter total hip arthroplasty: 10 to 12 year follow-up

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**Background.** Reliable early evaluation of new prostheses or related developments in small patient groups is desirable before widespread introduction. In this prospective long-term clinical and Roentgen Stereophotogrammetric Analysis (RSA) follow-up study of the Exeter Total Hip Arthroplasty (THA), we test the hypothesis that early migration is related to (late) implant failure due to mechanical loosening and assess the associated diagnostic performance.

**Methods.** Thirty-nine consecutive patients (41 THAs) received a cemented Exeter stem and a cemented Exeter all-polyethylene cup and had prospective clinical and RSA follow-up. Mean length of follow-up was 9.4 years (standard deviation 3.2 years). No patients were lost to follow-up. Seventeen patients died during follow-up.

**Results.** Eleven (26.8%) acetabular components were found to be loose on conventional radiographs after a mean of 76 months (range: 12 – 140 months). During the first two postoperative years, the failed components showed markedly higher and more rapid cranial translation ( $p < 0.001$ ) and sagittal rotation (i.e. increased inclination,  $p = 0.004$ ). Both were strong risk factors for late mechanical loosening (hazard ratio: 19.9, 95%CI: 4.94 – 80.0,  $p < 0.001$  and 11.1, 95%CI: 2.83 – 43.9,  $p = 0.001$ ). For individual cases, eight of 11 failed components showed a distinctive pattern of excessive cranial migration over 1.76 mm combined with excessive sagittal rotation over  $2.53^\circ$  at two year follow-up. The diagnostic performance of both (excessive) cranial migration and (excessive) sagittal rotation for (late) mechanical loosening of the acetabular component was good (ROC-area under curve: 0.88, 95%CI: 0.74 – 1.01,  $p < 0.001$  and 0.84, 95%CI: 0.68 – 1.00,  $p = 0.001$  respectively).

**Conclusion.** Early (excessive) migration as measured by RSA has good diagnostic capabilities for detection of acetabular components at risk for future mechanical loosening and appears an appropriate method to assess performance of new implants or implant-related developments.

## *Session New applications*

### **Radiostereometric analysis: method validation for evaluation of sternal instability in a phantom**

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A major complication to open cardiac surgery is sternal instability, which can lead to much pain and discomfort for patients and may result in a prolonged hospital stay, recovery period, and increased mortality risk. The clinical diagnosis of sternal instability is determined by manual palpation. CT-imaging may be used to quantify the bony separation but bears the disadvantage of high radiation dose. We propose the use of Roentgen Stereophotogrammetric Analysis (RSA) for the evaluation of sternal instability and present a method validation in a phantom set-up.

**Material and methods:** Five sternum saw bones were subjected to a sternotomy. Eight tantalum markers were inserted in each half of the 5 sterni, and the sterni was then placed horizontally in a custom-made fixture. Stereoradiographs were made in 3 different positions (neutral +/- 15° cranio-caudal tilt) for each of 4 different set-ups, resulting in 60 stereoradiographs.

**Results:** In the sternum body mean X-translation was -0.102mm (SD=0.035), mean Y-translation was 0.380mm (SD=0.050) and the mean Z-translation was -0.874mm (SD=0.534). In the manubrium the mean X-translation was -0.144mm (SD=0.047), the mean Y-translation was 0.146mm (SD=0.066) and the mean Z-translation was -4.721mm (SD=0.624)

**Conclusion:** The clinical measure of interest is X- and Y-translations (separation and vertical displacement of the sternal halves) because if the bones are too far apart or constantly moving bone-bridging of the saw-gap cannot occur and painful and instable pseudoarthrosis will develop. This phantom study confirms that RSA is a very precise method for evaluation of the stability of sternal-osteosynthesis.

