

RM metal-metal cup study



**St. Maartenskliniek
Nijmegen
The Netherlands**

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I. History and introduction

The titanium coated RM cup has been used in the St. Maartenskliniek for more than 20 years. Initially there was a metal on polyethylene articulation, but later ceramic on polyethylene became the standard. The results of the titanium coated RM cup have been impressive for aseptic loosening with a survival of 99% after 10.7 years follow-up¹.

With the introduction of a RM cup with metal on metal articulation, the expected reduction of wear might even improve the survival of the RM cup implant. Still, the metal –metal version (Fig.1) is a different implant and the primary stability and early migration behaviour of this cup, although expected to be equal to the all polyethylene implant, needs to be studied.



Fig.1: The RM metal-metal cup

Considering this, a study was planned by the Mathys company and the Orthoresearch department of the St. Maartenskliniek. It was decided to do a randomised controlled study in patients receiving a primary total hip arthroplasty comparing the titanium-coated metal on metal RM cup to the titanium-coated all polyethylene RM cup. Two surgeons, Dr. M.Spruit and Dr. P.W.Pavlov were involved in the study. The femoral component was the first generation CBC stem from Mathys Orthopedics.

The study set-up and protocol were planned by Mathys Orthopedics. The orthoresearch department (Dr. J.van Limbeek and P.Anderson) of the St. Maartenskliniek determined the number of patients needed for the study based on expected differences. It was decided to use the EBRA (Ein Bild Röntgen Analysis) method to measure migration of the cup implants, because the method was user friendly, accurate and less time consuming and expensive compared to RSA (RadioStereophotogrammicAssay). The duration of follow-up was determined at 2 years.

II. Patient data collection and events related to including patients

There were 67 patients included for the study, but 12 patients had to be excluded from the study for different reasons. 7 patients were dropped from the study because they received different prosthesis, 2 patients had a revision of the femoral component and 3 patients were wrongly included. Therefore the total number in the study was 55 (Table I).

Table I: patient demographics

	Metal-metal	Polyethylene-ceramic
number	31	24
Pavlov/Spruit	12/19	7/17
Left/right	11/20	13/11
Man/female	7/24	4/20
Age at OR	57.0 (SD 5.0)	57.7 (SD 6.2)
Height (m)	170.0 (SD 8.0)	169.5 (SD 7.8)
Weight (kg)	79.2 (SD 9.9)	74.8 (SD 10.4)

Remarks:

- ✚ Literature study showed that there was basically no difference in osteoporosis to be expected between men and women.
- ✚ Several patients could not be included because they needed bilateral arthroplasty during the 2 year study period.
- ✚ It was frequently hard to predict if patients could indeed have an uncemented cup, which prolonged the inclusion period and therefore the duration of the study.

III. Clinical results

The Harris Hip Scores of 55 patients are presented in Table II.

Table II: Harris Hip Scores

	Metal-metal	Polyethylene-ceramic
Preoperative score	59.9 (SD 13.8)	54.5 (SD 8.3)
12 month score	91.0 (SD 10.5)	94.3 (SD 6.8)
24 month score	92.7 (SD 13.1)	96.9 (SD 4.6)

There were no revisions in either group and there were no statistically significant differences between groups which both had excellent Harris Hip Scores. None of the patients has complained of pain or other symptoms on the last visit to the hospital.

IV. EBRA analysis

A number of patients (13) did not have complete radiographic series or for one of the following reasons the radiographs could not be used:

- ✚ The first x-ray was not compatible with the others in the series: no baseline
- ✚ No 24 month x-ray available ('no shows' in the outdoor clinic)
- ✚ Cup position and therefore cup-marker projection made x-ray not usable for measurement (Fig.2)
- ✚ X-ray of poor quality, not usable for drawing reference lines or determine center of rotation (Fig.3)
- ✚ No compatibility in a (x or y) direction between first and last measurement

