

# First experience with the Fitmore® Hip Stem: clinical and radiographic results at a minimum of 22 months of follow-up

Dr. Karl Stoffel\*, Kantonsspital Graubünden, Chur, Switzerland  
Dr. Wolfram Kluge, The Yorkshire Clinic, Bradford, UK  
Prof. Christian Götze, Auguste Viktoria Klinik, Bad Oeynhausen, Germany  
Dr. Andrea Camera, Ospedale Santa Corona, Pietra Ligure, Italy

## 1 Abstract

**Introduction:** The *Fitmore*® Hip Stem is a curved, shortened, uncemented stem with a fixation philosophy that facilitates an accurate reconstruction of the individual anatomy. The aim of this study was to obtain survival and outcome data on the *Fitmore* Hip Stem by analysis of standard clinical scoring systems, radiographs, and collecting adverse event records.

**Methods:** 194 consecutive patients (7 bilateral) having received primary total hip arthroplasty at four study sites were evaluated. Mean age at time of surgery was 64 years (range 29 – 93 years). In 112 cases a minimally invasive anterolateral approach (Watson-Jones) and in 89 cases a standard approach was used (61 direct lateral (Hardinge/Bauer), 19 posterior, 9 other).

**Results:** 146 cases have reached a mean follow-up of 30 months (range 22 – 46 months) and were included in the analysis (remaining cases: 11 deceased, 3 lost-to-follow-up, 1 revised, and 40 cases with follow-up < 22months). The mean Harris Hip Score increased markedly after surgery from 51.8 (range 3 – 92) points pre-operatively to 95.1 (range 58 – 100) points at the time of last follow-up. There were five hip related complications including one stem revision due to aseptic loosening. This results in a Kaplan-Meier survival rate of 99.4% at 3 years.

**Conclusion:** The data from this study demonstrates excellent clinical and radiographic results with a very low complication rate for the *Fitmore* Hip Stem at 30 months of follow-up.

## 2 Introduction

The *Fitmore* Hip Stem is a curved, shortened, uncemented stem that allows offset adjustment independent from the stem body size. Its fixation philosophy is based upon an apposition to the calcar, supported by the three medial curvatures that closely follow the natural cortex. Primary fixation is further enhanced by a triple-tapered design and the slightly oversized Ti-VPS (titanium vacuum plasma spray) coating on the proximal part of the stem. Biomechanical testing has confirmed the excellent primary stability (rotation and migration) when comparing the *Fitmore* Hip Stem to the clinically well proven *CLS*® *Spotorno*® Stem<sup>1</sup> (Bieger et al.<sup>2</sup>). Additionally, due to the short length and the curved insertion, the stem is designed to preserve more bone both in the region of the greater trochanter as well as at the distal end.



\* Author. Current position and institution: Prof. Karl Stoffel, Fremantle Hospital (University of Western Australia), E-mail: karl.stoffel@uwa.edu.au

This report summarizes the first clinical and radiographic results of the *Fitmore* Hip Stem in a multi-center experience. Long-term data from this study will be collected to confirm the safe and effective use of the implant in primary total hip arthroplasty (THA).

### 3 Materials and Methods

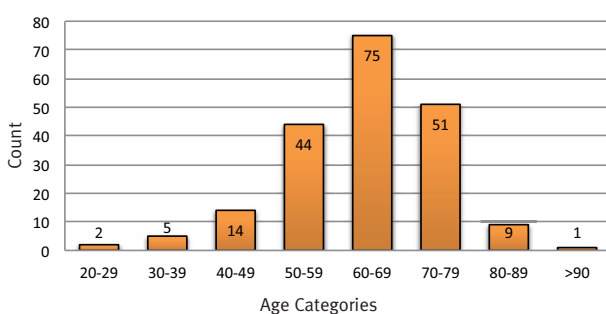
#### 3.1 Patients

In four hospitals (Kantonsspital Graubünden, Switzerland; The Yorkshire Clinic, UK; Auguste Viktoria Klinik, Germany; Ospedale Santa Corona, Italy) 201 consecutive THAs were performed on 194 patients between 28<sup>th</sup> February 2008 and 13<sup>th</sup> December 2010. At the time of this evaluation, 146 cases had reached a minimum follow-up of 22 months (mean: 30 months, range 22 – 46 months). Of the remaining 55 cases, 40 had reached a follow-up < 22 months, 11 had died, 3 were lost-to-follow-up, and 1 was revised. A summary of the patient demographic information can be found in Table 1 and Fig. 1.