### **Evaluation of One-Level Lumbar Fusions with Pedicle Screw Instrumentation and the Trabecular Metal Intervertebral Cage Using Radiostereometric Analysis**

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**Purpose.** Determining the success of spinal fusion surgery in a manner that maximizes precision while minimizing trauma to the patient remains a significant challenge for orthopaedic surgeons. Radiostereometric analysis (RSA) can detect the presence or absence of mobility between intervertebral segments (i.e. functional stability of the fusion) with a high degree of accuracy. Currently, RSA is being carried out to determine the success of a posterior lumbar interbody fusion using Trabecular Metal™ Cages (Zimmer Spine, Minneapolis MN) augmented with pedicle screw instrumentation.

**Methods.** Eighteen patients were recruited using strict inclusion criteria and six tantalum marker beads, 0.8mm in diameter, were inserted into the two vertebrae at the fused level during surgery. Using a calibration box, stereo RSA radiographs were taken within four days post-operatively and then again at six weeks and three, six, 12 and 24 months following surgery. At each follow up after the initial post-operative exam, RSA exams were taken with patients first in a supine position and then in a sitting position to determine the movement between the fused segments at that time point.

**Results.** Using a phantom model, in vitro precision was evaluated by taking 12 repeated measures of zero displacement and calculated as the standard deviation of these repeated measurements. In vitro precision was found to be 0.02 mm, 0.02 mm, and 0.02 mm for medial, proximal, and anterior translations respectively. In vivo precision, taking into account soft tissue interference, was calculated using double RSA clinical exams and was found to be 0.16 mm, 0.13 mm, 0.22 mm for medial, proximal and anterior translations respectively.

Fusion assessment shows relative motion between the two vertebrae, with average total motion of 0.57 mm, 0.94 mm and 0.68 mm at six weeks, three months, and six months respectively when comparing supine to seated positions of patients.

**Conclusions.** RSA analysis is challenging and care should be taken to ensure proper bead placement and optimal imaging protocols; however, RSA provides a superior measurement method to conventional radiography for assessing spinal fusions.

## Optimizing RSA for spinal fusion assessment

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The assessment of spinal fusion currently lacks an imaging modality that provides conclusive results. There is potential for RSA to fill this void as evidenced in previous research. The objective of this research is to optimize the system and protocols to allow accurate assessment of spinal fusion using RSA. This study investigates several factors that may improve spinal RSA:

- Introduction of dynamic imaging up to 30 fps
- A novel RSA bead system for use in spinal applications
- Multiple bead sizes for distinguishing adjacent vertebrae
- Optimal loading protocols analyzed by finite element modeling

RSA precision of the system in dynamic mode is compared to static mode using a moving phantom at different speeds. Initial results indicate there is no significant decrease in precision using the dynamic mode. The ability to visualize beads inserted into titanium pedicle screws is investigated using a spinal phantom setup that includes simulation of soft tissue scatter. The same setup is used for determining the RSA precision for different bead sizes ranging from 0.6 mm to 1 mm. Visual inspection indicates that the embedded tantalum beads are clearly visible, provided a proper imaging angle is used. Initial precision analysis indicates no significant difference between bead sizes.

FEA of spinal fusion at the L4-L5 level is performed using a validated spinal model including implants. Different loading cases are simulated at pre-, and post-op, as well as different levels of fusion. The outcome indicates that extension in a supine position may yield optimal RSA results.

## Component Stability in Primary Total Shoulder Arthroplasty: a Radiostereometric Analysis

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**Introduction** The purpose of this study is to further quantify and characterize the migration of pegged and keeled polyethylene glenoid components and uncemented humeral components.

The use of radiostereometric analysis (RSA) has enabled accurate and precise measurement of component migrations in these prostheses.

**Materials and Methods** This is a prospective study of component migration in 24 patients receiving primary total shoulder arthroplasty between the years of 2007 and 2009 with an uncemented stem. Patients received either a keeled or a pegged cemented polyethylene glenoid component. Tantalum beads were placed intra-operatively for RSA analysis. RSA radiographs were obtained at 6 weeks, 6 months, 1 year and annually thereafter.