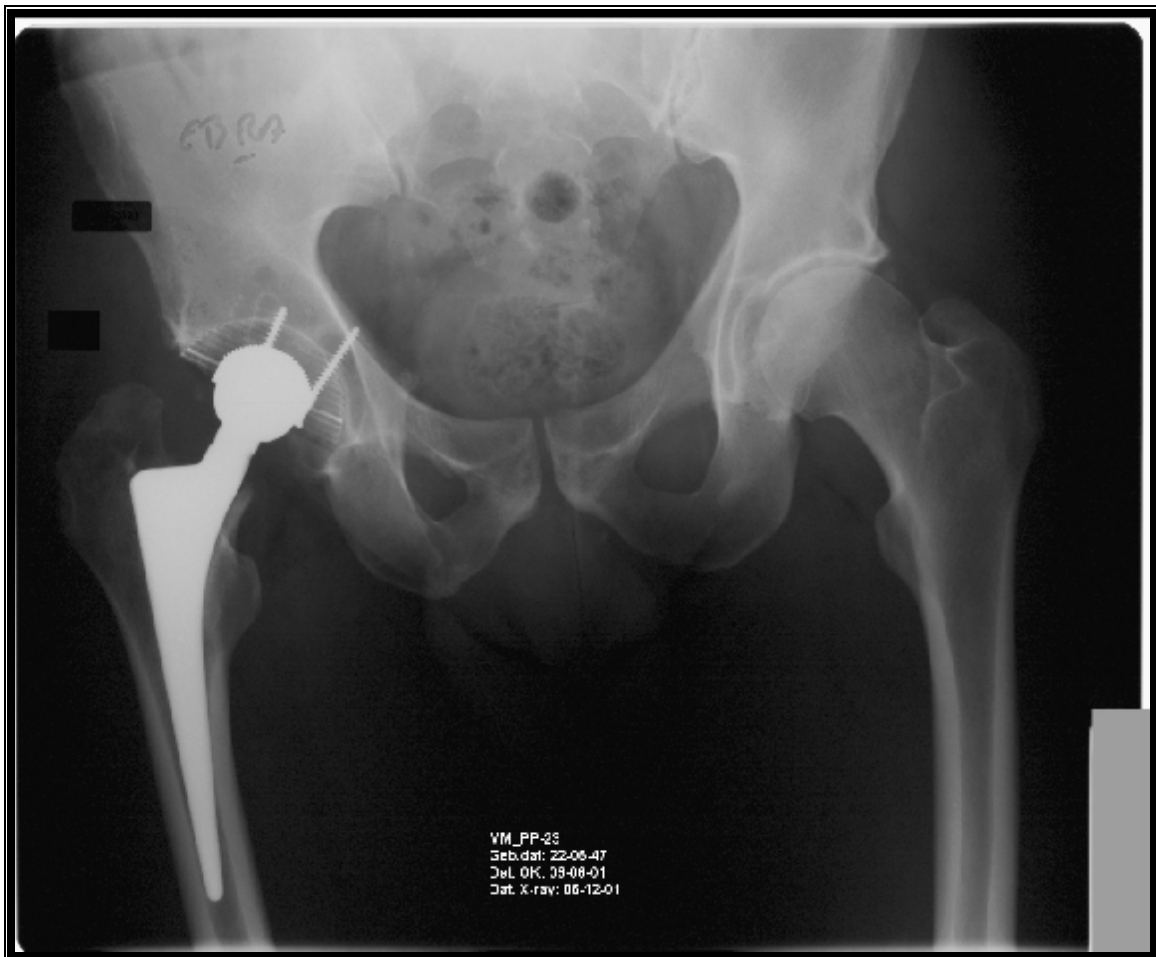


Fig.2: Metal-metal RM cup with no projected anteversion. Therefore the rim marker cannot be measured and the cup position cannot be defined.

Therefore unfortunately for only 32 patients migration measurements could be performed. Nine cups showed migration that was greater than 1.0 mm in at least one direction (Table III). With EBRA the change in anteversion can be determined. Progressive change is a confirmation that migration has occurred. Progressive change of anteversion was only seen in 5 cases.

