unique

PUBLICATIONS V.2.3

custom femoral prosthesis

Literature

Doctoral thesis

Aamodt, A. Development and preclinical evaluation of a custom-made femoral stem. NTNU, Trondheim 1999.

Publications

Aamodt, A., Lund-Larsen, J., Andersen, E., Benum, P. Schnell Husby, O. In vivo measurements show tensile axial strain in the proximal lateral aspect of the human femur. — J Orthop Res, 1997, 15: 927-931.

Aamodt A., Kvistad, K.A., Andersen, E., Lund-Larsen J., Eine, J., Schnell Husby, O., Benum, P. Determination of the Hounsfield value for CT-based design of custom femoral stems. An experimental study. — J Bone Joint Surgery [Br], 1999, 81(1): 143-147.

Benum, P., Aamodt, A. Customized femoral stems. Review of 10 years experimental clinical research. — Acta Orthopedica et Traumatologica Hellenica, Journal of the Hellenic Association of Orthopaedic Surgery and Traumatology, 2000; 51(4): 346-357. Athens.

Aamodt, A., Lund-Larsen, J., Eine, J., Andersen, E., Benum, P., Schnell Husby, O. Changes in proximal femoral strains following insertion of uncemented standard and custom femoral stems. An experimental study in human femurs. — J Bone Joint Surgery [Br], 2001, 83(6): 921-929.

Aamodt, A., Lund-Larsen, J., Eine, J., Andersen, E., Benum, P., Schnell Husby, O. Mechanical stability of custom and anatomical femoral stems. An experimental study in human femurs. — Hip International, 2002, 12(3): 263-273.

Proceedings

*Aamodt, A., Lund-Larsen, J., Benum, P., Andersen, E., Kvistad, K. A., Nordby, A., Husby, O.S. Mechanical stability of custom-made and anatomical femoral implants; stability score based on implant-bone geometry. — In: Proc. of the 6th Annual International Symposium on Custom-made Prostheses. Amelia Islands, Florida 1993.

*Kvistad, K. A., Aamodt, A., Lund-Larsen, J., Benum, P., Eine, J., Andersen, E., Husby, O.S., Nordby, A. Determination of the optimal bone density level for CT- based design of custom made hip prostheses. An experimental study on human cadaver femora.
— In: Proc. of the 6th Annual International Symposium on Custom-made Prostheses. Amelia Islands, Florida 1993.

*Lund-Larsen, J., Aamodt, A., Benum, P., Eine, J., Andersen, E., Kvistad, K.A., Nordby, A., Husby, O.S. Mechanical stability of femoral stem implants; introduction of a stability score based on implant–bone geometry. — In: Proc. of the 6th Annual International Symposium on Custom-made Prostheses. Amelia Islands, Florida 1993.

*Kvistad, KA. Aamodt, A., Lund-Larsen, J., Benum, P., Eine, J., Andersen, E., Husby, O .S., Nordby, A. From cadaveric experiments to clinical setting. A study of CT-accuracy.
— In: Proc. of the 7th Annual International Symposium on Custom-made Prostheses. Rome, Italy 1994.

*Aamodt, A. Mechanical simulator for testing of hip prostheses. — In: Proc. of the Annual meeting of the Norwegian Orthopaedic Society, Oslo 1994

*Aamodt, A., Lund -Larsen, J., Eine, J., Andersen, E., Benum, P., Husby, O. S. Proximal femoral strain; in-vivo and in-vitro measurements. — In: Proc. of the 8th Annual International Symposium on Custom-made Prostheses. Puerto Rico 1995.

*Lund-Larsen, J., Aamodt, A., Eine, J., Andersen, E., Benum, P., Husby, O. S. Micromotion of custom and anatomical femoral stems. — In: Proc. of the 8th Annual International Symposium on Custom-made Prostheses. Puerto Rico 1995.

*Aamodt, A., Lund-Larsen, Andersen, E., J. Eine, J., Benum, P. Strain in the proximal femur. *In-vitro* and *in-vivo* experiments. — In: Proc. of the Annual meeting of the Norwegian Orthopaedic Society, Oslo 1995.

*Aamodt, A., Lund-Larsen, J. Eine, J., Benum, P., Husby, O. S. Changes in proximal femoral strain following insertion of uncemented standard and custom femoral stems. — In: Proc. of the Annual meeting of the Norwegian Orthopaedic Society, Oslo 1995.

*Benum, P., Aamodt, A., Andersen, E., Eine, J., Funderud, A., Husby, O. S. Lund-Larsen, J., Kvistad, K.A., Nordby, A. Custom femoral stems- design principles and preliminary operative experience. — In: Proc. Nordic Orthopaedic Federation, (NOF) Bergen 1996, 12.

*Aamodt, A., Lund-Larsen, J. Andersen, E., Eine, J., Benum, P., Husby, O. S. Changes in proximal femoral strain following insertion of uncemented standard and custom femoral stems. — In: Proc. Nordic Orthopaedic Federation, (NOF) Bergen 1996, 12-13.

*Aamodt, A., Lund-Larsen, J., Andersen, E., Eine, J., Benum, P., Husby, O. S. Proximal femoral strain - in vivo and in vitro measurements. — In: Proc. Nordic Orthopaedic Federation, (NOF) Bergen 1996, 16.

*Aamodt, A., Lund-Larsen, J. Eine, J., Benum, P., Husby, O. S. Changes in proximal femoral strain following insertion of uncemented standard and custom femoral stems. — In: Proc. of the 9th Annual International Symposium for Technology in Arthroplasty. Amsterdam 1996.

*Benum, P., Aamodt, A., Andersen, E., Eine, J., Funderud, A., Husby, O.S., Lund-Larsen, J., Kvistad, KA., Nordby, A. Custom femoral stems. Design principles and preliminary operative experience. — In: Proc. European Hip Society. Helsinki, 1996.

*Aamodt, A., Benum, P. Restoration of the hip biomechanics after implantation of customized femoral stems. — In: Proc. of the Annual meeting of the Norwegian Orthopaedic Society, Oslo 1996.

*Benum, P., Aamodt, A., Husby, O.S. Optimization of the biomechanics of the hip using custom femoral stems. — In: Proc. EFORT. Barcelona, 1997.

*Aamodt, A., Lund-Larsen, J., Eine, J., Andersen, E., Benum, P., Husby O. S. *In vitro* measurement of initial stability of custom and anatomical femoral stems. — The 10th Annual International Symposium For Technology in Arthroplasty. ISTA 1997, San Diego, USA.

*Benum, P., Husby O. S., Aamodt, A., Andersen, E., Eine, J., Funderud, A. Computeraided preoperative assessment of femoral components in hip arthroplasty. — The 12th Annual International Symposium For Technology in Arthroplasty. ISTA 1999, Chicago-Illinois, USA.

Aamodt, A., Benum, P. Bone remodelling around uncemented, custom-made femoral stems. — The 12th Annual International Symposium For Technology in Arthroplasty. ISTA 1999, Chicago-Illinois, USA.

Aamodt, A., Lund-Hansen, H., Aamodt, M., Benum, P. Early migration of an uncemented, custom-made femoral stem. Evaluation of 15 hips using radiostereometry. — The 12th Annual International Symposium For Technology in Arthroplasty. ISTA 1999, Chicago-Illinois, USA.

