PORTLAND ORTHOPAEDICS™

Clinical Audit of Margron Primary and Revision THA Stems

Contents

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Overview

- This report is designed to comply with: Therapeutic Goods Regulations, Regulation 2000-Schedule 8
- Clinical data has been collected on all patients receiving the Margron Hip Replacement Prosthesis in the chief researcher's practice, under normal conditions of use.
- The clinical trial has been set up in 1997according to ethics committee Geneva convention requirements.
- Data collection commenced with the 1st patient implanted in 1997 ,and continues to be collected in the ongoing prospective study, data being stored in a devoted (Orthowave)Hip Survey computer programme.
- Data has been collected on 507 cases on a Case by Case basis since the 1st hip was inserted in Oct 1997, and only 2 patients have been lost to follow-up. No case has been lost from the sub series of the last 140 primary hip patients over the last 2 years.

Data Collection Parameters:

- Patient demographics, including age, weight, height, BMI (body mass index), co-morbidities, date of surgery, primary hip diagnosis.
- Pre and post-operative clinical assessment of the hip, including the SF12 (patient satisfaction score-modified), Harris Hip Score, Pain Score, ROM (range of movement) and X-rays, and over the last 2 years the WOMAC score. Results are collected at 6, 12, 24, 52 weeks post-op, and then annually / biannually in the prospective study.
- X-Ray and DEXA studies were carried out at the same time intervals on the 1st 80 patients. When it was seen that the femoral bone stock was retained on DEXA around the hip as with other prostheses reported in the literature, further patients were not recruited into the DEXA study. Results have been presented at international meetings. X-Ray studies are continued on all patients at the timelines listed above.
- Complications and Incidents are followed and statistically analyzed, and the clinical results are presented of the last 140 primary hips implanted over the previous 2 years, and also the 54 (37+17) revision hips since 1998.

Clinical Audit of Margron Primary and Revision THA Stems

HISTORY: The Margron stem and neck was 1st released in 1997, initially with 6 external diameter sizes for use as an uncemented primary prosthesis. The original system was further developed, the range being extended to include 2 reduced diameter sizes for small femora, and longer lengths of each diameter stems were added for revision and tumour surgery.

Immediate locking of the stem into the femur was measurable using a torque wrench, and when 20Nm (or more) of locking was obtained patients were initially instructed that immediate full weight bearing would be possible, using crutches. This advice has since been reduced to part weight bearing with crutches, and the instructions for use adjusted accordingly.

Several changes were then introduced in 2003:

i) Adjustment to the original design stem pilot was made to prevent possible distal femoral impingement and thigh pain. The pilot was reduced in width and length (by 3cms) see figure 1 and figure 2 below.

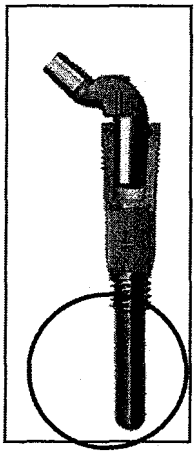


Figure 1
Original Pilot

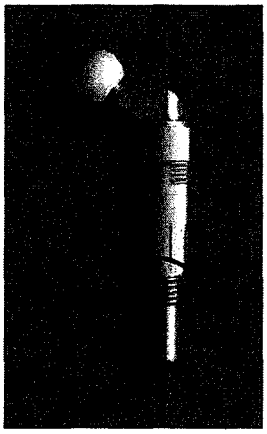


Figure 2
Modified Pilot

ii) The original modular neck profile was also reduced in both the body and taper regions, and this has increased the hip range of motion available before impingement occurs with reduced potential for dislocation. The new neck now has an extremely large range of motion in comparison to other prostheses (see figure 3 and 4 below).

