Anatomically adapted, HA coated SBG stem – Ten years of successful implantation

Anatomisch adaptierte, HA beschichtete SBG Prothese – 10 Jahre erfolgreiche Anwendung

Key words: SBG stem, hip arthroplasty, cementless, anatomic adapted shape, HA-coating

For stable implantation of anatomically conforming femur prostheses, modifications that accommodate curvature and torsion are necessary. In accordance to this concept, the anatomically shaped SBG stem has been developed. The first consecutive interventions were evaluated. 194 primary arthroplasties with un Cemented, HA coated SBG stems were performed. Mean patient age was 61 years. 143 patients with 151 (78%) SBG stems were followed-up clinically and radiologically after an average of 10.9–11 years.

So far, only one implant had to be revised. Survivorship with revision of the femoral component is 99.5% at ten years. The mean postoperative Harris Hip Score was 92. Patients over 75 years had a score of 89; younger patients under 40 years scored 94.

Sclerotic lines were seen in zone I or VII in 8%. Minor femoral remodelling (Type 1) occurred proximally in 75%. Minor thickening of the femur at the level of the tip of the prosthesis could be observed in 27% of the cases. There is no correlation between compacta thickening and clinical symptoms ($p=0.15$).

The anatomical shape, the oval diameter and the longitudinal grooves secure stable primary fixation. Together with the HA coating, which enhances osseointegration, the SBG stem has a high success rate in the medium and long term.

Introduction

Based on the principle that an endoprosthesis should be anatomically correct and induce an optimal uniform load transfer, a femur component should be available as a right and left-sided version. If an implant should conform completely to the anatomy of a patient, this implant will be custom-made. This is of course technically complex and expensive and not suitable for routine clinical use. Furthermore, in order to implant a femur component, compromises between the ideal anatomical form and practicability for implantation must be made. A component that has the exact same s-shaped curve and torque of the proximal femur can not be implanted (Fig. 1a), because – due to necessary preparatory bone resection – the reamed opening would be larger than the reamer and component. Hollow spaces between bone and shaft would be the result; this contradicts the principle of an ideal anatomical press fit. Only modified components without complete anatomical congruency can be implanted. This especially concerns

Schlüsselwörter: SBG Prothese, zementfreie Hüftendoprothetik, anatomisch adaptierte Form, HA-Beschichtung


Postoperativ wurde ein Harris Hip Score-Wert von 92 erreicht, wobei die Patienten unter 40 Jahren einen Score-Wert von 94, Patienten über 75 Jahre von 89 haben. Sklerosierungen zeigten sich maximal in Zone I oder VII (Typ 1) in 8%. Ein geringes Remodellieren des Schaftes (Typ 1) trat proximal in 75% der Fälle auf. Keine Korrelation zwischen compacta Veränderung und klinischen Symptomen lässt sich ($p=0.15$).

Durch die anatomisch adaptierte Form, den ovalen Querschnitt sowie Längsrillen wird primär eine optimale Rotationssicherheit erreicht. Zusammen mit der Titanlegierung sowie der HA-Beschichtung werden damit ausgewiesene Langzeitergebnisse erreicht.
Material and Methods

Implant design

The SBG (Stolzalpe-Buchner-Graf) stem (Fig. 2a-c) has an anatomically adapted form [8]. The medial (Fig. 2b) and lateral (Fig. 2c) sides are flat. The surface is completely covered by fine longitudinal grooves. The ventral surface at the cortical planum is flat and corresponds to the anterior or inner surface of the cortical bone. The long axis of the stem is twisted by 30° (Fig. 2d, e) and has torque similar to a screw, i.e. to the torque of the femur. The stem is made of a titanium alloy (Ti 6Al 4V). The surface is completely corundum blasted for improved osseointegration. The proximal two thirds of the stem has a 150 μm thick hydroxyapatite coating (Osprovit®, Geramtec, Plochingen, Germany [20]). Twelve different sizes are available for both the right and left joint.

The taper has a modular system on which either straight or swivel sleeves can be attached in order to procure a specific position (valgus or varus; retro- or antetorsion, Fig. 2f, g). The femoral head can be turned in steps of 30° by 360° which enables an individual positioning, not only in length but also in cases with difficult anatomy, just like a building block system.