**Results** RSA analysis showed median total humeral component subsidence at 1 year to be  $-0.03 \pm 0.06$  mm and  $0.03 \pm 0.16$  mm at 2 years. The median 1 year translations in the pegged and keeled components were  $0.00 \pm 0.04$  mm and  $0.01 \pm 0.08$  mm, respectively and  $-0.05 \pm 0.11$  mm and  $-0.07 \pm 0.11$  mm at 2 years. The median 1 year rotations in the pegged and keeled components were  $-0.13 \pm 0.09$  and  $-0.47 \pm 0.19$  degrees, respectively and  $0.58 \pm 0.42$  and  $-0.01 \pm 0.32$  degrees at 2 years. Comparison of anatomic and non-anatomic position of the glenoid showed 1 year translation to be  $0.06 \pm 0.04$  mm and  $-0.06 \pm 0.10$  mm, respectively, and at 2 years to be  $-0.06 \pm 0.09$  mm and  $-0.11 \pm 0.16$  mm. Median rotational stability in the anatomic and non-anatomic position at 1 year was  $-0.47 \pm 0.13$  and  $-0.18 \pm 0.25$  degrees and at 2 years  $-0.07 \pm 0.36$  and  $0.18 \pm 0.39$  degrees.

**Discussion** The early results from our study indicate that uncemented humeral components and glenoid components are stable and experience little subsidence and rotation within the first two years after implantation. Additional follow-up will be necessary to understand the long-term stability of these components.

## **Longitudinal Migration and Inducible Displacement of a Mobile Bearing Total Ankle Arthroplasty System**

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**Purpose:** To assess the biomechanical stability of the talar and tibial components of the Mobility (DePuy, Warsaw IN) total ankle arthroplasty system (TAA) using longitudinal migration (LM) and inducible displacement (ID) measures.

**Method:** One surgeon implanted the Mobility TAA in 20 patients (mean (SD): age=60 (13); BMI=29 (3)). Uniplanar oblique RSA x-ray exams were taken within 2 days after surgery and at 1.5, 3, 6, 12 & 24 months. ID exams with the patient standing and fully weight-bearing on the index ankle were taken at 3, 6, 12 & 24 months. LM and ID micromotions (x, y, z, Rx, Ry, Rz, MTPM) were assessed using Model-based RSA 3.2 using pose estimation in the implant-based coordinate system. The Elementary Geometric Shapes module was used to assess the micromotion of the tibial component's spherical tip due to implant symmetry.

**Results:** Median MTPM for implant LM at 2 years was 1.23 mm (0.39-1.95 mm) for the talar component and 0.96 mm (0.17-2.28 mm) for the tibial component. Generally, for each patient and implant component the slope of the LM curves decreased over time. Both components showed initial subsidence into the bone with stabilization by 1 year. Median MTPM ID for the talar component at 1 and 2 years was 0.39 mm (0.27-1.06 mm). Almost all ID's were below the detection limit of 0.85 mm. Median MTPM ID for the tibial component at 1 and 2 years was 0.08 mm (0.03-0.19 mm) which was below the 0.22 mm detection limit.

**Conclusion:** The components subside directly into the bone in the direction of primary loading during standing or walking. For most of the patients the 2 year LM demonstrates a typical stabilization pattern seen in many RSA studies of other implants. The components showed no measurable ID.

## *Session: Dynamic RSA and fluoroscopy*

### **Linking fluoroscopy to RSA: clinical evaluation of the ROCC and Triathlon total knee prostheses**

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**Background** The mobile-bearing variant of a single-radius design is assumed to provide more freedom of motion compared to the fixed-bearing variant because the insert does not restrict the natural movements of the femoral component. This would reduce the contact stresses and wear which in turn may have a positive effect on the fixation of the prosthesis to the bone and thereby decreases the risk for loosening.

**Purpose** The aim of this prospective randomized study was to evaluate early migration of the tibial component and kinematics of a mobile-bearing and fixed-bearing total knee prosthesis of the same single-radius design.

**Methods** According to a prospective randomized protocol 20 Triathlon single-radius posterior stabilized knee prostheses were implanted (9 mobile-bearing and 11 fixed-bearing). Fluoroscopy and roentgen stereophotogrammetric analysis were performed 6 and 12 months post-operatively.