**Table 1** Demographics for all THA patients

Factor	Total (N=201)	Male (N=106)	Female (N=95)
Age (yrs): Mean (SD)/Range	64.0 (11.1) / 29.2 – 93.6	62.4	65.9
Height (cm)	169.5	175.4	162.9
Weight (kg)	78.0	83.3	71.9
BMI (kg/m <sup>2</sup> ): Mean (SD)/Range	27.1 (4.3) / 17.3 - 39.7	27.2	27.0
OP-Side: Right vs. Left	93 R / 108 L	53 R / 53 L	40 R / 55 L

**Fig. 1** Age distribution.



The main diagnosis was osteoarthritis (90.5%), followed by avascular necrosis (3.0%), acute fracture (2.0%), osteonecrosis (2.0%), post-traumatic arthritis (1.0%), subluxation of the hip (0.5%), rheumatoid arthritis (0.5%) and M. Perthes (0.5%). Of the 201 THAs, a minimally invasive approach (Watson-Jones) was performed in 112 cases (55.7%) while a standard approach was used in 89 cases (44.3%: 61 direct lateral, 19 posterior, 9 other). Mean surgery time was 95 minutes (SD 36, range 35 – 220 minutes) and mean length of hospital stay was 9 days (SD 4, range 3 – 26 days).

#### 3.2 Implants

All patients received the *Fitmore* Hip Stem femoral component. This short curved stem is made from an osteophilic titanium alloy (TiAl6V4) with a rough blasted distal part and a Ti-VPS coated proximal part which has been shown to enhance bone ongrowth<sup>3</sup>. Each stem features a trapezoidal cross section and a triple taper. The *Fitmore* Hip Stem portfolio offers 4 families (A, B, B extended and C) with 3 different medial curvature designs and ‘B extended’ being the extended offset version for family B (Fig. 2A).

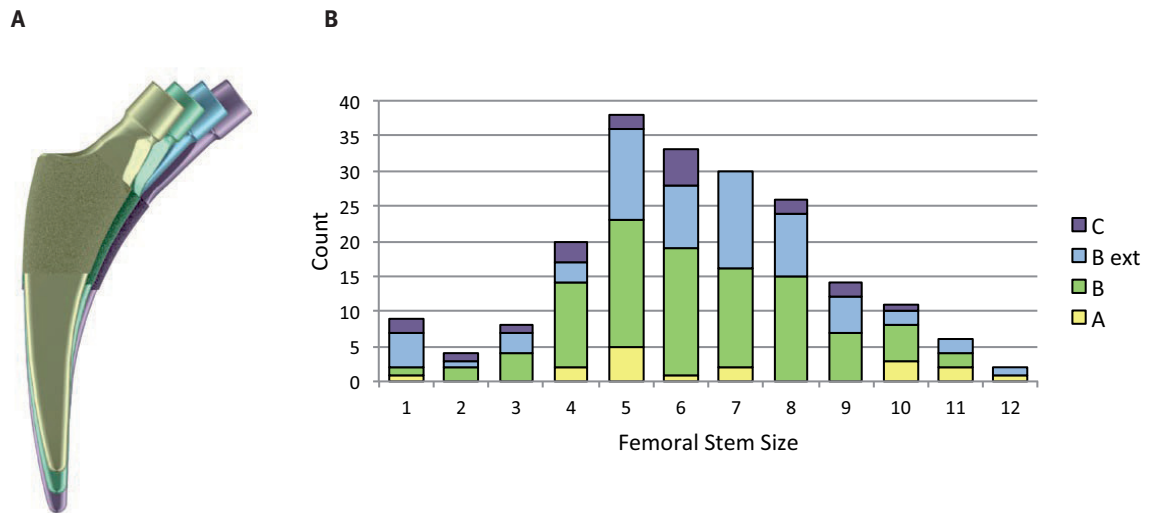
Each family consists of 14 different sizes. In this

study, mainly offset families B and B extended were used (48.8% and 33.3%, respectively). Fig. 2B shows the sizes used in this study per each family.