Table III: Migration measurement values of 9 cups exceeding 1 mm in at least one direction

Study nr	Cup	x-direction (mm)	y-direction (mm)	Cup size
01	Mom Rm	1.3	1.9	52
03	Rm	1.2	1.1	52
05	Mom Rm	-1.6	0.4	56
15	Mom Rm	0.9	-1.6	50
17	Mom Rm	0.4	1.4	60
21	Mom Rm	-1.2	-2.6	50
22	RM	0.7	1.6	50
36	RM	-1.5	1.5	50
40	RM	1.2	2.9	52

These measurements show once again that there are no differences between the two groups. The number of study patients is limited and not enough to draw any conclusions. A further study of follow-up would be necessary to determine whether the slight migration values found in this study are actually clinically relevant. Considering the clinical performance with high Harris hip scores and the fact that up till now no revisions were necessary, we think they are not relevant.

V. Problems with the EBRA measurement method in general and in this study

- ✚ We did not test EBRA with respect to precision. The accuracy level found in literature is 1.0 mm migration, but the observer variability and type of implant were not taken into account. The value we chose in this study to indicate migration is the same as the lowest value that can be detected by EBRA. In retrospect we should not have chosen EBRA as the means of determining migration. Additionally, the number of patients needed to have enough power for the analysis was underestimated.
- ✚ EBRA was probably not a good choice for the metal-metal articulation. The metal cup liner may reduce the view of the rim marker on the cup (Fig.2). This was associated with a cup inclination of 10° or less and resulted in exclusion from the analysis. For similar reasons the head outline may be obscured by the metal liner in the cup (Fig.3).

