Medacta International

M.O.R.E. Journal

SUPPLEMENT

APRIL 2016

The official Journal of the M.O.R.E. INSTITUTE

MEDACTA ORTHOPAEDIC RESEARCH AND EDUCATION

AMIStem-H ODEP study results

5 Years Preliminary Clinical Outcomes

RICHARD E. FIELD, CLAUDIO DORA, EDWARD CRAWFURD

AMIS

ANTERIOR MINIMALLY INVASIVE SURGERY
IN HIP REPLACEMENT

MORE THAN
200,000
AMIS

Leader in **Anterior Approach** Education

MEDACTA.COM

Medacta International

AMIStem-H ODEP study results

5 Years Preliminary Clinical Outcomes

RICHARD E. FIELD - South West London Elective Orthopaedic Centre, Epsom, UK
CLAUDIO DORA - Universitätsklinik Balgrist, Zürich, CH
EDWARD CRAWFURD - Northampton General Hospital, UK

INTRODUCTION

The AMIStem primary hip system (Medacta International SA, Castel San Pietro, Switzerland) is being evaluated through an ethics and research committee approved, ten-year, multi-surgeon, multi-centre, prospective, clinical and radiographic surveillance study, under normal conditions of use.
The clinical centres involved in the study are the Northampton General Hospital (UK), the Universitätsklinik Balgrist (CH) and the South West London Elective Orthopaedic Centre (UK).
The study is ongoing. We report and discuss preliminary results at a maximum of five years.

PATIENTS AND METHODS

The study was designed to comply with the UK Orthopaedic Data Evaluation Panel (ODEP) recommendations (Table 1).

Patient satisfaction is assessed using the Oxford Hip Score.
The clinical assessment of the patient is undertaken through the Harris Hip score.
The improvement in quality of life is assessed using the EuroQol-5D score.
These instruments are completed pre- and post-operatively, at defined intervals.

	Pre-op	Peri-op	Post-op	6 Mon.	1 Yrs.	2 Yrs.	3 Yrs.	5 Yrs.	7 Yrs.	10 Yrs.
Medical History	✓									
Operative Details		✓								
Harris Hip Score	✓			✓			✓	✓	✓	✓
X-rays analysis	✓		✓	✓			✓	✓	✓	✓
EQ-5D score	✓			✓	✓	✓	Annually for 10 years			
Oxford Hip Score	✓			✓	✓	✓				

Table 1. Study schedule compatible with ODEP method

From March 2010 to November 2015, a total of 421 patients were enrolled in the study.
Table 2a and 2b summarise the patient demographics.

Demographics *(421 patients)*	
Age *(years)*	M: 62.9(18-84) F: 64.2 (33-85)
BMI *(Kg/m²)*	M:28.7(17.8-40.7) F:27.3(17.3-41.4)

Table 2a. Patient demographics

Pre-operative diagnosis *(number of patients and %)*	
Osteoarthritis	394 (93.6 %)
Avascular necrosis	16 (3.8 %)
Inflammatory Arthritis	3 (0.7 %)
Rheumatoid Arthritis	1 (0.2%)
Fracture	1 (0.2%)
Unreported	6 (1.4%)

Table 2b. Patient demographics

RESULTS

From March 2010 to November 2015, 4 patients died in the follow-up, 10 patients withdrew from the study and 7 patients underwent revision surgery as showed in the table below.
Revisions per 100 observed component years is 0.52 as shown in Table 6.

Total number of patients	421
Deceased	4
Lost/ Withdrawn	10
Revised	7

Table 3. Current study population

Lost reasons *(# lost)*	
Pain-seeking second opinion	3 (0.74%)
Unable to make further consultation	1 (0.25%)
Dissatisfaction with administrative organisation of rehabilitation	1 (0.25%)
No more interested in taking part to the study	4 (0.98%)
Acetabular loosening	1 (0.25%)
Total	10 (2.46%)

Table 5. Lost reasons

Revision causes *(# revisions)*	
Aseptic loosening	4 (0.98%)
Deep infection	1 (0.25%)
Dislocation	1 (0.25%)
Undersized stem	1 (0.25%)
Total	7 (1.72%)

Table 4. Revision causes

Total observation years	1394
Revisions / 100 observation years	0.52
Revisions / 100 observation years cementless stems English NJR Registry	0.71

Table 6. Current revision rate

Table 7 shows the scores for those patients who reached each time point.