On the acetabular side, mainly three different acetabular cups were used (*Fitmore*<sup>®</sup> Cup, *Allofit*<sup>®</sup> Cup and *Trabecular Metal*<sup>™</sup> Modular Cup) with an articulation of metal-on-poly in the majority of cases. An overview over articulation, acetabular cup, and head size usage is shown in Fig. 3 and Table 2.

**Fig. 2**

(A) *Fitmore* Hip Stem families: A (yellow), B (green), B extended (blue) and C (violet).  
 (B) *Fitmore* Hip Stem sizes used per family.



**3.3 Analysis**

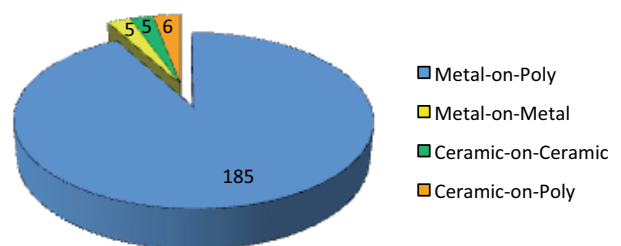
Patients were assessed pre- and post-operatively in a clinical examination which included determination of thigh pain and range of motion (degrees of flexion) as well as documentation of the Harris Hip Score (HHS)<sup>4</sup>, the Oxford Hip Score (scale 12 – 60, with 12 being the best outcome)<sup>5</sup> and the general health questionnaire EQ-5D (EuroQol, scale 0 – 1, with 1 being the highest score)<sup>6</sup>. Location of radiolucent lines (minimum 1 mm) was recorded according to the zones described by Gruen et al.<sup>7</sup> Heterotopic ossification was classified according to Brooker et al.<sup>8</sup> Subsidence was defined as vertical stem movement of more

than 5 mm according to Callaghan et al.<sup>9</sup> Additionally, cortical distal hypertrophies were evaluated at one center (Kantonsspital Graubünden). The statistical analysis was performed with IBM SPSS Statistics 20 (IBM Corp., NY) using T-test for related samples, Mann-Whitney-U-test, Pearson Chi Square and Fisher’s Exact test. All tests were 2-sided and the significance level was set as  $\alpha=0.05$ . A Kaplan-Meier survivorship analysis with corresponding 95% confidence interval was performed with end-point defined as revision for aseptic loosening of the stem.

**Table 2** Acetabular Components

<b>(A) Acetabular Cup</b>	
<i>Fitmore</i> Cup:	55.7% (112)
<i>Allofit</i> Cup:	27.8% (56)
<i>Trabecular Metal</i> Modular Cup:	11.4% (23)
<i>Durom</i> ® Cup:	2.0% (4)
Other Cups:	3.0% (6)
<b>(B) Head Size</b>	
28 mm:	1.5% (3)
32 mm:	72.6% (146)
36 mm:	23.4% (47)
40, 48 mm:	1.0% (2)
46 mm:	1.5% (3)