**Results** The 1 year post-operative roentgen stereophotogrammetric analysis results showed considerable early migrations in 3 mobile-bearing patients and 1 fixed-bearing patient. The range of knee flexion was the same for the mobile-bearing and fixed-bearing group. The mobile insert was following the femoral component during motion.

**Conclusion** This study showed no apparent distinction in early migration and kinematics between mobile-bearing and fixed-bearing single-radius total 55 knee prostheses. Despite the mobile insert was following the femoral component during motion, and therefore performed as intended, no kinematic advantages of the mobile-bearing total knee prosthesis were seen.

## **Rotational instability following tibia plateau levelling osteotomy in the canine cranial cruciate ligament deficient stifle: first in-vivo results**

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**Materials:** Three client owned dogs with complete or partial rupture of the cranial cruciate ligament (CrCL) in one stifle and an unaffected contra lateral stifle.

**Methods:** Following bony healing of tibia plateau levelling osteotomy 3D stifle kinematics of the treated and unaffected stifle were assessed using a biplanar fluoroscopic setup. High-speed cinematography of each stifle was performed with the dogs walking on a treadmill. Estimation of the 3D-pose of the femur and tibia based on the synchronised fluoroscopic images was done using model based 3D/2D registration based on summed edge/intensity digital reconstructed radiographs and general normalized correlation. Maya, a leading 3D animations software was used for 3D animation of the virtual stifles. Qualitative comparison of the 3D kinematics of the normal and affected stifle during the first 150 frames of stance phase was done by simple visual inspection of the 3D animations within Maya. Quantitative measurements of the relative motion of the femur in relation to the tibia using bone embedded coordinate frames is currently under way.

**Results:** Automated tracking of tibia and femur within the synchronised fluoroscopic images resulted in highly accurate 3D animations of the stifles. Despite absence of cranio-caudal instability, all TPLO stifles showed varying degree of internal/external rotational instability.

**Discussion:** Biplanar fluoroscopic cinematography allowed for the first time to investigate the in-vivo effect of TPLO in dogs with CrCL insufficiency. Despite of elimination of cranio-caudal instability, 3D kinematics of a TPLO stifle significantly differ when compared to the normal, contra lateral stifle.

## **Fluoroscopy-based motion analysis of the replaced joint in total ankle replacement**

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An innovative three-part total ankle replacement design allows complete congruence at the components throughout the flexion arc due to the compatibility between the prosthetic articular surfaces and the retained ligaments, in this replicating normal kinematics at the replaced joint. This study wants to assess whether the design claims are met in patients during activities.

Twelve patients implanted with the BOX Ankle (Finsbury-Orthopaedics, Leatherhead-Surrey, UK) were analyzed by videofluoroscopy at 6, 12 and 24 months follow-up (FU), during flexion against gravity (FaG) and double leg stance in maximum plantar- and dorsi-flexion (MaP-MaD). Reference frames for the prosthesis components were defined onto the corresponding CAD models. Three-dimensional component positions and orientations were obtained from each image by an iterative procedure which allows the best alignment (0.5 mm/1.0° accuracy) between CAD model and contour of the silhouette.

Larger flexion was observed in the replaced joints with larger anterior-posterior (AP) meniscal-to-tibial motion in MaP-MaD ( $R^2=0.38$ ,  $R^2=0.66$  and  $R^2=0.40$ , at the three FUs;  $p<0.05$ ). In FaG, the mean range of flexion was respectively 17.6°, 17.7°, and 16.2°, couple to 3.3, 3.3, and 3.2 mm AP meniscal-to-tibial translation. The inclination angle in frontal and transverse planes of the mean helical axis was  $3.7\pm 3.8^\circ$  and  $-4.7\pm 5.1^\circ$ , respectively, similarly to known values in normal ankles.

The considerable AP meniscal-to-tibial motion and its coupling with flexion, revealed natural motion is restored and maintained at the replaced joint according to the original biomechanical design. This was supported also by continuous moving path of the instantaneous helical axis.