		Preop	6 months follow up	1-year follow-up	2-year follow-up	3-year follow-up	4-year follow-up	5-year follow-up
		(n=421)	(n=381)	(n=324)	(n=265)	(n=211)	(n=142)	(n=63)
CLINICAL EVALUATION	**FLEXION** *(°)*	82.74±17.29	91.28±21.94			94.64±21.71		96.38±18.66
	HHS *(0-100)*	45.62±14.06	89.89±15.38			90.95±14.20		94.29±9.68
PATIENT SELF ASSESSMENT	**EQ-5D** *(0÷1)*	0.46±0.29	0.86±0.22	0.88±0.21	0.88±0.20	0.87±0.18	0.88±0.18	0.84±0.18
	HEALTH STATE *(0÷100)*	67.10±21.52	83.31±15.52	84.19±16.40	81.78±18.57	82.71±16.72	82.49±16.06	81.07±15.95
	OXFORD *(0÷48)*	21.77±8.18	41.41±8.53	41.68±9.19	41.62±9.10	42.62±8.38	42.11±8.29	42.76±6.57

Table 7. Clinical assessment and patients reported scores

Kaplan-Meier survivorship analysis showed a cumulative survival rate at 5 years of 97.75% considering any reason for revision (Figure 1).

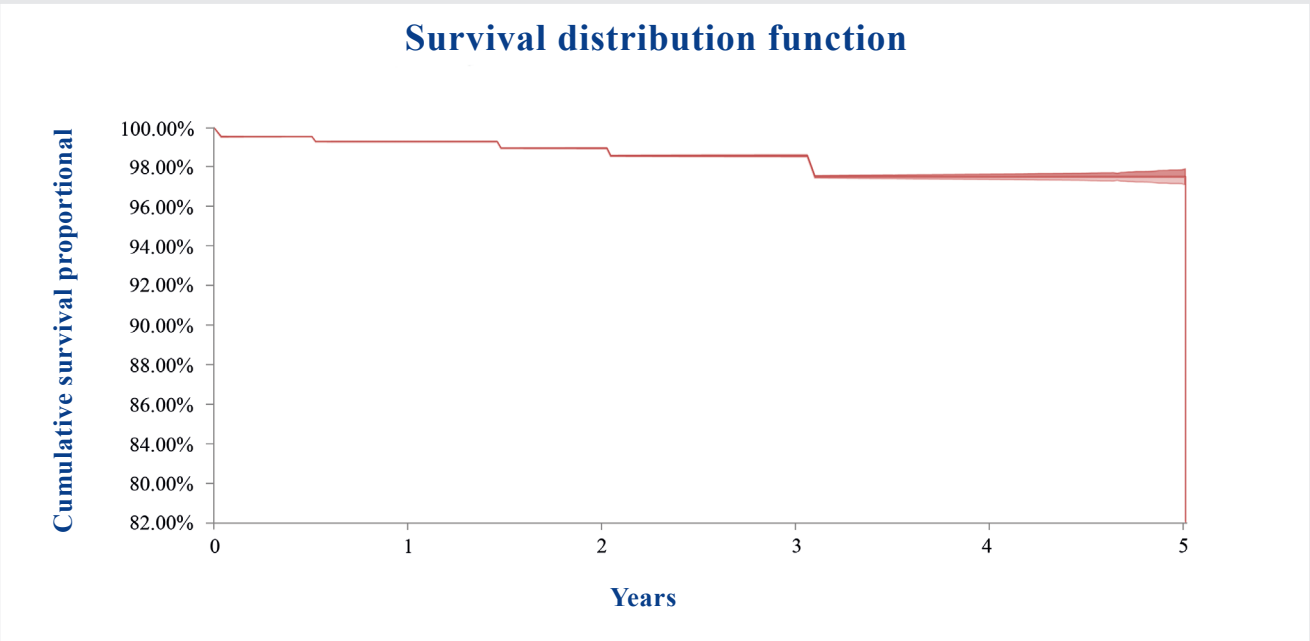

Figure 1. Kaplan-Meier analysis

Results from modified Harris hip, Oxford and EQ-5d scores, reported in Table 7, are shown graphically in the charts below.

