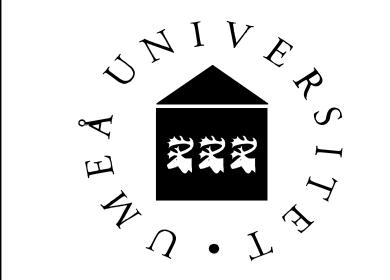


## **10 YEAR RSA FOLLOW UP OF THE SHP STEM**

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### Conclusion

The design of the SHP stem was aiming to be fully stable inside the cement mantle, but this study contradicts the theoretical calculations when examined in vivo. In our patient group however no adverse clinical effects have been shown so far, except one case of early loosening. Still we believe that the level of migration makes it necessary to continue with close follow up after 10 years.

#### Introduction

Using finite element analysis and mathematical shape optimization Scientific Hip Prosthesis -SHP (Promotion/Biomet, Fig 1a and b) was developed and introduced on the market. To examine the migration pattern of this new stem design, a prospective randomized study was initiated in 1994. Results after 2 years showed increased subsidence and retroversion. We therefore consider it important to present now the 10 year results.

#### **Materials and methods**

**40** primary total hip replacements were implanted by one of the senior authors. Patients (data in table 1) were randomized to either the **SHP** (*Fig 1 a and b*) **prosthesis group or the** control group that received a conventional cemented Lubinus SP2 (Waldemar Link) stem (Fig 2). All stems were operated using third generation cementing technique and Palacos Gentamicin cement. Both stems were provided with tantalum markers for RSA measurements.



Fig 1b. X-ray of SHP

#### Results

At the 10-year follow-up 10 patients from each group could be evaluated. Of the initial 40 patients 12 had deceased, 1 was revised and 3 didn't come. 4 cases did not meet the **RSA** quality requirements and couldn't be evaluated. **RSA:** Data was consistent with previous results, showing significant increased subsidence for the SHP group. We also found dorsal migration of the SHP stem that was significantly larger than the control.

**Clinical:** 1 patient in the SHP group was revised after 5 years due to aseptic loosening of the stem and cement fracture. All remaining patients in the SHP group reported well functioning hips. So did all patients in the SP2 group except two patients that had problems with repeated luxations and pain in one case and unexplained pain in the other. There were no revisions in the SP2 group.

	n	Mean value (signed)	<b>Median</b> (signed)	Std deviation	Mann- Whitney U-test
<b>Stem subsidence (mm)</b> Proximal (+)/Distal (-)					
SP 2	10	-0.2	-0.2	0.2	<0.0005
SHP	10	-1.0	-0.9	0.5	
<b>Femoral head translations (mm)</b> Anterior (+)/Posterior (-)					
SP 2	10	-0.2	-0.2	0.4	<0.0005
SHP	10	-2.3	-2.4	1.5	

# Fig 2. The SP2 stem

Stem migration at the 10 year follow up

	LUBINUS SP 2	SHP
Male/Female	8 / 12	8 / 12
Age	67 (52 - 78)	<b>67</b> ( <i>55</i> – <i>78</i> )
Primary/secondary arthrosis	19/1	18/2
Charnley group (1/2/3)	13/4/3	14/5/1
Weight (kg)	71 (53 – 92)	70 (48 – 100)

 Table 1: Patient data Median (Range)

Fig 1a. The SHP stem

#### Discussion

The 10 year results continue to show increased migration in the SHP group. In contrast to other designs (Exeter) the philosophy of the SHP stem is to stay fixed by its shape only. Therefore we consider the subsidence as an alarming sign. The reason for the subsidence is not clear. One can speculate that the SHP is more sensitive to the quality of the cement mantle. A suboptimal mantle would disturb the theoretical calculations based on an optimal situation, thus leading to unpredictable results. In this study it seems as the subsidence in the end doesn't stabilize the stem similar to the exeter philosophy and revision for aseptic loosening may be an impeding fate for these stems. Also concerns regarding abrasive particles and increased wear of the acetabular component must be raised. However, clinically the SHP patients still perform well after 10 years.