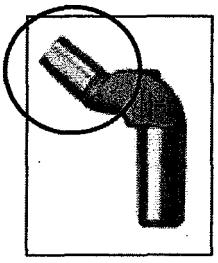


Figure 3
Original Neck

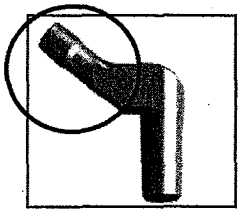


Figure 4
Modified Neck

iii) Adjustments to the operative technique were also made after analyzing the initial 5-year results, including the use of longer rather than wider prostheses stems, routine capsular closure, and emphasizing the contraindication of the system as a primary hip in patients with osteoporosis bone.

iv) In early 2004 the new generation neck range was progressively introduced, longer rather than wider stems were advised, and in the chief investigator's series, capsular closure performed on each case. A more conservative postoperative regime was advised. All long pilot stems were replaced in the field. The above has resulted in improved patients' outcome(see chief investigators series of primary and revision THR)

Margron Stem Primary Cases: Chief Investigator's Series

30th October 2003 – 30th October 2005 (last 24 months) n:140

Dislocations Single	4	2.9%
1 cup changed angle	1	0.7%
Periprosthetic Fracture	3	2.1%
2 intra-op (1 small DDH femora , 1 late fall in an alcoholic)		
Aseptic Loosening	0	0%
Infection (washout)	2	1.9%
Haematoma	1	0.7%
DVT / PE	3	2.1%
Cup Impingement exchanged	1	0.7%

Stem Survivorship

2/140 stems exchanged in DDH : 98.1%

Cup Survivorship

2/140 cups exchanged : 98.1%

Overall cup/stem survivorship : 97.1%

1st july 2004 – 30th October (last 15 months) n: 100

Dislocations Single	1	1%
Dislocations Multiple	0	0%
Periprosthetic Fracture (DDH femur)	1	1%
Aseptic Loosening	1	1%
Infection (washout)	1	1%
Haematoma	1	1%
DVT / PE	1	1%
Cup Impingement (changed)	1	1%

Stem Survivorship

1/100 stems exchanged in DDH : 99%

Cup Survivorship

1/100 cups exchanged : 99%

Overall cup/stem survivorship : 98%

The Margron hip replacement system had been used on 507 primary hip patients in the chief investigator's series over 8 years to June 2005, **and in 37 patients** as revision stems.The revision hip system has been used in both simple and severe revision situations and after tumour resection of the upper femur.

18 of the 37 hips fell into the Mallory III femoral deficiency classification (severe proximal bone loss).

Of the initial series of 37 revision hip replacements between Dec 1997 and Aug 2003, four hips required revision. aseptic loosening : 2 (both patients revised)

- infection : 1 (superficial)
- dislocation : 1 (closed reduction without recurrence)
- intraop fracture : 2 (1 revised to longer stem... 1settled with circlage wiring.
- Pain Score preop: 12.5, postop: 38.8
- Harris Hip Score preop: 41.1, postop: 78.3
- Revision Stem survivorship : 89.2%
- Note: Similar series in the literature report 79% survivorship

Since the stem and neck design changes were introduced a further 17 revision stems were inserted between Dec 2003 and Sept 2005.

In this late series **only two complication** have occurred. Neither patient required open revision surgery.

i) The 1st patient was completely non compliant with a head injury and marked short and long term memory loss, and presented with recurrent postoperative dislocations after THRs elsewhere. Following revision THR with a Margron stem she redislocated 3x, but has been stable now for 12/12 following the application of a hip spika splint for a 3 months period.

ii) The 2nd patient with a flail polio hip presented with missing proximal bone stock, and a loose uncemented cup and stem inserted ~15 years earlier. Post-op she developed 3x dislocations in the revision THR. Patient non-compliance + lack of muscular control around the hip was the cause, as the hip was fully stable at closed reduction. Dislocations ceased with hip spika application and have not recurred since spika removal and better compliance.

Aetiology of Primary Margron THRs (n:140)		
Osteoarthritis	87	62%
AVN	20	14%
DDH	13	9%
RA / Ank Spond.	9	6%
Trauma	7	5%
Other	4	4%
Total	**140**	**100%**