Figure 2. Modified HHS, Oxford and EQ-5D scores

Figure 3. Box plot of modified HHS, Oxford and EQ-5D scores

DISCUSSION

The ODEP Panel have recommended that for a 10A rating, data be provided on a minimum cohort of 500 hips/knees at the start of a surveillance study (consisting of data from beyond the developing centre and from more than 3 centres/surgeons) demonstrating Kaplan - Meier survivorship data of better than or equal to 90% (showing confidence limits on the data with the lower limit of 90%) at the benchmark of ten years. A maximum of 20% loss to follow-up is permitted [1]. None of the surgeons involved in our study were involved in the design of the AMIStem femoral component. To date, we have only recruited 421 patients and only 63 of these have reached the five year time point. In consequence, any results derived from our data set are preliminary. At present our cumulative loss to follow up is 2.4% which is well within the 20% limit for final 10 year data. Our survival and outcome data is all reported with 95% confidence limits which exceeds the ODEP 90% requirement.
Our dataset provides 3-year outcome data for 50% of our study subjects (211 patients) and 5-year outcome data for 15% (63 patients). The results of the first 63 patients, at five years, remain consistent with the three-year data. Radiological analysis is not included in this report but will be provided in future updates.

In 2014 the ODEP Panel awarded the AMIStem-H a 3A* rating. This was revised to a 5A rating in March 2016. Review of PubMed and Google Scholar datasets did not identify any publications on the clinical performance of the AMIStem-H femoral component. It must be assumed that the ODEP rating has been awarded on the basis of UK National Joint Registry (NJR) data. The results of the Oxford score at 6-month and 5-year follow-ups are in line with the results published by the Annual Report (2014) of the New Zealand Joint Registry, all Total Hip Arthroplasties (including cemented stems). The average of the EQ-5D at 1-year follow-up is higher than the value from the same time-point published by the Annual Report (2013) of Swedish Hip Arthroplasty Register. The survival rate at 5 years after surgery is 97.75% with any reason for revision as endpoint. This result is comparable to the lower end of the cumulative revision rate at 5 years of all cementless stems published by the 12th Annual Report (2015) of the English NJR Registry (2,12 to 3,28% excluding metal on metal and ceramic on metal bearings).

This is the first report from the post market ODEP compliant surveillance study of the AMIStem femoral component. The only comparison, with comparable implants, that we have been able to undertake is Revisions per 100 observed component years. At present this is 0.5 for the AMIStem which compares favorably against the NJR rate for uncemented femoral components 0.71. It is known that the revision rate of uncemented femoral components exceeds that of cemented femoral components in the early years due to the higher rate of periprosthetic fractures in the former group. It is encouraging that we do not see this problem in the early data of this study.

In this study, we have observed that the clinical and patient-reported scores have reached long term levels by the six-month review; and remain consistent thereafter. The only variable that does not follow this pattern is the 5-year EQ-5D score which shows a small decline. While this was not statistically significant, it may simply reflect the increase in age of the study subject and their deteriorating general health.

The great majority of the cases were performed through the AMIS (Anterior Minimally Invasive Surgery) approach. As it is known that the principle advantages of this approach are seen in the early months after surgery. This study indicates that hip replacement using the AMIS technique provides full functional recovery by six months.

It is anticipated that study subject recruitment of the full 500 patient cohort will be completed in 2016. Over the next 10 years this surveillance study will provide robust outcome data for the AMIStem-H femoral component and identify whether it continues to perform as well as other established tried and tested uncemented implants.

CONCLUSION

ODEP studies are structured to include a diverse spectrum of study subjects and should provide results that a typical hip surgeon could expect in their normal practice. The provisional results presented in this report have been obtained from a broad spectrum of patients with degenerative hip disease, from two countries and three surgical teams. Our preliminary data indicates that the AMIStem-H, implanted using the AMIS (Anterior Minimally Invasive Surgery) approach provides a safe and reliable solution for cementless total hip arthroplasty and provides very good medium term results for implant survival and clinical outcome evaluations.