Surgical technique

The implantation procedure is easily performed. The anatomical reamer finds „its own way“ with self settlement and must not be guided by the surgeon. The anatomy – whether valgus, varus; retro- or antetorsion – can not be altered by the surgeon. Both reamer and stem adapt automatically to the anatomy.

Patients

194 SBG stems which had been implanted between August 1990 and December 1991 in primary arthroplasties of the hip were evaluated. Mean age of the 185 patients at the time of surgery was 61 years (Table 1).

In 64 cases, the anatomy was severely deformed necessitating the swivel sleeve system in order to procure a more normal biomechanical condition. Most of these patients had received varus or valgus osteotomy in previous years or had very difficult anatomies due to pelvic osteotomy.

The patients received 2g Cephamandol (Mandok®) immediately before surgery. In case of prolonged surgery the dose of antibiotics was repeated. Surgery was conducted under laminar-flow; the approach in the supine position was anterolateral. Unrestricted loading was allowed directly after surgery as far as possible. Crutches were recommended for six weeks for recuperation; sport activities could be resumed after 3 postoperative months.
### Table 1: Patient data

<table>
<thead>
<tr>
<th>Period</th>
<th>8/1990 - 12/1991</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of implants</td>
<td>194</td>
</tr>
<tr>
<td>Patients</td>
<td>185</td>
</tr>
<tr>
<td>Average age</td>
<td>61 years (17-80)</td>
</tr>
<tr>
<td>Revision</td>
<td>1 (traumatic femoral fracture)</td>
</tr>
<tr>
<td>No follow-up</td>
<td>43</td>
</tr>
<tr>
<td>(not available, FU &lt; 9 years, died)</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Number of implants</td>
<td>151 (78%)</td>
</tr>
<tr>
<td>Number of patients</td>
<td>143</td>
</tr>
<tr>
<td>Years (min., max.)</td>
<td>10 (9-11)</td>
</tr>
</tbody>
</table>

#### Follow-up

143 patients with 151 (78%) total hip arthroplasties could be followed-up after an average of 10 years (9-11 years) either clinically or with a questionnaire. 43 patients had either died or were lost for at least 9 year follow-up. The results were analyzed using the Harris-Hip Score [11].

The results were also analyzed radiologically. X-rays were assessed for radiolucent lines, osseointegration, osteolysis, compacta thickening and newly formed bone trabeculae [4]. The assessment of heterotopic ossification was based on Brooker’s criteria [1].

#### Table 2: Results (Scores)

<table>
<thead>
<tr>
<th>HHS preop (min., max.)</th>
<th>41 (26-51)</th>
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<tbody>
<tr>
<td>HHS postop (min., max)</td>
<td>92 (57-100)</td>
</tr>
<tr>
<td>Pain score</td>
<td>42 (10-44)</td>
</tr>
<tr>
<td>HHS old patients (&gt;75a)</td>
<td>89</td>
</tr>
<tr>
<td>HHS young patients (&lt;40a)</td>
<td>94</td>
</tr>
</tbody>
</table>

### Clinical findings

The preoperative Harris Hip-Scores were poor in quite a number of cases with an average of 41 points. This increased to 92 points after 10 years. Patients under 40 years scored 94 points, those over 75 years scored 89 (Table 2).

58 patients were completely pain free, 26 were able to walk unlimited distances and participate in sports activities. 26 patients had uncharacteristic pain but were not limited in their activities and able to participate in sports.

The total score for male patients (94 points) was significantly higher (p<0.05) than for female patients (92 points). The score values decrease significantly as patient age at the time of surgery increased (r = -0.14).

### Radiographic findings (Table 3)

Proximal radiolucent lines were observed in zone I or VII in 8%. Therefore complete osseointegration without any radiolucency (type 0) was observed in 92% (Fig. 4b). Minimal remodeling (Fig. 4b, 5b) occurred in 75%, moderate in 2% and severe in 1%. At the height of the distal third of the shaft, thickening of the cortical bone was minimal in 27%, moderate in 9% and severe in 2%. We found no correlation (p = 0.24) between the total score and the grade of compacta thickening.

The formation of new bone trabecula was notably apparent in 27% (Fig. 5b). Heterotopic ossification grade 1 was observed in 58%, grade 2 in 14% and grade 3 in 9%.

The score for Brooker’s criteria III (87.1 points) was no-
tably decreased in comparison to stages 0-II with scores of 89.5 to 93.7 points (p=0.057).