## **Semi-automatic segmentation method for dynamic roentgen fluoroscopic stereophotogrammetric analysis**

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A new way to analyze accurately bones poses during motion is to use fluoroscopic data coupled with a roentgen stereophotogrammetric analysis (RSA).

The most time consuming work needed for a RSA study is to segment objects, select their contours on each image and fit a 3D model on them. Moreover, the time needed to perform this task dramatically increases when using dynamic fluoroscopic data, as you have to repeat it for each frame.

From our experience to analyze the knee joint kinematic during a treadmill gait task during 15s acquired at 30Hz, it takes between 3 and 10 minutes by frame using MB-RSA (Medis Specials, The Netherlands) to select the contour of the femoral and tibial component of the prosthesis and to fit their associated 3D model.

This study proposes a new semi-automatic segmentation method, made of four parallelizable steps to batch all the images before injecting them in MB-RSA to fit the 3D models. These steps are the following: 1. Edge preserving image denoising by Total Variation minimization; 2. Seed picking; 3. Contour extraction by active contour method using vector field convolution; 4. Manual wrong contour erasing.

This method reduces the user time as only steps 2 and 4 require user interactions. The mean time for each step is respectively around 7, 15, 30 seconds and 25 seconds. Using this method in a batch process, it becomes easy for the user to process each image before the launch of another batch to fit the 3D models.

## *Session: The hip*

### **Five year migration results of four cemented femoral stem designs in a randomised trial**

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While prosthesis migration is an important factor in the evaluation of implants, its significance is very much dependent on the design type studied. With a prospective randomised trial design we aimed to study the characteristic differences in migration of four cemented femoral stem designs using Radiostereometry (RSA) over 5 years.

164 patients undergoing cemented femoral hip replacement for osteoarthritis were randomised to receive either an Exeter (Howmedica Stryker), Ultima Tapered Polished Stem (TPS) (Depuy), Ultima Straight Stem (Johnson and Johnson) or Elite Plus (Depuy) stem. Each subject received the OGEE PE cemented acetabular component (Depuy). RSA examinations were performed at 1 week and 6, 12, 18, 24 and 60 months post surgery. They were analysed using the UMRSA system (RSA Biomedical AB, Umea, Sweden) and our local geometric stem measurement software.

Median linear proximal cup wear rate reduced to a minimum of 0.02-0.06mm/year in year two. Between 2 and 5 years the wear rate increased, and was significantly higher for the Elite stems ( $p < 0.05$  Kruskal Wallis) compared to TPS at 2 and 5 years.

Median Cup migration at 5 years was small, between 0.1-0.2mm and 0-0.5 degrees. It was lateral, proximal and posterior.

As expected, proximal stem migration was higher for the tapered polished designs. Differences in posterior tilt were observed within the tapered designs.

Patterns of migration are characterised by the stem design. There are some differences even between very similar designs. We will now continue to follow this group of patients to 10 years.

## **Proof of concept of long term (5 year) follow up with Model Based Roentgen Stereophotogrammetric Analysis (MBRSA) of metal on metal arthroplasty of the hip**

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In 2005 a large scale study at the university hospitals of Leuven, Belgium, was conducted in order to predict the outcome of custom made femoral implants in total hip arthroplasty using the Roentgen Stereophotogrammetric Analysis method. A total of 86 patients received a total hip replacement between September 2005 and November 2006. Now the same population was used in this research to report the outcome and migration of the acetabular component of a long term (5 year) follow up of 31 hips treated for their arthritic hip with a Pinnacle cup (Depuy, Johnson and Johnson, Warsaw, IN, USA). This acetabular implant component consists of a porous surface shell of titanium which allows for bone ongrowth, and a cobalt-chrome metal insert to form a metal-on-metal articulation with a custom made femoral component (Advanced Custom Made Implants, Leuven, Belgium).

This research was funded by the chair of Johnson and Johnson, for which prof. Mulier is holder, to support research in reconstructive hip surgery.