Benum, P. Customized non-cemented femoral stems in hip arthroplasty. State of the art and possible role in the future. — III Congreso Argentino-Brasileno, 1999, Buenos Aires, Argentina.

*Benum, P., Husby O.S., Aamodt, A. Computer-aided preoperative assessment of femoral components in hip arthroplasty. — In: Proceedings, Nordic Orthopaedic Federation (NOF), Tampere, Finland 2000.

Aamodt, A., Lund-Hanssen, H., Benum, P. The Unique custom-made, uncemented femoral stem; two years follow-up of 14 hips using RSA and DEXA. — In: Proceedings, Nordic Orthopaedic Federation (NOF), Tampere, Finland 2000.

Aamodt, A., Benum, P., Lund-Hanssen, H. The Unique custom-made, uncemented femoral stem; two years follow-up of 17 hips using RSA and DEXA. — The 13th Annual International Symposium For Technology in Arthroplasty. ISTA 2000, Berlin, Germany.

Nordsletten, L., Aamodt, A., Benum, P., Grant, P. The unique customized prosthesis (ucp) is more stable than the cemented elite plus femoral stem. A randomized prospective study with radiostereometric 1-year follow up. — The 14th Annual International Symposium For Technology in Arthroplasty, ISTA 2001, Maui, Hawaii.

Aamodt, A., Benum, P., Haugan, K. The unique customized, uncemented femoral stem. Clinical follow-up, RSA- and DEXA-measurements at two to three years.
— The 14th Annual International Symposium For Technology in Arthroplasty. ISTA 2001, Maui, Hawaii.

Aamodt, A., Benum, P. Bone remodelling after insertion of a customised femoral stem. Correlation between implant volume and stress shielding after 2 years measured with DEXA. — In: Proc. European Hip Society, Baveno, Italy 2002.

Benum, P., Aamodt, A., Haugan, K., Lund-Hanssen, H. The *unique* customised, uncemented femoral stem. Clinical follow-up, RSA-and DEXA measurements at two to three years. —In: Proc. European Hip Society, Baveno, Italy, 2002.

Aamodt Arild, P. Benum, K. Haugan, L. Persen, O. Schnell Husby. Implant migration and bone remodelling after insertion of a custom and standard uncemented femoral stem. a prospective, randomized rsa-and dexa study — The 6th EFFORT Congress, Helsinki, Finland 2003.

P. Benum, A. Aamodt, K. Haugan. Uncementeed custom femoral components in hip arthroplasty. a prospective clinical study.— The 6th EFFORT Congress, Helsinki, Finland 2003

A Aamodt, P. Benum. Correlation between periprosthetic bone loss and stem size after insertion of an uncemented, customized femoral prosthesis. —The 6th EFFORT Congress, Helsinki, Finland 2003.

S H Pettersen, S Muller, P O Østbyhaug, A Aamodt. Comparison of Case Specific Finite Element Simulations with Strain Gauge Measurements of the Proximal Femur. -- 16th Annual Symposium of the International Society for Technology in Arthroplasty, San Francisco, USA, 2003

P Benum, A Aamodt, K Haugan. Uncemented Custom Femoral Components in Hip Arthroplasty. A Prospective Clinical Study. - 16th Annual Symposium of the International Society for Technology in Arthroplasty, San Francisco, USA, 2003

Pål Benum, M.D, PH.D. , Arild Aamodt, M.D., PH.D. Custom femoral stems in osteopetrosis. Development of a guiding system for preparation of an intramedullary cavity. A case report.- 16th Annual Symposium of the International Society for Technology in Arthroplasty, San Francisco, USA, 2003

L Nordsletten, F Snorrason, P Grant , A Aamodt. Differences in stability between the Scandinavian Customized Prosthesis (SCP) and the cemented Elite Plus femoral stem. A randomized prospective study with radiostereometric 2 year follow up. - In: Proc. of the Annual meeting of the Norwegian Orthopaedic Society, Oslo, 2003.

* abstract is not enclosed.

Abstracts of Publications

IN VIVO MEASUREMENTS SHOW TENSILE AXIAL STRAIN IN THE PROXIMAL LATERAL ASPECT OF THE HUMAN FEMUR.
Aamodt, A; Lund-Larsen, J; Eine, J; Andersen, E; Benum, P; Husby, O S.
– *Journal of Orthopaedic Research, 1997, 15: 927-931.*
Abstract: Two conflicting theories exist concerning the stress pattern for the proximal lateral aspect of the human femur. According to the classic theory of Pauwels, a bending moment on the femur leads to compression medially and to tension laterally. The alternative theory is that muscle forces contribute to a moment-free loading of the femur, with both the medial and lateral cortices subjected to compression. To examine these theories, we measured the strain at the external surface of the proximal lateral aspect of the femur of two female patients undergoing surgery for "snapping hip syndrome." During the surgical procedure, a strain-gauge rosette was bonded to the lateral aspect of the femur and the cortical strain were monitored while the patient performed a series of activities. In both patients, principle tensile strain increased significantly during one-legged stance, walking, and stair climbing as compared with that during two-legged stance. During each loading situation, the principal tensile strain was aligned within 22 degrees to the longitudinal femoral axis. Dynamic strain measurements consistently revealed tensile axial strain at the lateral aspect of the femur during each activity. The present study supports the classic bending theory of Pauwels and demonstrates that the proximal lateral aspect of the femur is subjected to tension during the stance phase of gait.

DETERMINATION OF THE HOUNSFIELD VALUE FOR CT-BASED DESIGN OF CUSTOM FEMORAL STEMS
Arild Aamodt ; Kjell A. Kvistad ; Eivind Andersen ; Jon Lund-Larsen ; Jan Eine ; Pål Benum ; Otto S. Husby.
– *The Journal of Bone and Joint Surgery [Br], 1999, 81(1): 143-147.*
Abstract: CT and advanced computer-aided design techniques offer the means for designing customised femoral stems. Our aim was to determine the Hounsfield (HU) value of the bone at the corticocancellous interface, as part of the criteria for the design algorithm. We obtained transverse CT images from eight human cadaver femora. The proximal femoral canal was rasped until contact with dense cortical bone was achieved. The femora were cut into several sections corresponding to the slice positions of the CT images. After obtaining a computerised image of the anatomical sections using a scanner, the inner cortical contour was outlined and transferred to the corresponding CT image. The pixels beneath this contour represent the CT density of the bone remaining after surgical rasping. Contours were generated automatically at nine HU levels from 300 to 1100 and the mean distance between the transferred contour and each of the HU-generated contours was computed. The contour generated along the 600-HU pixels was closest to the inner cortical contour of the rasped femur and therefore 600 HU seem to be the CT density of the corticocancellous interface in the proximal part of cadaver femora. Generally, femoral bone with a CT density beyond 600 HU is not removable by conventional reamers. Thus, we recommend the 600 HU threshold as one of several criteria for the design of custom femoral implants from CT data.

