GTS (Global Tissue Sparing)
Femoral Hip Stem: Design validation through initial clinical results

Introduction
The GTS (Global Tissue Sparing) stem was developed by Professor Guido Grappiolo to address the demands for primary cementless stem for use in tissue sparing total hip arthroplasty. The benefits and potential complications of this surgical philosophy being summarised in the review article1 by Malik, A. and Dorr, L.D referenced below.

The femoral stem design aims to provide the critical features of tissue preservation and optimal implant stability which contribute towards good clinical efficacy and implant longevity:

**Tissue Preservation**
The GTS stem is designed to allow implantation during which the greater trochanter is preserved with limited disruption to the gluteus medius muscle thus enabling a minimally invasive surgical approach2–5 with maximum bone preservation. This is enabled by using a relative short stem (93.4 mm – 139 mm) with a pronounced reduced lateral shoulder which allows for a curved insertion of the stem into the metaphysis.

The tapered wedge design of the stem provides a metaphyseal press-fit limiting the invasion into the femoral canal, reducing distal load transfer and potentially eliminating post operative thigh pain.5 The limited destruction of proximal femoral bone during implantation of the GTS stem thus preserves bone stock making any subsequent revision arthroplasty easier.

**Optimal implant stability**
Immediate post operative implant axial stability is attained in the GTS design by the incorporation of a 9.6° tapered stem. Rotational stability is attained by the stems elliptica-octagonal cross section and longitudinal fins which cut through the compacted femoral bone (Fig. 2).

These longitudinal fins differ to conventional fin design in that they have an almost organic appearance. This unique design not only helps enhance rotational stability, but may also improve compression of the cancellous bone while also maximizing bone contact.

The stem geometry, together with the use of compression rasps, produces a tight interference fit with the bone which in the proximal portion of the stem can produce between 0.3 mm to 0.6 mm anterior/posterior and 1.8 mm of lateral press fit. In this manner bone can be conserved due to the compaction of the cancellous bone,7 which in other stem designs would be removed. Cancellous bone compaction in addition to providing primary stability8 preserves the intramedullary blood supply.

The in-vitro stability of the GTS stem has been evaluated9 against several cementless stems. The rotational stability at the proximal 2/3 anchorage being comparable to VerSys® E.T® and CLS® (Zimmer Inc.) designs. The CLS® stem has longitudinal ribs on its surface designed to enhance primary implant stability and provide fixation into cancellous bone.
Although there is clinical evidence that these ribs do not contribute toward bone ingrowth,10 other information11 would suggest that they are of assistance in attaining primary implant fixation and the maintaining bone mineral density in the proximal femur for significant periods post operatively.

The GTS stem an Interloc grit blasted surface to encourage bone apposition and facility secondary fixation. Evidence12 of bone on-growth exists from the use of this surface on other Biomet stems (Bi-Metric). The Interloc surface also provides a periarticular seal13 which, if polyethylene wear debris is present, provides a barrier to its transmission along the implant/bone surface interface and, therefore reducing the potential for polyethylene induced osteolysis.

Grit blast surface finishes have successfully been used in other press-fit stem designs with document14–16 excellent long-term implant survivorship. However, the surface finish on the GTS stem is coarser that the micro-porous surface treatment17 used on the CLS® stem.

Initial Clinical results
To date there have been two presentations/publications on the early clinical results from the use of the GTS stem. An immediate post operative radiographic evaluation by Professor Alessandro Massé18 and 1 year clinical results19 have been evaluated by Professor Guido Grappiolo.

Radiographic Evaluation.
The aim of this study was to determine whether the GTS stem was able to:
1. Reconstruct femoral offset
2. Restore the cervico-diaphyseal angle.
3. Minimise/eliminate leg length discrepancy.

The study involved reviewing radiographs from 54 patients with less than 5 months follow up. The average age of the patients was 59 years, but included those from >70 and <30 years (Figure 3.)

All patients had a total hip arthroplasty surgery, utilizing the GTS stem, at Istituto Clinico Humanitas di Rozzano, Milan, Italy. The etiopathology at the time of surgery was predominantly (81.5%) idiopathic osteoarthritis but also include patients who presented with developmental dysplasia of the hip, femoral head osteonecrosis, perthes, post traumatic arthritis and a previous hip resurfacing.