**Fig. 3** Articulation usage by number of cases.



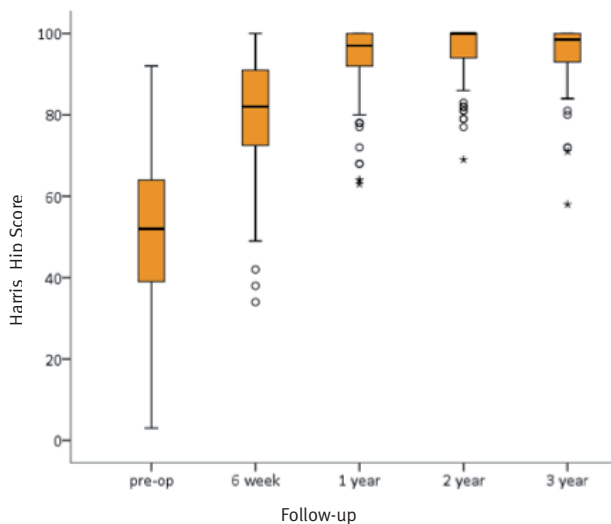
## 4 Results

### 4.1 Clinical Results

Of the 201 cases included in this study, 146 hips were clinically evaluated at an average of 30 months (range 22 – 46 months). Of the remaining 55 cases, 40 have reached a follow-up < 22 months, 11 died, 3 are lost-to-follow-up, and 1 was revised. The HHS increased significantly from 51.8 points (range 3 – 92) pre-operatively to 95.1 points (range 58 - 100) at the time of longest follow-up ( $p < 0.0001$ ). The improvement of the HHS is presented in Fig. 4. Range of motion (degree of flexion) also increased significantly from  $92.2^\circ$  (range  $30^\circ - 150^\circ$ ) pre-operatively to  $114.3^\circ$  (range  $90^\circ - 150^\circ$ ) at the time of last follow-up ( $p < 0.0001$ ).

**Fig. 4**

The median HHS: pre-operatively (N=162) and at 6 weeks (N=115), 1 year (N=154), 2 years (N=108) and 3 years (N=70) post surgery (Boxplot: ° outlier, \* extreme value).



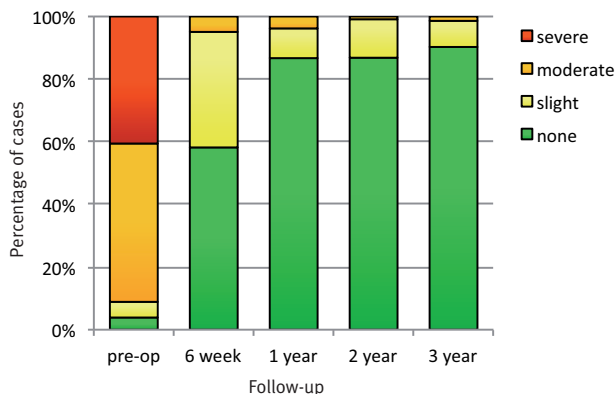
Thigh pain (as assessed by the surgeon) improved markedly with 51.4% of patients being pain-free at 6 weeks and 85.6% being pain-free (98.6% when including patients with only 'slight pain') at 3 years post surgery (Fig. 5).

The patient-completed Oxford Hip Score improved significantly ( $p < 0.0001$ ) from 40.2 points (range 22 – 58) pre-operatively to 15.4 points (range 12 – 36) at time of last follow-up. Also, the general health state as assessed by the EQ-

5D questionnaire improved significantly from a score of 0.49 (SD 0.30) pre-operatively to 0.91 (SD 0.16) at time of last follow-up ( $p < 0.0001$ ).

**Fig. 5**

Thigh pain classification: pre-operatively (N=180) and 6 weeks (N=122), 1 year (N=158), 2 years (N=114) and 3 years (N=72) post surgery.



### 4.2 Radiographic Results

Radiographic analysis of 146 hips at last follow-up (minimum 22 months) showed radiolucencies in 17 cases (mostly in Gruen zone 1 (N=8) and zone 5 (N=4, one of those additionally showed osteolysis in zone 5)). Heterotopic ossification was absent in 123 hips (84.2%), grade 1 in 10 hips (6.8%), grade 2 in 10 hips (6.8%) and grade 3 in 3 hips (2.1%). No stem showed subsidence of more than 5 mm at the time of last follow-up.

At one center, a consecutive subgroup of this study population (N=88) was analyzed in more detail at 1 year follow-up. In this cohort, the X-rays of 52.3% of patients (46/88) were found to display distal hypertrophies. Hypertrophies were mostly located in Gruen zone 3 (N=30) and in fewer cases in zone 5 (N=6) or other overlapping zones. Statistical analysis revealed that there was no significant difference between patients with or without hypertrophy in regards to demographic factors (age, gender, BMI), implant related factors (stem size, offset), and clinical outcome (HHS, thigh pain at 6 weeks or 1 year post surgery). All cases displaying radiographic hypertrophy were clinically asymptomatic.

### 4.3 Complications and Survival

In total, there were five hip related complications (2.5%), as detailed in Table 3.

At one year post surgery, there was one stem revision. Although radiographic evidence was negative for loosening, the patient described persistent thigh pain, a bone scan detected increased uptake, and aseptic loosening was eventually confirmed intra-operatively. A Kaplan-Meier survival analysis yielded 99.4% survivorship (95% confidence interval 98.4% – 100%) for revision due to aseptic loosening of the stem at 3 years (Fig. 6).