CUSTOMIZED FEMORAL STEMS. REVIEW OF 10 YEARS EXPERIMENTAL CLINICAL RESEARCH.
Benum, P., Aamodt, A.
– *Acta Orthopedica et Traumatologica Hellenica, Journal of the Hellenic Association of Orthopaedic Surgery and Traumatology, 2000; 51(4): 346-357. Athens.*
Abstract: A custom femoral stem research group was established at our institution in 1990. The purpose was to develop, by use of CT information and CAD-CAM technology, an uncemented stem with optimal fit to the proximal femur to achieve secure fixation and optimal strain distribution to the bone even in femurs with abnormal size and geometry. The aim of this paper is to present an overview of the experimental studies related to the development, the design principles, and our preliminary experience after five years clinical application. Experimental studies on cadaver femurs showed that the contours generated by the 600 threshold best represented the transitional zone between trabecular and inner cortical bone of the proximal femur. Hence the 600 treshold seemed to be suitable as one of several criteria for design of an uncemented femoral stem from CT data. Femoral stems with a proximal fit and HA coating were produced by CAD-CAM technique and inserted into cadaver femurs for stability testing, and studies of changes in proximal femoral strain. Standard anatomical femoral stems (Profile, DePuy) served as controls. The strain pattern in the bone was more favourable after application of the custom stems These stems also showed significant better torsional stability. A custom-made prosthesis, also with an individual design of the extrafemoral upper part, has been used in 200 hips without any major problems related to the prosthesis. All patients are followed prospectively. No loosening has been observed. Thirty-six hips have been followed for 3 years or more, average Charnley hip score at three years was 5,8. RSA studies of 17 hips up to two years have revealed excellent stability, DEXA studies have shown significant bone loss only in Gruen zone 7, and no loss from one to two years after the operation. We have experienced that this type of prosthesis is particular useful in femurs with highly abnormal shape of the upper femur. The

technique enables a better correction of highly abnormal femoral neck anteversion and normalization of the medial femoral head offset and leg length discrepancy than standard prostheses. Randomised prospective studies, including RSA and DEXA studies, are now performed, comparing the custom-made prosthesis to various types of standard prostheses. Hopefully, such studies will clarify whether use of this type of custom-made prosthesis is favourable also in hips without any major anatomical abnormalities.

CHANGES IN PROXIMAL FEMORAL STRAIN AFTER INSERTION OF UNCEMENTED STANDARD AND CUSTOMISED FEMORAL STEMS.

A. Aamodt ; J. Lund-Larsen ; J. Eine ; E. Andersen ; P. Benum ; O. S. Husby

– *The Journal of Bone and Joint Surgery [Br], 2001, 83(6): 921-929*

Abstract: We have compared the changes in the pattern of the principal strains in the proximal femur after insertion of eight uncemented anatomical stems and eight customised stems in human cadaver femora. During testing we aimed to reproduce the physiological loads on the proximal femur and to simulate single-leg stance and stair climbing. The strains in the intact femora were measured and there were no significant differences in principal tensile and compressive strains in the left and right femora of each pair. The two types of femoral stem were then inserted randomly into the left or right femora and the cortical strains were again measured. Both induced significant stress shielding in the proximal part of the metaphysis, but the deviation from the physiological strains was most pronounced after insertion of the anatomical stems. The principal compressive strain at the calcar was reduced by 90% for the anatomical stems and 67% for the customised stems. Medially, at the level of the lesser trochanter, the corresponding figures were 59% and 21%. The anatomical stems induced more stress concentration on the anterior aspect of the femur than did the customised stems. They also increased the hoop strains in the proximomedial femur. Our study shows a consistently more physiological pattern of strain in the proximal femur after insertion of customised stems compared with standard, anatomical stems.

MECHANICAL STABILITY OF CUSTOM AND ANATOMICAL FEMORAL STEMS.
AN EXPERIMENTAL STUDY IN HUMAN FEMURS.

Aamodt, A., Lund-Larsen, J., Eine, J., Andersen, E., Benum, P., Schnell Husby, O.

– *Hip International, 2002, 12(3): 263-273.*

Abstract: In this study we have compared the mechanical stability of custom (n=8) and anatomical (n=8), uncemented femoral components, following insertion into human cadaver femurs, during simulated single leg stance and stair climbing. In the custom group two specimens were excluded from the study due to detachment of the greater trochanter during cyclical loading. As a consequence of their mechanical behaviour both types of stems could be divided into subgroups of “unstable” and “stable” implants. In the course of one thousand loading cycles three anatomical stems and one custom stem migrated more than 1 mm, which was interpreted as mechanical loosening. This difference in rate of mechanical loosening was not significant. However, the majority of the stems were remarkably stable and showed micromotion of less than 18 µm and migration of less than 35 µm at the proximal implant bone interface. The corresponding figures for the tip of the stems were 243 µm and 170 µm, respectively. During torsional loading the custom stem showed less rotatoriy motion then the anatomical stem ($p<0.05$). For the remainder, there were no significant differences in magnitude of cyclical micromotion or migration for the two types of femoral stems.

Proceedings

BONE REMODELLING AROUND UNCEMENTED, CUSTOM-MADE FEMORAL STEMS

Arild Aamodt and Pål Benum.

Dept. of Orthopaedic Surgery, Trondheim University Hospital, 7006 Trondheim, Norway.

– *The 12th Annual International Symposium For Technology in Arthroplasty. ISTA 1999, Chicago-Illinois, USA.*

Insertion of a femoral stem will induce an alteration of the stress level within the bone of the proximal femur. The biological effects of this stress shielding may be a decrease in the quality and the strength of the bone stock as well as changes in the geometry of the femoral canal. It does not seem that even severe periprosthetic bone loss plays a major role in the process of aseptic loosening during the first years after a THR. However, the extent and consequences of stress shielding may be factors determining the success of uncemented femoral stems during the second decade after hip replacement.

Previously we have shown in experimental studies that a customized femoral stem preserves the longitudinal and the hoop strains in the proximal femur better than is the case with a standard anatomical stem. Although this is not a comparative study, the aim was to analyse quantitatively the bone remodelling around a custom-made femoral stem ("*Unique*", Scandinavian Customized Prosthesis as, Norway) using the DEXA technique. The custom stem is designed for proximal fit and load transfer and is coated with hydroxyl-apatite in the proximal part.

Twenty-seven hips were scanned immediately post-op and at three, six and twelve months after insertion. There were 13 females and 14 males with an average age of 45 (25-61) years. A Hologic QDR 4500 DEXA scanner was used and the bone mineral density (BMD) was measured in each of the seven Gruen zones in the frontal plane. The figures in the table below indicate the per cent change in BMD with the post-op value serving as reference.

	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7	All zones
3 months	-10	-12	-5	-3	-2	-10	-23	-8
6 months	-6	-9	-1	-2	0	-9	-29	-6
12 months	-4	-9	-4	-2	2	-10	-31	-6

Our results demonstrate a decrease in the BMD of less than 10% in all zones at one year, except for the proximal medial area where the bone loss was 31%. In zones 1 to 5 there has in fact been a gain in bone density from three to twelve months, whereas there has been a steady-state bone remodelling in zone 6 and 7 in the period from six to twelve months. Our results are similar to studies reporting the bone changes after insertion of standard, uncemented femoral stems designed for proximal loading.

EARLY MIGRATION OF AN UNCEMENTED, CUSTOM-MADE FEMORAL STEM.
EVALUATION OF 15 HIPS USING RADIOSTEREOMETRY.