Preoperative radiographs were reviewed to measure:
• Offset – femoral offset is the distance from the centre of rotation of the femoral head to a line bisecting the long axis of the femur
• Diaphysis/neck angle
• Leg length discrepancy
• Flare index - The ratio of the endosteal canal diameter 2 cm below the lesser trochanter and the endosteal canal diameter 10 cm below the lesser trochanter.
• Cortico-Medullary index – The ratio of the cortical bone diameter 10 cm below the lesser trochanter and the medullary canal diameter at the same level.
• Post operative radiographs were examined to measure the above parameter plus the metaphyseal filling rate and any signs of bone resorption.
• Metaphyseal filling rate – The ratio of the medullary canal dimension 2 cm above the lesser trochanter and the prosthesis dimension at the same level.

Fig. 4:
Radiograph at 1 year follow-up
Following the use of the GTS stem the reconstructed mean femoral offset was 50.23 mm compared with the mean preoperative value of 51.0 mm. A similar reconstruction of the native cervico-diaphyseal angle was attained, from a mean 130.7° before surgery to a mean 128.3° after surgery.

The use of the GTS stem produced no discernible increase in leg length. Pre-operatively the patient population had a mean leg length discrepancy of -1.2 cm. Post-operatively the mean discrepancy was reduced to 0.2 cm.

The flare index and cortical-medullary index measured preoperatively were 3.48 (S.D ±1.89) and 2.28 (S.D. ±1.2), respectively. The metaphyseal filling rate, an indication of how well the implant fits the proximal femur, was 1.44.

The post operative radiographs were also examined for signs of radiolucency or resorption. At a maximum of 6.7 months post-op. there were no signs of either radiolucency or resorption.

**Clinical Evaluation**

In early published clinical results, the use of the use of the stem is described in 570 total hip arthroplasties and the clinical and radiological results from 100 patients who had attained 1 year or more follow up is provided. The patient demographics, implants used and assessment methods used were as follows:

**Patient demographics:**

Five hundred and seventy GTS stems were implanted in 539 patients. The average age of the patients was 57.8 years (range 17.3 – 88.1) and 283 (52.5%) were male.

The patient's aetiology was predominantly (61%) idiopathic osteoarthritis but also included congenital dysplasia, aseptic necrosis of the femoral head and sequelae resulting from perthes disease and trauma. Posterior lateral surgical approach was used on all patients.

**Implants utilized:**

**Femoral Stems:**

485 procedures (85%) used Standard stems with 133° cervico-diaphyseal (CD) angle, 84 (17.3%) of which were size 0. The stem size distribution for standard and varus stems is provided in Figure 5 and Figure 6.
Acetabular Cups
Cementless acetabular cups were used in all surgeries. They included Exceed ABT (Biomet UK Ltd), M’a- Magnum (Biomet UK Ltd), Regenerex (Biomet Orthopaedics), Avantage (Biomet France) and others. The percentage of cup types used is shown in Figure 7.

Femoral head/acetabular liner articulation materials:
The Femoral head size used was either 32 mm or in the cases of larger cups 36 mm diameter. The majority (57%) of surgical procedures used ceramic on polyethylene articulating bearings of which 234 (77%) cases utilised vitamin E stabilised (E1) polyethylene. Other articulations included ceramic-on-ceramic, metal-on-metal and metal-on-polyethylene. The distribution of articulating surfaces used is given in Figure 8.
Method of clinical assessment:
The clinical efficacy of the GTS stem seen in the first 100 patients (all of whom were at least 12 months from surgery) was assessed by the use of Oxford Hip, Harris Hip scores and the incidence of adverse events. The hip scores were measured at 45 days, 3 months, 6 months and 1 year following surgery.

Results:
Pre-operative and post-operative scores were available for only 84 of the 100 patients documented in the publication. The Oxford hip score, undertaken by a patient administered questionnaire, increased from a mean pre-operative value of 24.85 (range 0-45) to a 12 month mean of 47.7 (range 44-48). As this score has a highest attainable value of 48 from patient and function questions, the scores obtained would indicate that GTS patients are attaining low pain and high hip function at 12 months post-op. Similarly, the Harris Hip Score in these same patients increased from a pre-operative mean of 53.9 (range 24-90) to a 12 month mean of 99.2 (range 93-100).