Table 1 Primary Margron Pain Scores

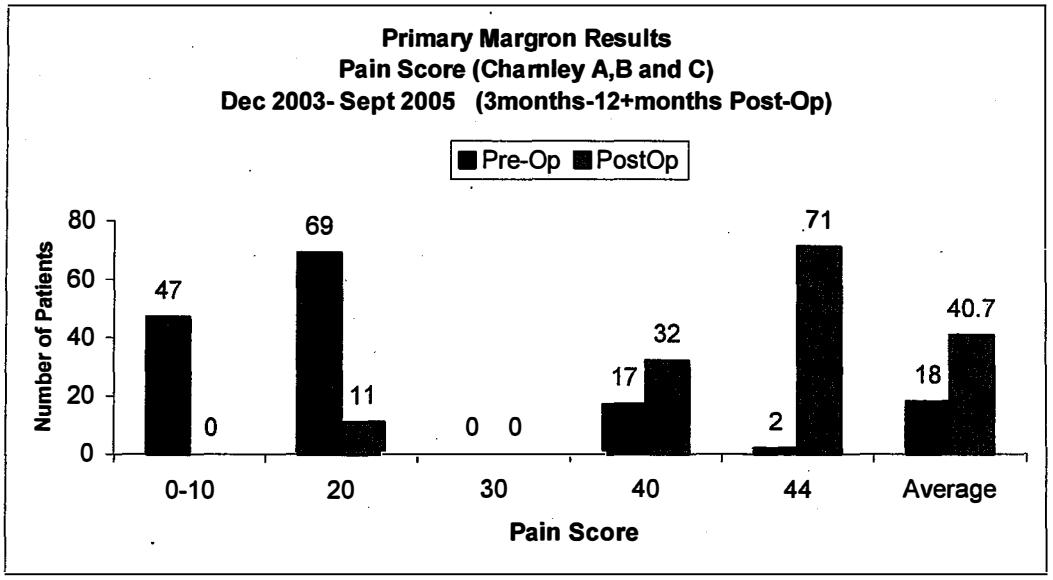


Table 2 Primary Margron Harris Hip Score