Arild Aamodt, Håkon Lund-Hanssen*, Mads Aamodt, Pål Benum.

Dept. of Orthopaedic Surgery and Radiology*, Trondheim University Hospital, 7006 Trondheim, Norway.

– *The 12th Annual International Symposium For Technology in Arthroplasty. ISTA 1999, Chicago-Illinois, USA.*

Excessive micromotion or progressive migration of hip prostheses may inhibit or weaken the biological fixation to the bone, induce the formation of a fibrous membrane at the interface and eventually lead to clinical signs of implant loosening. Radiostereometry (RSA) is a radiographic method to analyse the 3-dimensional displacement of prosthetic components within the bone. The accuracy of RSA in the hip has been determined to be approximately 0.2 mm, which is about an order of magnitude better than conventional radiography. Furthermore, there are strong indications that continuous and progressive migration of an implant indicates future loosening and that prostheses at risk for later loosening may be identified during the first post-op years using this method.

The aim of the present study was to measure the magnitude and the pattern of migration of an uncemented, custom-made femoral stem during the first year after insertion. Fifteen patients with a mean age of 45 (25-60) years had a THR using a custom stem ("*Unique*", Scandinavian Customized Prosthesis as, Norway), which is designed for proximal fit and load transfer. The proximal 50-70% of the stem is coated with hydroxy-apatite. RSA examinations were performed immediately post-op (reference examination) and after three, six and twelve months.

Segment motion. This motion refers to the translation (mm) of the entire rigid-body segment representing the prosthesis (*Table 1*).

	medial-lateral	proximal-distal	anterior-posterior
3 months	0.14	0.13	0.18
6 months	0.15	0.12	0.16
12 months	0.14	0.11	0.13

Table 1.Segment motion

The mean translation in any direction was less than 0.18 mm, however, the maximum translations for a single femoral stem was 0.60, 0.56 and 0.65 mm along the X-, Y- and Z axis, respectively. An interesting observation was that most of the migration occurred during the first three months and that the prostheses thereafter stabilized.
Point motion. This motion refers to the length of the translation of one single point on the implant. *Table 2* shows the mean translations of the markers at the medial neck-stem junction (P1), the shoulder (P2) and the tip of the stem (P3).

	P1	P2	P3
3 months	0.40	0.29	0.96
6 months	0.38	0.32	0.71
12 months	0.37	0.24	0.89

Table 2. Point motion

Conclusion. The custom stem seems to be very stable during the first postoperative year and none of the stems displayed progressive migration. This may indicate that biological fixation of the femoral stems has been achieved.

CUSTOMIZED NON-CEMENTED FEMORAL STEMS IN HIP ARTHROPLASTY.
STATE OF THE ART AND POSSIBLE ROLE IN THE FUTURE.

Pål Benum, Orthopaedic Department, Trondheim University Hospital, 7000 Trondheim, Norway

– *In: Poc. III Congreso Argentino-Brasileno, 1999, Buenos Aires, Argentina.*

Use of standard (”off the shelf”) non-cemented femoral stems has to some extent proved successful in total hip replacement. However, several problems have been identified with such stems such as intraoperative cracks and fractures, early loosening, secondary proximal femoral bone loss due to stress shielding, femoral osteolysis and thigh pain. Most of these problems are probably related to a geometric mismatch between the stem and the endosteal bone due to the great variety of the size and shape of the upper femur. In some individuals also highly abnormal femoral neck anteversion forces the prosthesis into an unacceptable position causing instability of the reconstructed joint. Due to these problems several research groups have developed customized femoral stems to optimize the fit of the stem to the femur and to optimize the biomechanics of the joint.
Methods for design and production. Production of customized femoral stems with an optimal individual fit is based on CAD-CAM- technology in which a 3D-computer model of the medullary cavity forms the basis for the programming of the CNC-milling machine. Basically, three different methods have been used to decide the geometry of the medullary cavity; conventional radiography, intraoperative modeling and computed tomography (CT). The latter method has proved superior in terms of accuracy and practical applicability. Hence, the computer-aided design of customized femoral stems is nowadays usually based on CT-information.
When designing a custom-femoral stem from CT-data, it is of utmost importance to define the most suitable boundaries between the prosthesis and the bone. A bone-contouring algorithm is used in this process. A density level between 500 and 800 HU is usually applied, alternatively a dynamic density threshold technique or a relative thresholding is used. Furthermore, the design has to be modified to enable insertion of the stem. Modifications have also to be performed to obtain contact to compact bone in certain areas, and to spare trabecular bone in the trochanteric region. Finally, the extramedulary part of the prosthesis is designed to achieve optimal offset of the femoral head and adequate anteversion of the femoral neck in order to optimize the biomechanics of the hip. This design will also within certain limits allow correction of leg length discrepancy.
Experimental studies. It has been shown in various experimental studies that an improved fit to compact bone is obtained in CT-based custom femoral stems when compared to standard stems. The increased area of close contact to the surrounding bone should favor a more secure fixation of hydroxylapatite or porous coated prostheses since the area of bone contact, and the width of the gap between implants and bone, might be critical for bony in growth. Theoretically, the improved fit should also be of importance since micromotions exceeding 150 microns might prevent osteointegration. However, most experimental studies have not shown any big difference between the stability of custom and standard anatomic stems after insertion into normal cadaveric femurs, during loading corresponding to walking activities. The level of micromotions in both types of prostheses has been found to be well below the critical level for bony in growth. However, it should be noted that the results

might have been different if tests had been performed on prostheses implanted into femurs with abnormal shape. Theoretically, the improved fit to the most proximal part of the femur which is obtained in custom stems should lead to less stress-shielding of the proximal bone stock than standard prostheses. This has also been verified by experimental investigations, which have shown more favourable stress distribution to the bone in custom prostheses. Provided that this also will be true after bony in growth, this should lead to less proximal bone atrophy. However, research is still needed to determine the ideal length of intimate contact to compact bone, and the length of the coated area, to achieve minimal stress-shielding, and yet sufficient immediate stability.

Clinical experience. CT-based non-cemented custom stems, coated with hydroxylapatite, were at some centers taken into use in the late 80's. Problems in terms of intraoperative fractures, and early subsidence, were encountered in some of the early series. However, later such problems have been nearly eliminated due to improved design of the prostheses, and there have been presented several enthusiastic reports about the preliminary clinical results after use of custom stems. However, in the literature there is still lack of information about long term results, this is probably partly due to the fact that a relatively few number of patients have been followed for 10 years or more. Furthermore, there has not been published any study of comparable series of patients treated with custom and standard femoral stems. Hence, there is so far no clinical evidence that the potential advantages of custom stems mentioned above really will contribute to improved long term results in patients were non-cemented standard stems have proved to give reasonable results. However, there seems to be no doubt that non-cemented custom femoral stems can be successfully used in femurs with highly abnormal width and geometry of the proximal intramedulary cavity, were standard non-cemented stems hardly can be used. It has also been experienced that use of non-cemented custom stems eliminates the need for removal of bone by intramedulary reaming in some cases of extremely narrow femurs, where such reaming would be necessary if cemented stems should be used. Finally, it is a general experience that use of custom stems offers greater possibilities to achieve ideal anteversion, medial femoral head offset and leg length correction than other types of prostheses in hips with highly abnormal shape of the upper end of the femur.