Adverse events:
The incidence of intra-operative complication in this series was small. Intra-operatively there were 5 cases (0.9%) of spitting of the femur above the lesser trochanter these complications occurring early on in the learning curve associated with this new system. All the implants were stable, however in 3 cases circlage wiring was used and in the other 2 cases transverse screws were used to close the split.

Postoperatively there was one adverse event (traumatic fracture) due to a patient falling in the rehabilitation phase. This patient subsequently had revision surgery. Three further required wound debridement due to suspected sepsis.

Planned studies

RSA evaluation:
In order to verify the in vitro stability studies and provide evidence for regulatory agencies, an in vivo stability/motion study is planned for the GTS stem. The evaluation will compare the stability (both primary and secondary) of the GTS against that of the HA coated Taperloc stem in patients undergoing primary uncemented total hip arthroplasty.

In the planned 50 patient randomised controlled trial the stability and motion of both implants will be determine via the model based RSA method, all patients will receive the uncemented Regenerex cup.

The study will be undertaken at the MC Haaglanden Hospital, Netherlands and RSA measurements will be taken pre-operatively and at 3 months, 6 months, 1 year, 2 years and 5 years intervals. Bone mineral density measurements will so be taken via DEXA at the same time intervals to determine the effect on the imposition of the stems on bone remodelling in the proximal femur.

Using the RSA technique the study will be able to measure stem position translation in the x, y and z directions with an accuracy of between 0.05 and 0.5 mm and rotational changes to an accuracy of between 0.15° and 1.15°. The hypotheses for the study being that the implant stability for the GTS is equal to that of the well documented, clinically proven Taperloc stem in the initial two years and also thereafter.

Multicentre clinical evaluation:
To date all the clinical data on the GTS stem has results from its use by Professor Grappiolo and his colleagues. To confirm the initial promising clinical results and verify that the GTS stem is capable of providing excellent performance in the hands of other clinicians, a multi-centre clinical study is being initiated.

This prospective study will determine long-term implant efficacy for both standard and varus versions of the GTS stem. 250 patients will be recruited from 5 clinical centres (50 patients each). This will include 125 patients with standard stems and 125 patients with varized stems. These hospitals will be in Germany(2), Italy, Spain and France.

Patients will be included if they present with the following etiologies:
- Primary and secondary coxarthrosis
- Inflammatory (Rheumatoid) arthritis
- Avascular necrosis of the femoral head
- Sequelae from previous operations to the hip
- Congenital hip dysplasia.
The primary outcome measure for this evaluation will be the mean Harris Hip score at 2 years post operative. The secondary outcome measures include:

- Radiographic evaluation
- Patient satisfaction, measured using EQ5-D
- Incidence and nature of adverse events and complications
- Implant survivorship.

Patients will have a follow-up examined at 3 months, 1 year, 2 year, 3 year, 5 year, 7 year and at 10 years.

**Conclusion**

Several design features incorporated in the GTS stem have been validated and documented in peer reviewed publications. These include tissue preservation, bone conservation and the use of a grit-basted surface finish.

The initial stability of the stem has been evaluated against other documented brands via in vitro mechanical testing, the stability of the GTS stem being equivalent to stems with long-term clinical results.

Early results from its clinical use confirm that the GTS stem is able to reconstruct the native hip anatomy in terms of the restoration of the cervico-diaphyseal angle and femoral neck offset.

Initial clinical outcomes, although of very short-term nature, indicate that the GTS stem is able to reconstruct the native hip anatomy and provide patients with pain relief and good hip function. A low incidence of complications associated with the use of the GTS has been documented. The majority of which occurred intra-operatively and may be associated with the learning curve present with the introduction of any new implant system.

Provision has been made to quantify the stability of the stem in an RSA investigation and determine its clinical outcome in other non-designer clinical centres by the use of a multi-centre study.

**References**


9. Laboratory report. Standardized in vitro characterisation of the initial fixation behaviour and medio-lateral bending behaviour of the GTS stem in composite femurs. Laboratory of Biomechanics and Implant Research, Heidelberg University Hospital. Data on file at Biomet.


18. Massè, A. *et al.* GTS user group meeting, Milan, April, 2011.


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