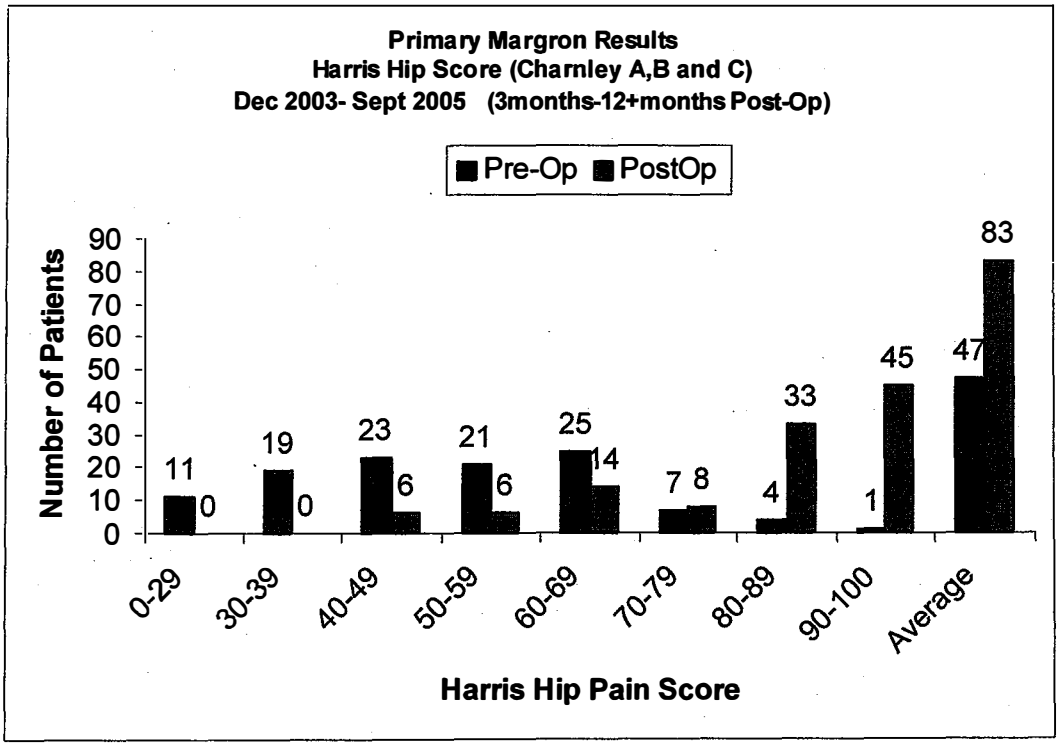


Table 3 Revision Margron Pain Scores

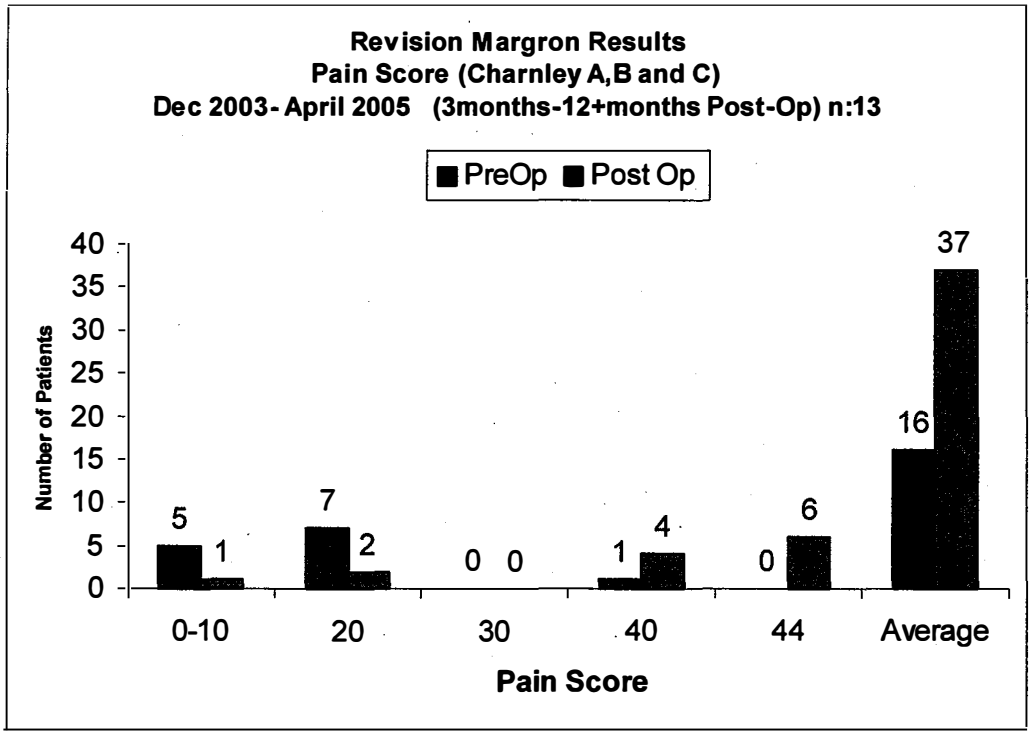
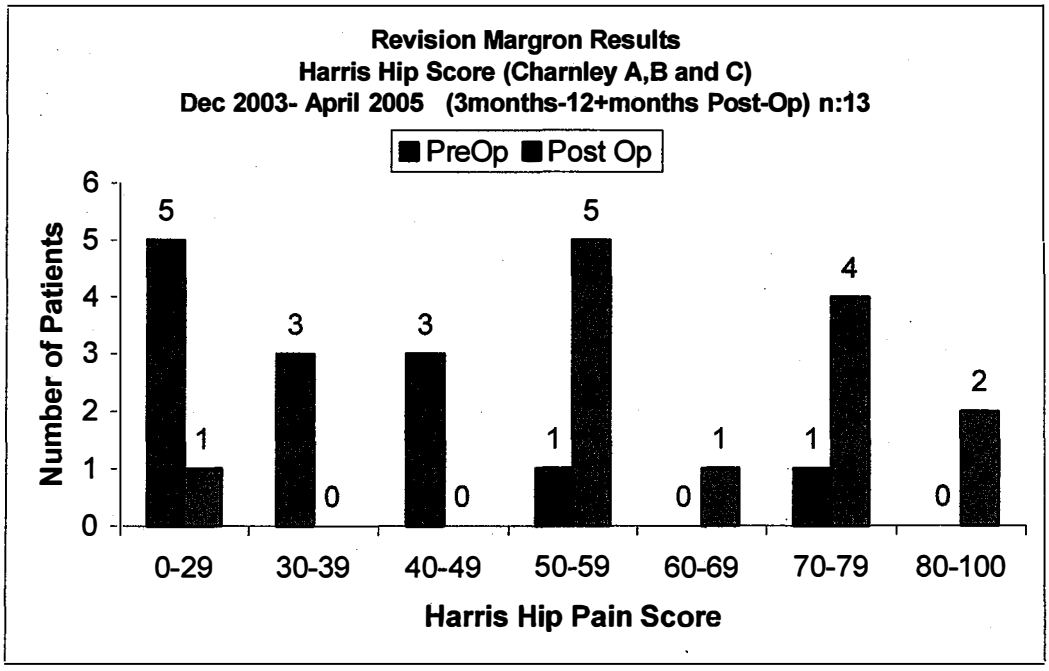