Costs. Although the production costs have been reduced during the last years, the costs of customized non-cemented femoral stems are still considerably higher than that of standard femoral components. At the present the costs varies between the different production companies in the range of 2500 to 5000 $. Thus the costs of such custom stems are comparable to some prostheses of multimodular design.

Possible role in the future. In the future non-cemented custom femoral stems will probably be more commonly used than to day in highly abnormal femurs. However, it remains to se whether it will be justified to use such stems more generally as an alternative to standard stems in young patients. At the present randomized prospective studies are performed concerning the microstability, using RSA, and the periprosthetic bone remodeling, using DEXA, comparing custom stems to varying types of standard stems. Results of such studies will indicate whether it is justified to try out the use of non-cemented custom stems on a larger scale in patients with normal size and shape of the upper en of the femur. Further improvements in technology will probably in a few years lower the production costs to such extent that custom prostheses will be available at a cost, which will be acceptable for more general use than to day.

THE "*UNIQUE*" CUSTOM-MADE, UNCEMENTED FEMORAL STEM.
TWO YEARS FOLLOW-UP OF 14 HIPS USING RSA AND DEXA.

Aamodt, Arild, Lund-Hanssen, Håkon* and Benum, Pål.
Department of Orthopaedic Surgery and Radiology*, Trondheim University Hospital, 7006 Trondheim, Norway.

– *In: Proceedings, Nordic Orthopaedic Federation (NOF), 2000, Tampere, Finland.*

Abstract: There are strong indications that continuous and progressive migration of an implant can predict future loosening and that prostheses at risk for later loosening may be identified during the first post-op years using radiostereometry (RSA). Also, insertion of a femoral stem will induce an alteration of the stress level within the bone of the proximal femur. Although periprosthetic bone loss does not seem to play a major role in the process of aseptic loosening during the first years after a THR, the extent and consequences of stress shielding may be factors determining the success of uncemented femoral stems during the second decade after hip replacement. The aim of the present study was to measure the magnitude and the pattern of migration of an uncemented, custom-made femoral stem as well as the bone remodeling of the proximal femur during the first two year after insertion. Fourteen patients with a mean age of 45 (25-60) years had a THR using a custom-made stem ("*unique*", Scandinavian Customized Prosthesis as, Norway), which is designed for proximal fit and load transfer. The proximal 50-70% of the stem is coated with hydroxy-apatite. RSA and DEXA examinations were performed immediately post-op (reference examination) and after 3, 6, 12 and 24 months.

Results:
Implant motion. Mean translation (mm) of the prosthesis:

	medial-lateral	proximal-distal	anterior-posterior
3 months	0.02	0.04	0.05
6 months	0.04	0.01	0.00
12 months	0.01	0.00	0.07
24 months	0.12	0.03	0.13

Bone remodelling. Mean bone mineral density (BMD) in per cent of the post-op BMD value:

	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7	All zones
6 months	91	92	99	97	100	89	68	92
12 months	93	87	96	94	99	88	65	90
24 months	93	88	99	94	97	86	61	91

Conclusion: The custom stem seems to be very stable during the first two postoperative years, with an average migration in any direction of less than 0.14 mm. This may indicate that biological fixation of the femoral stems has been achieved. The change in the BMD was less than 15% in all Gruen zones at two years, except for the proximal medial area where the bone loss was 39%.

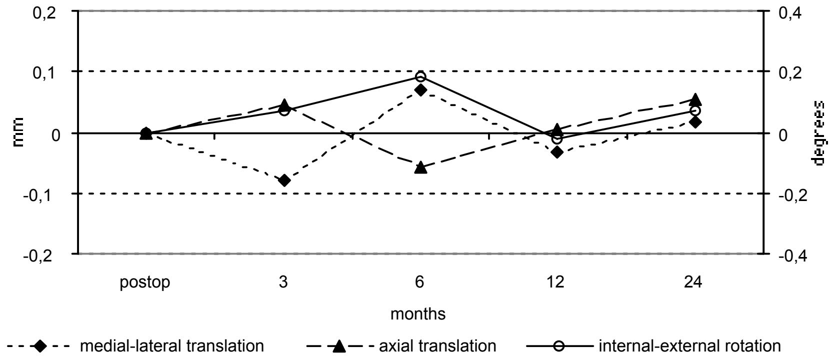
THE *UNIQUE* CUSTOM-MADE, UNCEMENTED FEMORAL STEM. TWO YEARS FOLLOW-UP OF 17 HIPS USING RSA AND DEXA.

Aamodt, Arild, Benum, Pål and Lund-Hanssen, Håkon*.
Department of Orthopaedic Surgery and Radiology*, Trondheim University Hospital, 7006 Trondheim, Norway.

– *The 13th Annual International Symposium For Technology in Arthroplasty, ISTA 2000, Berlin, Germany*

The aim of the present study was to measure the magnitude and the pattern of migration of an uncemented, custom-made femoral stem as well as the bone remodeling of the proximal femur during the first two year after insertion. Seventeen patients with a mean age of 45 (27-60) years had a THR using a custom-made stem (*unique*, Scandinavian Customized Prosthesis as, Norway), which is designed for proximal fit and load transfer. The proximal 50-70% of the stem is coated with hydroxy-apatite. Röntgenstereographic analysis (RSA) and DEXA examinations were performed immediately post-op (reference examination) and after 3, 6, 12 and 24 months in order to measure the micromovements of the prosthesis and the periprosthetic bone remodeling, respectively.

Results:
Implant motion. Mean translation (mm) and rotation (degrees) of the prosthesis:



Bone remodelling. Mean bone mineral density (BMD) in per cent of the post-op BMD value:

	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7	All
6 mnths	90	88	99	98	99	91	70	93
12 mnths	93	86	96	97	101	89	66	92
24 mnths	93	86	99	96	98	87	64	92

Conclusion: The custom stem seems to be very stable during the first two postoperative years, with an average migration in any direction of less than 0.14 mm. This may indicate that biological fixation of the femoral stems has been achieved. The change in the BMD was less than 15% in all Gruen zones at two years, except for the proximal medial area where the bone loss was 36%.

THE UNIQUE CUSTOMIZED PROSTHESIS (UCP) IS MORE STABLE THAN THE CEMENTED ELITE PLUS FEMORAL STEM A RANDOMIZED PROSPECTIVE STUDY WITH RADIOSTEREOMETRIC 1-YEAR FOLLOW UP

L Nordsletten[1], A Aamodt[2], P Benum[2], P Grant[1]
[1]Oslo Orthopaedic University Clinic and [2]Trondheim Orthopaedic University Clinic

– *The 14th Annual International Symposium For Technology in Arthroplasty, ISTA 2001, Maui, Hawaii.*

New prosthesis designs should be compared to a standard implant in randomized studies evaluated by radiostereometric analysis (RSA). The Unique customized prosthesis (UCP) is a newly developed concept for fitting uncemented prosthesis to the exact internal shape of the proximal femur [1]. We evaluated the new UCP design with the null hypothesis that this implant would be no more stable than a standard cemented implant.