## **Measuring joint surface proximity using a biplanar X-ray system, with application to the hip**

Katharine Wilson, Angela Kedgley, David Wilson

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Joint surface proximity, or the distance between the articular surfaces, has implications for healthy joint mechanics. Joint space narrowing and deformities can alter the loading environment around a joint, and are commonly associated with cartilage loss and osteoarthritis. While biplanar x-ray has shown highly accurate bone-tracking capabilities in the literature, the errors that accumulate during analysis of joint surface proximity have not been quantified. The aim of this study was to quantify the accuracy of biplanar x-ray to measure joint surface proximity, and apply this system to the hip in vitro.

Accuracy of the biplanar x-ray system was tested by attaching radio-opaque beads to a phantom hip joint, and displacing the joint using a linear micrometer. Biplanar radiographs were acquired after each displacement, and bead motion was tracked using 3D motion-tracking software. The joint surfaces were segmented from a CT image and registered with the tracked bead motion. The joint surfaces could then be tracked relative to each other, and the minimum distance between the phantom femoral head and acetabulum was calculated after each displacement. A computer model of the phantom joint was used to validate the measured distances, and it was found that the biplanar x-ray system was able to track joint surfaces with accuracy up to 0.118 mm. The joint surface proximity analysis is currently being applied to the hip in vitro. Radio-opaque beads will be inserted into the femoral neck and acetabulum of a cadaver hip joint, and the joint surfaces will be tracked during cyclic loading.

## **The effect of adding tobramycin to Simplex P cement on femoral stem micromotion as measured by radiostereometric analysis - A two year randomized controlled trial**

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The performance of antibiotic-laden cement (ABLC) had been tested in vitro with no significant deterioration in mechanical properties. However, no studies have directly compared tobramycin-laden bone cement to standard bone cement in a clinical setting.

Twenty-nine patients (30 hips) were randomized to receive an Exeter (Stryker Orthopaedics) femoral stem cemented with either Simplex P (standard) or Simplex T (tobramycin-laden) cement. Follow-up occurred over 2 years with scheduled radiostereometric (RSA) examinations.

All stems migrated distally and experienced some degree of retroversion. No statistically or clinically significant differences in subsidence or retroversion of the stems were found between the Simplex T and Simplex P cement groups after 2 years. Rates of subsidence and retroversion were consistent with previous studies of Exeter stems.

The addition of tobramycin to Simplex P bone cement does not significantly affect the subsidence of the femoral stem after 2 years; however, further studies are required to confirm this finding for long-term implantation.

## **Two-year Results of an RCT Using RSA to Compare Minimally Invasive Surgery (MIS) to Standard Exposure in Primary Uncemented Ceramic Modular THA**

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Purpose: To determine if MIS for primary hip replacement surgery increases the risk of long term aseptic loosening as predicted by implant micromotion measured with radiostereometric analysis (RSA).

Method: Ninety patients undergoing primary THA for osteoarthritis (exclusion criteria: post-traumatic arthritis, rheumatoid arthritis, hip dysplasia, previous hip infection) were randomized to undergo THR surgery utilizing the standard direct lateral approach (n=45; 24 male; age=58 yrs; BMI=27) or MIS via a one-incision direct lateral approach using specific instrumentation (n=45; 23 male; age=55; BMI=29). Uncemented acetabular and femoral (ProfemurZ) components were used with ceramic on ceramic bearings. The femur was marked with 9 tantalum beads placed in the greater trochanter, lesser trochanter, and femoral shaft distal to the tip of the prosthesis. Post-operative care was standardized according to the care maps at our institution. Primary outcome measure was femoral stem MTPM (maximum total point motion) measured using Model-based RSA. Stereo supine X-rays were taken before weight bearing and 3, 6, and 12 months postoperatively. At the same time intervals Harris Hip Score, Oxford-12, WOMAC, and SF36 questionnaires were administered. Rates of infection, dislocation and revision were recorded.

Results: Nine patients were lost to follow-up (4 due to missing post-op exams; 5 did not have enough beads placed during surgery). Ten patients were revised (2 due to failure of the ceramic femoral head; 8 due to long (38.5 mm) neck fractures at 17-30 months postop). There were no differences between groups for all outcome measures. Mean MTPM at 24 months was 3.0mm (SD=2.0mm) for the MIS group and 2.9mm (SD=2.1mm) for the standard group.