Table 4 Revision Margron Harris Hip Scores



Clinical Essential Principles

The prosthesis must function correctly on standard cases , allowing :

1 Early remobilisation with assisted part or full weight bearing, with an average hospital stay of 5-7 days.

- A length of hospital stay chart has been kept, and a comparison with other surgeons practicing in the area. Length of stay has been constantly at the average for the geographic area.

2 A dislocation rate at or below a level in the literature of 2%

- Chief Investigator's Series last 100 cases

3 A fracture rate intra-op and post-op of 2-3% or below.

- Chief Investigator's Series last 100 cases.

4 An infection rate at or below 0.5%

- Chief Investigator's Series last 100 cases

5 Bone resorbtion around the stem equal or below the literature average standard of 30% in Gruen zones 1 and 7 on DEXA.

- The prospective DEXA study, carried out over 7 years shows well maintained bone stock, equal to other prostheses in the market. Bone is lost mainly in the 1st year, and then settles down to a static state
- The results of the study were presented at the American Academy

6 Aseptic loosening rate of 2% or below.

- The clinical results of the prospective study of the last 140 cases show no aseptic loosening.

7 Thigh and knee pain rate of 2-3% or less.

- The clinical results of the prospective study of the last 140 cases show a thigh pain rate of 2.9%.

8 Range of hip motion of 90 flexion, and 20-30° in abd, add, ext, and rotation.

- Hip range of motion of the Margron has been tracked on an each case basis, and the average flexion is >90degrees, with abd, add and ext and int rotation at 30 degrees

9 Have 4-vector adjustability at the end of stem insertion.

- The system does allow full 4 vector adjustability at the end of stem preparation. This is especially useful in the presence of distorted proximal femur anatomy, such as take down of a hip fusion. Offset is

able to be regained. (Offset, leg length, neck length, anteversion angle).

10 Have sizes to fit all variations of the human femur.

- The extended range of necks and stems has allowed primary and revision THR at both ends of the spectrum of femur size.
- The Revision System must cope with all requirements of the Primary Hip, and as well be able to:

  I. Bypass long segments of femoral bone stock loss, and still have full 4 vector adjustability.

  II. Be strong enough to bypass long segments of femoral bone stock loss without component failure at

  1. the bone/prosthesis interface, and
  2. the modularity junctions

- Results: Clinically, the revision system has proven its ability to cope with the above. The functional SF12 and Harris Hip and Pain Scores of the prospective clinical study over 7 years show the ability of the system to cope with the worst situations of revision and tumour surgery.

11 Long Term Fixation in Bone.

- DEXA and X-Ray studies have shown this to have occurred over the 7 year prospective study.
- The Australian Hip Register comments that there is a flat survival line after initial fixation has occurred.
- Clinically there has been no evidence of osteolysis in the last 140 primary cases or in the revision series. One case of neck impingement against the cup edge had generated wear particles, and osteolysis was seen. This was an isolated case. The cup angle was too flat and was changed (reported in the last 100 cases of the chief investigator).

Conclusion

- The Margron Primary Hip system stem survival rate in the last 140, and especially the last 100 cases, is equal to or better than other uncemented stems on the Australian Joint Register at 98%.
- The single dislocation rate in the last 100 cases is at 1%,equal to other prostheses on the register.
- The recurrent dislocation rate in the last 100 primary cases is 0%.
- The early periprosthetic # rate is 2.1%, 2 #'s occurring in DDH cases with small femora, and 1 late # in an alcoholic patient after a fall.

- The Margron Revision system stem has been used for end point cases, and has results equal to or better than the literature, especially when used for Paprosky III cases.