REFERENCES

1. http://www.odep.org.uk/Portals/0/Forms/ODEP_Rating_Criteria_Hips_Knees.pdf

Headquarters

Medacta International SA
Strada Regina - 6874 Castel San Pietro - Switzerland
Phone +41 91 696 60 60 - Fax +41 91 696 60 66 - info@medacta.ch

Representative

Switzerland - Frauenfeld
Gewerbestrasse 3 - 8500 Frauenfeld
Phone +41 (0) 848 423 423 - Fax +41 (0) 848 423 424 - info@medacta-swiss.ch

Subsidiaries

Australia - Medacta Australia PTY.LTD
Unit A1, 16 Mars Road - Lane Cove - NSW 2066
Phone +61 (2) 94202944 - Fax +61 (2) 94202578 - info@medacta.com.au

Belgium - Medacta Belgium B.V.B.A./S.P.R.L.
5a Rue de la Maîtrise - 1400 Nivelles
Phone +32 (0) 67 555 482 - Fax +32 (0) 67 555 483 - info@medacta.be

Canada - Medacta Canada Inc.
31 McBrine Drive, Unit 11- N2R 1J1 - Kitchener, Ontario
Phone +1 519 279 1934 - Fax +1 519 279 1938 - info@medacta.ca

China - Medacta China
Room B, 32/F, New SH Intl Tower - No. 360 Pudong South Road - Shanghai 200120, China
Phone +86 21 5835 1149 - info@medacta.cn

France - Medacta France SAS
6 Rue du Commandant d'Estienne d'Orves - Parc des Chanteraines - 92390 Villeneuve - La Garenne
Phone +33 147 39 07 22 - Fax +33 147 39 73 17 - info@medacta.fr

Germany - Medacta Ortho GmbH
Jahnstrasse 86 - D - 73037 Göppingen
Phone +49 (0) 7161 50 44 30 - Fax +49 (0) 7161 50 44 320 - info@medacta.com

Italy - Medacta Italia Srl
Via G. Stephenson, 94 - 20157 Milano
Phone +39 02 390 181 - Fax +39 02 390 00 704 - mail@medacta.it

Japan - Medacta Japan CO. LTD
Chichibuya Bldgs. 2F 3-7-4 Kojimachi, Chiyoda-ku, Tokyo 102-0083
Phone +81 (0) 3 6272 8797 - Fax +81 (0) 3 6272 8798 - info@medacta.co.jp

Spain - Medacta España SLU
Avda de las Jacarandas - 2 - Edificio CREA Oficina 631- 46100 - Burjassot
Phone +34 (0) 963 484 688 - Fax +34 (0) 963 484 688 - info@medacta.es

UK - Medacta UK Limited
16 Greenfields Business Park - Wheatfield Way - Hinckley - Leicestershire - LE10 1BB
Phone +44 (0) 1455 613026 - Fax +44 (0) 1455 611446 - info@medacta.co.uk

USA - Medacta USA, Inc.
1556 West Carroll Avenue - Chicago - IL 60607
Phone +1 312 878 2381 - Fax +1 312 546 6881 - info@medacta.us.com

Distributors

Argentina	**Austria**	**Belarus**	**Brazil**	**Bulgaria**	**Colombia**	**Greece**
Indonesia	**Ireland**	**Israel**	**Kuwait**	**Luxemburg**	**Malaysia**	**Mexico**
New Zealand	**Norway**	**Slovenia**	**South Africa**	**Vietnam**		

M.O.R.E.
INSTITUTE
MEDACTA ORTHOPAEDIC
RESEARCH AND EDUCATION

At the M.O.R.E. Institute the surgeon is never alone when discovering new technologies

Over the last 10 years, the AMIS Education Program has enabled a successful diffusion of the AMIS approach to total hip arthroplasty the world over.

MORE.MEDACTA.COM

Medacta
International

99.14astem.1CL2 rev.01