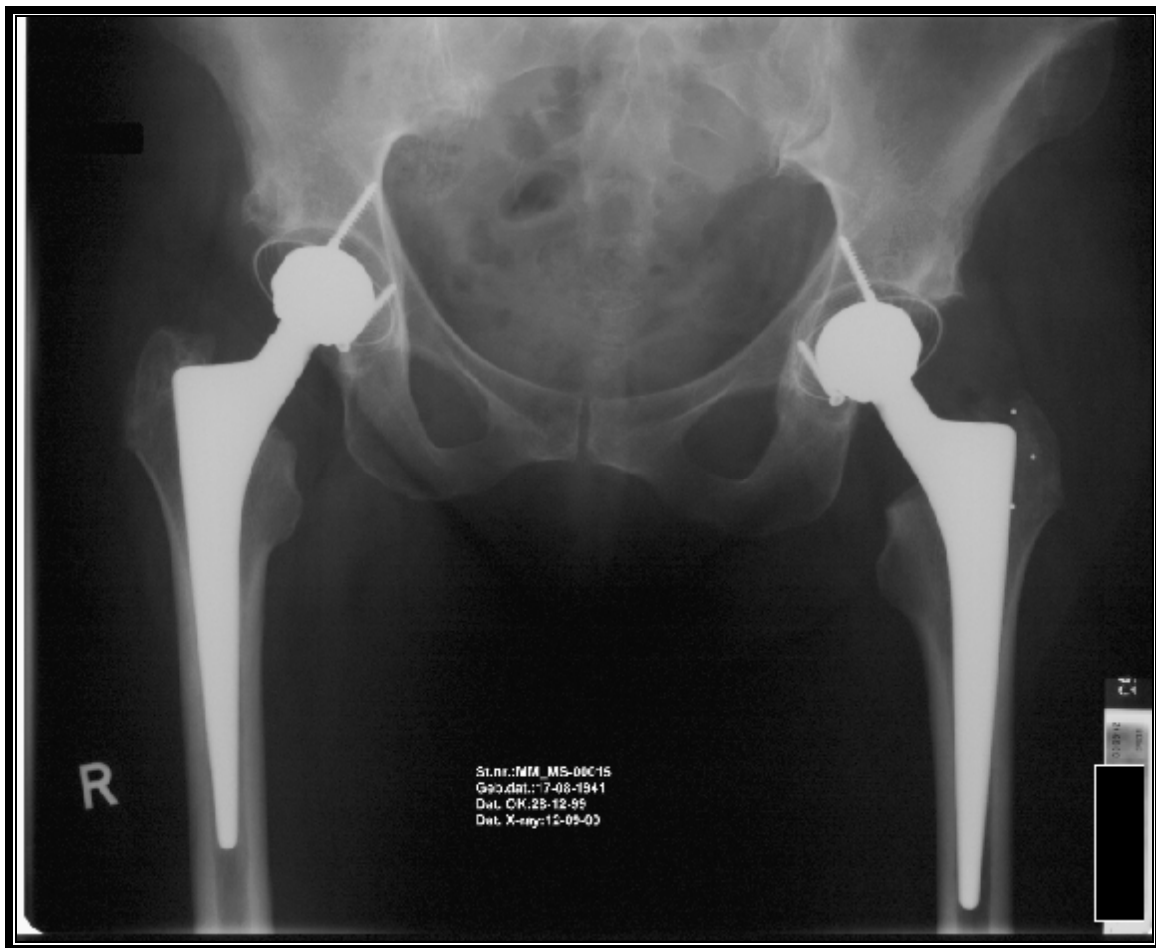


Fig.3: Head contour cannot be marked and therefore the center of rotation cannot be defined.

- ✚ In the study all x-rays needed to be scanned and this was a problem during a long period in which we could not scan because of a defect scanner. Scans made with a new scanner were not compatible with the EBRA software and had to be scanned again in another hospital. All patients had already been included in the study and therefore this was not a reason to stop the study.
- ✚ Compatibility was not 90%, but a disappointing 65-83% ^{2,3}. We were overly self-confident that this would not be a problem for us.
- ✚ EBRA makes a weighted average depending on the compatibility of each of the x-rays in the series in relation to the others. While this reduces noise from random error, it is to be expected that the method underestimates the amount of migration present ². Furthermore the values will always be dependent upon which x-rays within the series were chosen.
- ✚ There was a substantial lack of agreement between measurements obtained by the St.Maartenskliniek and researchers of Mathys Orthopedics in Bettlach. The agreement was less than 50% in 37 cases in which the same data were used, and furthermore there was limited (cases 03, 15 and 22) agreement as to which cups showed migration. For a scientific study the method does not seem to be reliable enough and the inconsistencies indicate how sensitive to interpretation this type of migration measurement is.

VI. Difficulties encountered with running the experiment

- ✚ It took much longer to include patients as fewer patients than expected met the strict criteria.
- ✚ We did not want to put patients at a disadvantage if they had to wait for surgery by one of the two surgeons.
- ✚ It was difficult to keep track of appointments that were changed.
- ✚ There were not enough checks to control forms being filled in properly.
- ✚ X-rays were lost.
- ✚ Patients needed a second operation and could not follow the normal data collection schema.

VII. Conclusions

1. The clinical performance of the RM metal-metal cup after 2 years of follow-up was reliable with no revisions and good Harris Hip Scores reported.
2. There were no clinical and radiological differences reported compared to the all polyethylene RM cup.
3. EBRA was not the appropriate migration measurement method for this study of a metal-metal articulation cup implant.
4. EBRA lacked accuracy and was not reliable or reproducible between different researchers.
5. This randomised controlled study was devaluated and frustrated because of methodological flaws and 'EBRA difficulties' encountered during the study.
6. Research assistants are key to collect data and to keep track of all patients entering a study in order to avoid missing data and to prevent incomplete study results.

VIII. References

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Epilogue

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M. Spruit, MD, PhD
Chief Orthopedics St. Maartenskliniek

Mrs. P.G. Anderson
Orthoresearch Department St. Maartenskliniek