Material and Methods. 38 patients, mean age 51.6 years (31-65) were randomized to a UCP HA coated femoral stem or an Elite Plus (DePuy) cemented stem. All patients were implanted with a Duraloc (DePuy) uncemented cup except one patient with a protrusio who was primary impaction grafted with a cemented cup. Most patients received a Zirconium head, and all heads were 28 mm. The femoral stems were fitted with 3 tantalum balls and 4-10 tantalum balls were implanted in the femur during operation. RSA pictures were taken postoperatively, after 6 and 12 months.

Results. The Elite Plus stem rotated more into retroversion after 6 and 12 months (0.79° versus 0.31° after 12 months, P<0.05). Nearly all of this rotation took place during the first 6 months. The Elite Plus stem migrated medially while the UCP migrated laterally (0.04 mm medially versus 0.03 mm laterally, P=0.06). The Elite Plus stem also migrated more distally than the UCP (0.17 mm versus -0.06 mm, P=0.055).

Discussion. Customized implants were more stable than the cemented Elite Plus prosthesis. Compared to other results with the Elite Plus rotations and migrations were small in this study [2]. Initially all patients had good clinical results, and only by long time follow up any clinical differences due to the small differences in stability as measured by RSA can be found.

References: 1. Aamodt, A., *et al. J Bone Joint Surg Br* **81**, 143-7. (1999).
2. Alfaro-Adrian, J., *et al. J Bone Joint Surg Br* **81**, 130-4 (1999).

THE *UNIQUE* CUSTOMISED, UNCEMENTED FEMORAL STEM. CLINICAL FOLLOW-UP, RSA- AND DEXA-MEASUREMENTS AT TWO TO THREE YEARS.

A. Aamodt, P. Benum and K. Haugan.
Department of Orthopaedic Surgery, Trondheim University Hospital, 7006 Trondheim, Norway.

– *The 14th Annual International Symposium For Technology in Arthroplasty, ISTA 2001, Maui, Hawaii.*

A customised, uncemented femoral stem was introduced clinically in 1995 after several years of development and pre-clinical testing. All the patients operated in our hospital have entered a prospective clinical study. The aim of this study is to present the short-term clinical data. Furthermore, the measurement of implant migration and the periprosthetic bone remodelling at two years is also reported.

Materials and methods: The femoral stem is designed from preoperative CT-scans, machined in Ti-alloy and circumferentially coated with a 50µm hydroxylapatite (HA) layer in the proximal 50-70%. Fifty-one patients (median age 52 years) have been followed clinically for a minimum of 3 years using the Merle-d'Aubignè score. Migration of the femoral stem has been measured with radiostereometry (RSA), the precision of the measurements is better than 0.080 mm for translations and 0.30º for rotations. Periprosthetic bone remodelling is expressed as the change in bone mineral density (BMD) in 7 zones (Gruen) relative to the postoperative values. RSA- and DEXA measurements have been performed postoperatively and then after 3, 6, 12 and 24 months.

Results: One stem had to be revised after 3 months due to a periprosthetic fracture. The clinical scores were as follows (preop/3 years): Pain 2.6/5.5, ROM 3.7/5.7, function 2.7/5.9, total score 9.1/17.1. Six patients complained of thigh pain during the fist 2 years, however, this complication resolved spontaneously in 5 patients within the 3 years follow-up.

The mean subsidence after two years was 0.055 mm (SE ±0.045 mm) and the mean axial rotation was 0.29º (SE ± 0.12º). The mean bone loss in zone 7 was 34%; in the other zones the bone loss was less than 14%. The mean bone loss in all zones was 8%.

Discussion: The short-term clinical experiences with this patient-specific, cementless femoral stem are encouraging. The stem seems to be very stable during the first two postoperative years indicating that biological fixation of the femoral stems has been achieved. The change in the BMD was less than 14% in all Gruen zones, except for the proximal medial area where the bone loss was 34%.

BONE REMODELLING AFTER INSERTION OF A CUSTOMISED FEMORAL STEM. CORRELATION BETWEEN IMPLANT VOLUME AND STRESS SHIELDING AFTER 2 YEARS MEASURED WITH DEXA

P. Benum and A. Aamodt.
Department of Orthopaedic Surgery, Trondheim University Hospital, 7006 Trondheim, Norway.

– In: Proc. European Hip Society, Baveno, Italy, 2002.

An argument against the use of canal-filling, customised femoral stems has been that such implants have a large cross-sectional area and therefore are stiffer than standard, uncemented implants, thus inducing more stress shielding and bone loss in the proximal femur. The purpose of this study was to evaluate the association between the volume of the femoral stem and the change in periprosthetic bone mineral density (BMD) measured with DEXA.

Material and methods. Forty-eight patients with a mean age of 46 years had a THR using a customised femoral stem (Unique, SCP, Norway). BMD was measured in the 7 Gruen zones postoperatively and after then 3, 6, 12 and 24 months. Based on the 3-D computer model of the implant the volume of the intrafemoral part of the stem was computed. The association between the relative change in BMD at the 2 years follow-up and the volume of the stem was assessed using correlation analyses.

Results. No statistically significant correlation between the volume of the intrafemoral part of the stem and change in BMD could be found for the most proximal zones (1, 6 and 7). Neither was there an association between the postoperative BMD value and the degree of stress shielding. However, a weak correlation between the volume of the stem and change in BMD was found in Gruen zones 2, 4, 5 and for the overall BMD in all zones.

Discussion. No consistent or strong association between the volume of the femoral stem and the periprosthetic stress shielding at 2 years postoperatively was found in this study. In particular, the bone remodelling in the most proximal part of the femur was not correlated to the size of the stem. Contrary to other studies, our findings imply that stem size or stiffness is not a major determinant for proximal femoral stress shielding following THR.

THE *UNIQUE* CUSTOMISED, UNCEMENTED FEMORAL STEM. CLINICAL FOLLOW-UP, RSA-AND DEXA MEASUREMENTS AT TWO TO THREE YEARS.

Benum, P., Aamodt, A., Haugan, K., Lund-Hanssen, H
Department of Orthopaedic Surgery, Trondheim University Hospital, 7006 Trondheim, Norway.

– In: Proc. European Hip Society, Baveno, Italy, 2002

A customised, uncemented femoral stem was introduced clinically in 1995 after several years of development and pre-clinical testing. All the patients operated in our hospital have entered a prospective clinical study. The aim of this study is to present the short-term clinical data. Furthermore, the measurement of implant migration and the periprosthetic bone remodelling at two years is also reported.

Materials and methods: The femoral stem is designed from preoperative CT-scans, machined in Ti-alloy and circumferentially coated with a 50µm hydroxylapatite (HA) layer in the proximal 50-70%. Fifty-one patients (median age 52 years) have been followed clinically for a minimum of 3 years using the Merle-d'Aubignè score. Migration of the femoral stem has been measured with radiostereometry (RSA), the precision of the measurements is better than 0.080 mm for translations and 0.30º for rotations. Periprosthetic bone remodelling is expressed as the change in bone mineral density (BMD) in 7 zones (Gruen) relative to the postoperative values. RSA- and DEXA measurements have been performed postoperatively and then after 3, 6, 12 and 24 months.