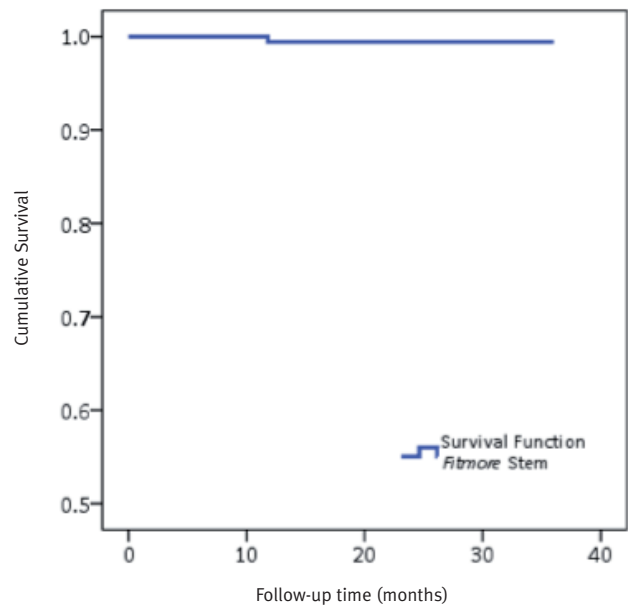
**Table 3** Reported Adverse Events

Complication	Comments / Treatment
1 posterior dislocation	Closed reduction; single event.
1 aseptic stem loosening	Revision surgery at 1 year post surgery; aseptic loosening confirmed. Revised to an uncemented stem.
1 fracture of femoral shaft	Normal post-operative X-rays, visible periprosthetic fracture Type Vancouver B2 at 6 weeks post-operatively with no trauma in the history. No secondary subsidence and no thigh pain. Conservative treatment.
1 deep infection	Early treatment by wound irrigation with debridement and IV antibiotics. Resolved.
1 nerve deficit	Post-operative sciatic nerve deficit. 85% resolved at 2 years post surgery.

## 5 Conclusion

The clinical and radiographic outcomes of the *Fitmore* Hip Stem in short-term are excellent and comparable with those published in the literature for modern uncemented stems<sup>1, 10</sup>. At a mean follow-up of 30 months more than 98% of patients were reported to be pain-free or had only slight pain. At last follow-up, the mean Harris Hip Score improved significantly from 58.1