Histology

The SBG stem that was removed six months after implantation due to a fall showed integrative and adherent osseous ongrowth on the contact areas all over the hydroxylapatite coated surface (Fig. 6). Resorbtion lacunas were observed in some areas, where the hydroxylapatite coating had „peeled off“ and was being replaced by new bony tissue [14].

Discussion

So far there are no long-term results with anatomic-adapted HA-coated stems. There are some straight stem designs with highly successful results at 10 years or more. Ender [7] had a survival rate of 95% at 12 years with his AML stem. The femoral revision rate was 1.4% and the loosening rate 1.7%. Kim [13] used the same stem and reported a 98% survival rate at 11 years, whereby the revision rate was 1.9% and the loosening 5.8%.

Grappiolo [9] had a 7% revision rate for the CLS stem after 12.6 years: Two hips were revised for aseptic loosening, five for septic loosening and twelve hips with osseointegrated stems for severe progressive femoral osteolysis. Survivorship of the femoral component was 95 percent at ten years and 90 percent at fourteen years. Schramm [17] had no femoral revisions after 10 years for the CLS stem implanted in young patients.

Burt [2] used the Trilock stem and found a 95% survival rate at ten years although there was a revision rate of 6.1%. Loose femoral components were observed in 3%.

McLaughlin [15] described a 98% survival rate at 12 years with the Taperlock. There were two revisions but no loose femoral stems.

Gübel [10] calculated a 99% probability of survival with the Zweymüller SL stem at ten years. Studies of our own [5] had a 10-year survival of 97% for the Zweymüller SL stem. Two stems were revised because of late infection. The same study showed a 63.9% survival rate for the Schenker SK stem.

The life-table analysis of Eigentner [6] indicated an overall survival rate of 97.1% after 11 years for the Biconact stem. The proximally plasma spray coated Biconact stem had no sclerotic lines in this area, whereas radioluencies could be observed in the distal zones from 2.9% to 10.9%. Although there was proximal fixation 12.7% of distal cortical thickening could be observed. Additionally 79.4% of mild remodelling occurred.

The increase of compacta at the level of the shaft tip in our study may be an indication of distally intensified induction of load due to the great variability of the femur.

Intraoperative shaft fractures occurred in 4.5% in the beginning of our series because the attempt was made to turn the implant in a certain direction during surgery. This apparently caused disjointing which led to the frac-

Figure 3. Survivorship analysis. The Kaplan Meier survival curve, with revision of the femoral component is 99.5% (95% CI 98.4-100) at 10 years.

Figure 4. Complete Osseointegration (Type 0) and remodeling Zone VII (Type 1). Fig. 6a shows the postoperative situation.

Figure 5. Correct postoperative situation (a). Newly formed trabeculae 7 years postoperatively in Zone VI (b).
tures. If the SBG component was allowed to settle in with- out force, these fractures did not occur. However, more an- teversion may be reproduced.

In the beginning of the 90’s we had not yet routinely ad- ministered prophylactic treatment against ossification. As a result, 25% of the cases had heterotopic ossification grade 2 or 3 at follow-up.

The swivel system optimizes biomechanics [19] and reduces the danger of impingement using hard-hard pair- ings. There was no case of dislocation in the patient collect- ive and verifies the efficiency of the swivel sleeve system. The taper of the stem is designed according to a building block system. The sleeve system procures the best biome- chanical position for optimal fit and mobility; even in cases with difficult anatomy and with previously implanted acetabulum and stem.

The above mentioned explanted SBG-component did not belong to the followed-up collective. However the his- torical analysis thereof confirmed the positive osseointegrative qualities of the hydroxyapatite coating. Our observa- tions confirm the reports on rapid HA-induced osseo- integration [12, 14, 16, 18]. Early on, a three dimensional trabecular network is created that can positively influence the proximal transmission of load. Within 6 weeks after surgery, the HA-coating is diffused by new bone that sticks to the titanium surface [14]. HA can only „attach“ bone, but cannot compensate for a poor implant design, insufficient rotational stability or inadequate surface design.

If soft tissue conditions are unproblematic, patients can be mobilized immediately after surgery and practice loading during four point gait exercises. In most cases, patients can walk without crutches after 6 postoperative weeks.

The SBG prosthesis is a user-friendly component that can be implanted to fit specific anatomies. The HA coating guarantees early osseointegration. As only one implant was revised in our patient collective after almost 10 postoperative years, this implant can be recommended.

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References


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