Results: One stem had to be revised after 3 months due to a periprosthetic fracture. The clinical scores were as follows (preop/3 years): Pain 2.6/5.5, ROM 3.7/5.7, function 2.7/5.9, total score 9.1/17.1. Six patients complained of thigh pain during the fist 2 years, however, this complication resolved spontaneously in 5 patients within the 3 years follow-up. The mean subsidence after two years was 0.055 mm (SE ±0.045 mm) and the mean axial rotation was 0.29º (SE ± 0.12º). The mean bone loss in zone 7 was 34%; in the other zones the bone loss was less than 14%. The mean bone loss in all zones was 8%.

Discussion: The short-term clinical experiences with this patient-specific, cementless femoral stem are encouraging. The stem seems to be very stable during the first two postoperative years indicating that biological fixation of the femoral stems has been achieved. The change in the BMD was less than 14% in all Gruen zones, except for the proximal medial area where the bone loss was 34%.

IMPLANT MIGRATION AND BONE REMODELLING AFTER INSERTION OF A CUSTOM AND STANDARD UNCEMENTED FEMORAL STEM. A PROSPECTIVE, RANDOMIZED RSA-AND DEXA STUDY

Aamodt Arild, P. Benum, K. Haugan, L. Persen, O. Schnell Husby. Dept. of Orthopaedic Surgery, Trondheim University Hospital, Norway

– *The 6th EFORT Congress, Helsinki, Finland 2003*

Aims: The aim of this study was to measure implant migration and bone remodelling of the proximal femur two years after insertion of a customized or a standard femoral stem.

Materials and methods: In a prospective, randomized study 26 hips (26 patients) have been examined postoperatively and after3, 6, 12 and 24 months using radiostereometry (RSA) and DEXA. Thirteen hips received a customized femoral stem (Unique, SCP as) and 13 hips received a standard uncemented femoral stem (ABG®, Stryker-Howmedica). An uncemented acetabular cup (Duraloc®, DePuy) was used in all hips. The mean age of the patients was 55 (24-67) years.

Results: The median displacement of the custom/standard femoral stems was 0.04/0.01 mm along the medial-lateral axis, 0.08/0.02 mm along the proximal-distal axis and 0.03/0.08 mm along the anterior-posterior axis, respectively. Statistically, there was no difference between the two groups. One custom stem subsided 5.2 mm at one year, but showed no further migration at two years. The mean decrease in bone mineral density (BMD) in all Gruen zones was 6% in the Custom-group and 7% in the ABG-group. The most pronounced bone loss was seen in Zone 7 and was 21% and 25% for the two groups, respectively.

Discussion: We found no statistically significant difference in short-term stem migration comparing a customized and a standard, uncemented femoral stem. Furthermore, the changes in bone mineral density were almost equal in femurs with either type of prosthesis.

UNCEMENTEED CUSTOM FEMORAL COMPONENTS IN HIP ARTHROPLASTY. A PROSPECTIVE CLINICAL STUDY

P. Benum, A. Aamodt, K. Haugan. Orthopaedic Department, University Hospital of Trondheim, Trondheim, Norway

– *The 6th EFORT Congress, Helsinki, Finland 2003*

The aim of this paper is to present our 7 years experience with the use of a custom femoral stem with proximal HA-coating (Unique SCP). This prosthesis was developed to optimise the fixation and the strain distribution to the proximal femur and also the biomechanics of the hip in uncemented femoral stems.

Methods: 226 hips have been operated. Mean age was 51.5 years (24-66). 44.7% of the hips were dysplastic. The prostheses were designed to optimise anteversion and leg length correction. All patients were followed with radiological and clinical examination. The maximum observation time is 7 years. Merle D'Aubigne score was used.

Results: Three patients sustained a peroperative fissure in the proximal femur (1.3%), the fissures were treated successfully with cerclage wires. One patient sustained a femoral fracture 3 months postoperatively. A dislocation of the joint occurred by severe injuries in three patients later than three months after the operation (1.3%). These joints have been stable after non-operative reduction. Thigh pain after two years was seen in only one patient. Average total score at 3 years (82 patients) was 5.68 (preop 3.12), at 5 years (28 patients) 5.65 (preop 3.12). The pain scores at the corresponding observations were 5.65 (preop 2.71) and 5.75 (preop 2.71). There have been no radiological signs of loosening or severe bone loss in observations up to 7 years postoperatively.

Conclusions: The rate of peroperative fissures, postoperative dislocations and thigh pain is low in this type of prostheses compared to most type of uncemented standard stems. This is probably due to an optimised design. The mid-terms clinical results up to seven years postop are excellent.

CORRELATION BETWEEN PERIPROSTHETIC BONE LOSS AND STEM SIZE AFTER INSERTION OF AN UNCEMENTED, CUSTOMIZED FEMORAL PROSTHESIS

Arild Aamodt, P. Benum. Dept. of Orthopaedic Surgery, Trondheim University Hospital, Norway

– *The 6th EFORT Congress, Helsinki, Finland 2003*

Aims: An argument against the use of canal-filling, customized femoral stems has been that such implants have a large cross-sectional area and therefore are stiffer than standard, uncemented implants and thus induce more stress shielding and bone loss in the proximal femur. The purpose of this study was to evaluate the association between the volume of an uncemented, customized femoral stem and the postoperative changes in periprosthetic bone mineral density (BMD) measured with DEXA.

Material and methods: Forty-eight patients with a mean age of 46 years had a THR using a customized femoral stem (Unique, SCP, Norway). BMD was measured in the 7 Gruen zones postoperatively and after then 3, 6, 12 and 24 months. Based on the 3-D computer model of the implant the volume of the intrafemoral part of the stem was computed. The association between therelative change in BMD at the 2 years follow-up and the volume of the stem was assessed using Pearson's correlation test.

Results: A statistically significant correlation between the volume of the intrafemoral part of the stem and change in BMD was found in Gruen zones 2, 4, 5 and for the overall BMD in all zones. No such correlation could be found for the most proximal zones (1, 6 and 7).
Conclusions: No consistent or strong association between the volume of the femoral stem and the periprosthetic stress shielding at 2 years postoperatively was found in this study. In particular, the bone remodelling in the most proximal part of the femur was not correlated to the size of the stem. Contrary to other studies, our findings imply that stem size or stiffness is not a major determinantfor proximal femoral stress shielding following total hip replacement.¨

COMPARISON OF CASE SPECIFIC FINITE ELEMENT SIMULATIONS WITH STRAIN GAUGE MEASUREMENTS OF THE PROXIMAL FEMUR
Sune Hansborg Pettersen, MSc , Sébastien Muller, MSc , Per Olav Østbyhaug, MD , Arild Aamodt, MD, PhD
- 16th Annual Symposium of the International Society for Technology in Arthroplasty, San Francisco, USA, 2003
Background: CT imaging of the proximal femur has made it possible to reconstruct the geometry of the femur using regular CAD-software, and to perform case specific finite element analyses. We thereby have a method to assess stress and strain patterns in a specific bone before and after implantation of the femoral stem. Methods: Finite element models of five human cadaver femurs - intact and with prosthesis - were created based on CT data, using a threshold of 600 HU to distinguish between cortical and cancellous bone. Four homogeneous linear elastic orthotropic material sets were tested for cortical bone (stiffness from 22 GPa to 14.5 GPa in axial direction). Stair climbing load was simulated, and the computed strains compared with strain gauge measurements on the medial and the lateral side of the cadaver femurs. Relative mean square errors (RMSE) were used to assess the accuracy of the simulations. Results: The intact femurs yielded average RMSE of 2% for axial strain and 12% for transversal strain. For implanted femurs the results were somewhat inferior, with RMSE of 10% and 22% for axial and transversal strain, respectively. The deviation was particularly evident in the most proximal regions, especially near the lesser trochanter where the computed strains were generally smaller than measured. Conclusions: The results of implanted femurs may give inaccurate estimates of the proximal stress shielding. However, the results of intact femurs were very satisfactory. More effort should be put into investigating the inhomogeneous character of bone tissue, correlating material properties with CT values in order to create more realistic finite element models. Clinical Relevance: Finite element analyses can be used as a pre-clinical tool in the evaluation of various prosthetic designs to give a physiologically preferable load pattern in the femur.