**Fig. 6** Kaplan-Meier Survival: Stem revision (aseptic loosening).

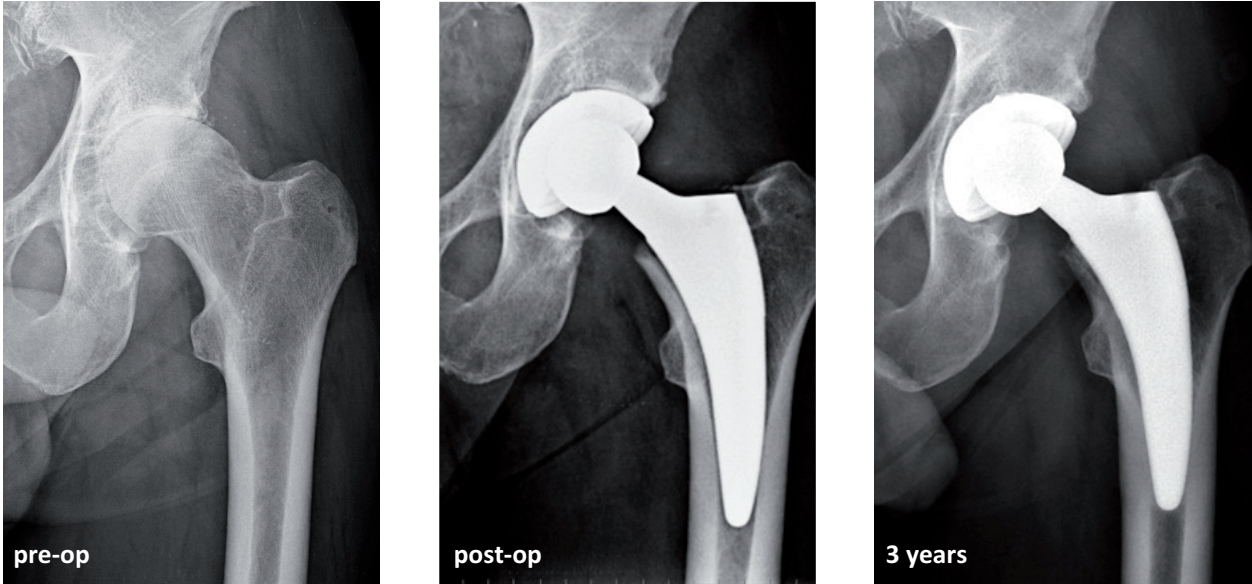


points pre-operatively to 95.1 points. There was no radiographic evidence of stem loosening or evidence of stem subsidence greater than 5 mm, and patient self assessment questionnaires supported very high patient satisfaction with everyday function. There was one reported stem revision at 1 year post surgery, where aseptic loosening was confirmed intra-operatively. The Kaplan-Meier survival analysis yielded 99.4% at 3 years.

Long-term examinations will allow more definite conclusions. However, at this stage the *Fitmore* Hip Stem can be considered a safe and effective implant (Fig. 7) with a very low complication rate and a clinical outcome comparable to other very well performing uncemented stems<sup>1</sup>.

**Fig. 7**

Outcome after surgery with the *Fitmore* Hip Stem. Pre-operative X-ray (left), immediate post-operative X-ray (middle) and 3-year post-operative X-ray (right).



## References

1. Kärrholm J., Garellick G., Rogmark C.: The Swedish National Hip Arthroplasty Register: Annual Report 2007. Sahlgrenska University Hospital 2009, Sahlgrenska.
2. Bieger R., Ignatius A., Decking R., Claes L., Reichel H., Dürselen L.: Primary stability and strain distribution of cementless hip stems as a function of implant design. *Clin Biomech (Bristol, Avon)*. 2012 Feb;27(2):158-64.
3. Bourne R.B., Rorabeck C.H., Burkart B.C., Kirk P.G.: Ingrowth Surfaces. Plasma spray coating to titanium alloy hip replacements. *Clin Orthop Relat Res*. 1994 Jan;(298):37-46.
4. Harris W.H.: Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment by mold arthroplasty. An end-result study using a new method of result evaluation. *J Bone Joint Surg Am*. 1969 Jun;51(4):737-55.
5. Dawson J., Fitzpatrick R., Carr A., Murray D.: Questionnaire on the perceptions of patients about total hip replacement. *J Bone Joint Surg Br*. 1996 Mar;78(2):185-90.
6. Hurst N.P., Kind P., Ruta D., Hunter M., Stubbings A.: Measuring health-related quality of life in rheumatoid arthritis: validity, responsiveness and reliability of Euroqol (EQ-5D). *Br J Rheumatol*. 1997 May;36(5):551-9.
7. Gruen T.A., McNiece G.M., Amstutz H.C.: „Modes of failure“ of cemented stem-type femoral components. *Clin Orthop Relat Res*. 1979 Jun;(141):17-27.
8. Brooker A.F., Bowerman J.W., Robinson R.A., Riley L.H.Jr.: Ectopic ossification following total hip replacement: Incidence and a method of classification. *J Bone Joint Surg Am*. 1973 Dec;55(8):1629-32.
9. Callaghan J.J., Salvati E.A., Pellicci P.M., Wilson P.D.Jr., Ranawat C.S.: Results of revision for mechanical failure after cemented total hip replacement. 1979 to 1982. A two to five-year follow-up. *J Bone Joint Surg Am*. 1985 Sep;67(7):1074-85.
10. Guidance on the Selection of Prostheses for Primary Total Hip Replacement. Technology Appraisal Guidance – No.2. National Institute for Clinical Excellence. Review Date April 2003. [www.nice.org.uk](http://www.nice.org.uk)

This clinical study was sponsored by Zimmer GmbH, Winterthur, Switzerland.

Lit.No. 06.02358.012 – Ed.2012-05 ZHUB



+H84406023580121/\$120501E12Z