Conclusion: No difference between groups at one year indicates MIS for uncemented primary THR through a direct lateral approach does not appear to negatively affect stability of the femoral stem. However, there was a high rate of femoral neck fracture in the study cohort that was not related to micromotion or treatment group that indicates a problem with the design of the titanium alloy modular femoral neck.



## Low BMD increases stem migration in cementless total hip arthroplasty

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**INTRODUCTION:** In cementless total hip replacement, osteoporosis and age-related geometric changes of the proximal femur may jeopardize the achievement of immediate press-fit stability of an anatomically shaped femoral stem.

**MATERIAL AND METHODS:** This study included 57 consecutive female patients with advanced hip osteoarthritis. Exclusion criteria included ongoing bisphosphonate/corticosteroid therapy, severe osteoporosis (T-score < -3.5) and postoperative fracture. All patients received an RSA-marked hydroxyapatite coated hip prosthesis (ABG II, Stryker Inc). RSA imaging was performed after surgery and at 3, 6, 12, and 24 months. The minimum difference in migration that could be detected with 95% power was 0.42 mm for y translation and 1.81 degrees for y rotation.

**RESULTS:** Of the thirty-nine eligible patients (mean age 64, range 41-78), twelve (31%) had normal BMD and twenty-seven (69%) low systemic preoperative BMD (osteopenia or osteoporosis). Twenty-one patients (54%) had Dorr type A and eighteen (46%) Dorr type B geometry of the proximal femur. Patients with low systemic BMD showed significantly ( $p=0.04$ ) more stem subsidence (y translation) than patients with normal BMD. Systemic BMD did not predict the degree of rotation. In logistic regression analysis, age and local preoperative BMD were risk factors for delayed translational stability (OR 1.1, 95CI% 1.0 to 1.2,  $p=0.02$ ). The canal flare index, as a parameter of age-related geometric changes, was a risk factor for delayed rotational stability (OR 3.1, 95CI% 1.1 to 8.9,  $p=0.04$ ).

**CONCLUSIONS:** Both systemic and local low BMD and age-related changes of the proximal femur are risk factors for migration and delayed stabilization of cementless femoral stems.

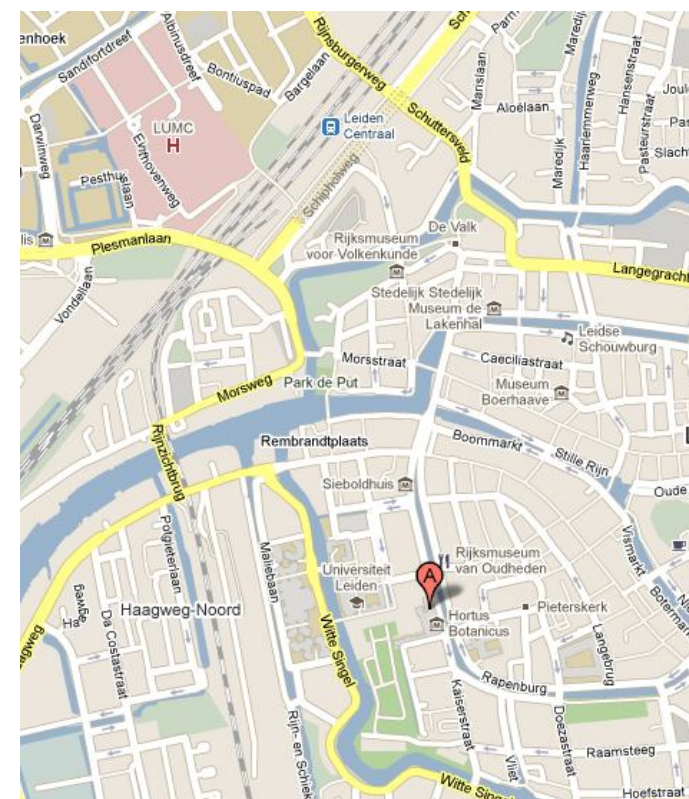
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