UNCEMENTED CUSTOM FEMORAL COMPONENTS IN HIP ARTHROPLASTY. A PROSPECTIVE CLINICAL STUDY
Pål Benum, M.D, PH.D. , Arild Aamodt, M.D., PH.D , Kristin Haugan
- 16th Annual Symposium of the International Society for Technology in Arthroplasty, San Francisco, USA, 2003
The aim of this paper is to present the preliminary results of a prospective clinical study of a CT-based custom femoral stem (Unique SCP).
Patients and methods. 302 hips have been operated. 59.6 % of the patients were women. Mean age was 51.5 years (24-66). 40.1 % of the hips were dysplastic. The prostheses were designed to obtain a femoral neck anteversion of 10 degrees after insertion, optimized medial femoral head offset and correction of leg length discrepancies up to 3 cm. All patients have been followed radiologically and clinically ; 95 for 3 years, 40 for 5 years and 14 for 7 years. Merle d'Aubigné score was used. RSA and DEXA-studies have been performed in some groups of the patients.
Results. We have experienced that the use of this type of prosthesis offers obvious advantages in abnormal size and geometry of the upper femur. An intraoperative fissure in the proximal femur was seen in 3 patients (1.0 %). These were treated successfully with wires. One patient sustained a femoral fracture 3 months postoperatively. A dislocation of the joint occurred by severe injuries in three patients later than three months after the operation (1.0%), all these joints have been stable after non-operative reduction. Average total score at 3, 5 and 7 years was 16.98 , 17.19 and 17.39, respectively. The pain scores at the corresponding observations were 5.62, 5.79 and 5.77. There have been no radiological signs of loosening. DEXA-studies have shown good preservation of the femoral bone stock. RSA showed no significant migration of the stems.
Conclusions. Use of custom femoral components enable optimization of the biomechanics of the hip and eliminates the need for highly modular femoral stems. The rate of mechanical complications is relatively low indicating adequate fit of the stem and adequate design of the neck . The mid-term clinical results up to 7 years are promising.

CUSTOM FEMORAL STEMS IN OSTEOPETROSIS. DEVELOPMENT OF A GUIDING SYSTEM FOR PREPARATION OF AN INTRAMEDULLARY CAVITY. A CASE REPORT
Pål Benum, M.D, PH.D. , Arild Aamodt, M.D., PH.D.
- 16th Annual Symposium of the International Society for Technology in Arthroplasty, San Francisco, USA, 2003
Background: Insertion of femoral stems in hip replacement in patients suffering from osteopetrosis has been reported to be extremely difficult since obliteration of the intramedullary cavity of the femur and an increased

hardness of the bone prevent a well controlled reaming of the cavity. Hence we developed a method that could secure a safe insertion of a femoral component in such patients.

Material and methods: A 32 years old woman affected by benign autosomal dominant osteopetrosis presented with severe complains due to osteoarthritis of both hips. CT revealed an extreme density of the cortical and trabecular bone of both femurs, and almost complete obliteration of the intramedullary cavity. It was obvious that free-hand reaming of a cavity suiting a standard prosthesis would carry a considerable risk of penetration and fracture of the femur. Hence we developed a CT-based uncemented custom component and a guiding device for resection of the femoral neck and preparation of a suitable intramedullary cavity. Clamps fitting exactly to the circumference of the proximal femur at defined levels were made by CNC-machining to secure a correct position of the device. A block with channels for various drill bits guided the preparation of the cavity for the prosthesis. A custom broach was then used. The two hips were operated within a period of 6 months, the last operation was recently performed.

Results: In both hips the method enabled insertion of a prosthesis with an accurate fit. No problems were experienced during the operations. Six months following the first operation the patient had an excellent function of the hip and she was free of pain. X-rays showed no signs of loosening.

Conclusion: The presented method seems to secure a safe insertion of a femoral component of adequate size and geometry in femurs with an obliterated intramedullary cavity.

DIFFERENCES IN STABILITY BETWEEN THE SCANDINAVIAN CUSTOMIZED PROSTHESIS (SCP) AND THE CEMENTED ELITE PLUS FEMORAL STEM

A randomized prospective study with radiostereometric 2 year follow up

L Nordsletten, F Snorrason, P Grant , A Aamodt2,
Orthopaedic Centre, Ullevål University Hospital and 2Orthopaedic Clinic, St Olavs Hospital Trondheim, Norway

In: Proc. of the Annual meeting of the Norwegian Orthopaedic Society, Oslo, 2003.

New prosthesis designs should be compared to a standard implant in randomized studies evaluated by radiostereometric analysis (RSA). The Unique customized prosthesis (UCP) is a newly developed concept for fitting uncemented prosthesis to the exact internal shape of the proximal femur [1]. We evaluated the new UCP design with the null hypothesis that this implant would be no more stable than a standard cemented implant.

Material and Methods

38 patients, mean age 51.6 years (31-65) were randomized to a SCP HA coated femoral stem or an Elite Plus (DePuy) cemented stem. All patients were implanted with a Duraloc (DePuy) uncemented cup except one patient with a protrusio who was primary impaction grafted with a cemented cup. Most patients received a Zirconium head, and all heads were 28 mm. The femoral stems were fitted with 3 tantalum balls and 4-10 tantalum balls were implanted in the femur during operation. RSA pictures were taken postoperatively, after 6, 12 and 24 months.

Results

The Elite Plus stem rotated more into retroversion after 6, 12 and 24 months (0.64° vs 0.11° after 6 month, 0.64° vs 0.25° after 12 months,1.06° vs 0.11°, P=0.01). Subsidence after 2 year was 0.18 for Elite Plus and 0.13 for SCP, (not significant). In the other directions there were no significant differences in rotations or translations, but the variability was higher in the Elite Plus group.

Discussion

The customized SCP stem were more stable in retrorotation than the cemented Elite Plus stem. Compared to other results with the Elite Plus rotations and migrations were small in this study [2]. The excellent stability of the SCP stem is promising for long term stem fixation.

Ref

1. Aamodt, A., et al. J Bone Joint Surg Br 81, 143-7. (1999).
2. Alfaro-Adrian, J., et al. J Bone Joint Surg Br 81, 130-4 (1999).