Midterm Results After Coated and Uncoated TKA: A Randomized Controlled Study
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Total knee arthroplasty (TKA) is an effective treatment option for advanced osteoarthritis of the knee.1 Although patients clearly benefit from joint replacement in terms of mobility and quality of life, implant-specific local and systemic adverse effects, due to corrosion, wear, and release of metal ions, still constitute a matter of concern.2,3 The release of metallo-organic complexes may trigger local and systemic toxic effects, activate the immune system,4 induce a delayed-type hypersensitivity reaction5-7 and may even contribute to the pathophysiological mechanism of aseptic loosening.2

Elevated metal ion concentrations8 and increased rates of metal hypersensitivities have been reported9,10 after TKA. However, the influence of these findings on outcome after TKA remains unclear.

According to guidelines,11 patients with hypersensitivity to implant materials usually receive hypoallergenic implants. Reduction of metal ion release by coating of a standard implant is a common solution. In vitro biomechanical tests demonstrated a reduction of metal ion release and superior tribological characteristics of these coated TKA implants and thus, less polyethylene wear particles.12-15 However, it is unknown whether these costly implants add a patient-relevant value in vivo with regard to hypersensitivity reactions, metal...
ion release and improved long-term results by reduced wear. There have even been reports about less favorable clinical results and blistering of the coating caused by differences in stiffness between implant and coating. A novel 7-layer coating system has been developed to solve these problems by a gradient change in stiffness between the implant body and the final coating layer.

The current study was initiated to investigate this novel coating system in comparison to the standard implant. This is a follow-up report of an earlier published study, comparing the midterm outcomes between coated and uncoated TKA.

**MATERIALS AND METHODS**

After institutional review board approval and informed consent of each patient, a total of 120 patients without known hypersensitivities against implant materials were randomly assigned to receive a coated TKA implant (n=61) or an uncoated standard TKA implant (n=59). Both implants were similar except for the coating. Before surgery, 3 months after surgery and yearly thereafter, the Oxford Knee Score (OKS, maximum 48 points) was filled in. Nonresponders were contacted by phone. Adverse events were assessed at all visits.

A total of 111 patients were available for the last follow-up at 4 years, 58 in the coated group and 53 in the standard group (Figure 1). Three patients had died, 1 patient (standard group) underwent revision TKA after 34 months because of medial instability and chronic patellar dislocation, 3 patients refused to continue participation, and 2 patients were unable to respond because of severe illness unrelated to the TKA.

**Implant**

The Columbus Knee System (B. Braun, Aesculap, Tuttlingen, Germany) is a CE-certified TKA, and all metal components consist of a CoCrMo-alloy (ISO 5832-4) containing 58.65% to 64.65% cobalt, 26.5% to 30.0% chromium, 4.5% to 7.0% molybdenum, and less than 1.0% nickel. A multilayer coating system (Advanced Surface, B. Braun) was developed to reduce ion release and includes a thin adhesive chromium layer, 5 alternating intermediate chromium nitride-chromium carbonitride (CrN-CrCN) layers, and a final shielding layer of zirconium nitride (ZrN). This 7-layer coating system was applied on the CoCr-Mo knee implants using a physical vapor deposition method with a total thickness of about 4 µm.

**Operative Procedure**

A coated or uncoated unconstrained cemented TKA with a fixed polyethylene insert was implanted without patellar resurfacing in all patients. All operations were performed with a tourniquet after a single 1.5-g dose of antibiotics (cefuroxime), using a medial parapatellar approach and a conventional measured resection technique. Full weight bearing was allowed postoperatively, and mobilization began from postoperative day 1.

**Statistical Analysis**

Data description was based on means and standard deviation for continuous variables and absolute and relative frequencies for categorical variables. Comparisons
between treatment groups were done by paired t-test for continuous variables and chi-square test for categorical variables. Implant survival was analyzed using the Kaplan-Meier function, and differences between groups were compared using the log-rank test. Significance level was set at \(P<.05\). The software SPSS for Windows version 21.0; (IBM Corp, Armonk, New York) was used for data analysis.

RESULTS

The 2 groups were not different with regard to preoperative and perioperative data, such as gender, age, body mass index, length of hospital stay, cut-sew-time and comorbidities (Table).

With regard to implant survival both groups demonstrated excellent midterm results with only 1 revision in the standard TKA group (Figure 2). There was no significant difference between both groups (\(P = .296\)).

Adverse Events

Two patients with coated TKA implants underwent reoperations without implant revision because of hematoma shortly after surgery.

Four patients with standard TKA implants underwent reoperations without implant revision: 1 wound dehiscence after a fall, 1 deep infection treated with debridement and irrigation and inlay exchange 7 months after surgery, 1 open arthrolysis after failed manipulation under anaesthesia 32 months after surgery, and 1 secondary patellar replacement 34 months after surgery.

Patient-Reported Outcome

The OKS improved substantially in both groups from 21.6 points (SD, 6.2) preoperatively to 39.5 points (SD, 7.8) 4 years after surgery in the coated group and from 21.9 points (SD, 7.6) to 39.2 points (SD, 7.9) in the standard group, respectively. Over the course of the successive follow-ups a steady improvement was realized until 2 years after surgery. The subscores demonstrated a more pronounced improvement in the OKS pain component (coated TKA 108%, standard TKA 100%) and less

<table>
<thead>
<tr>
<th>Preoperative Data for the Remaining 111 Patients</th>
<th>Coated TKA n=58</th>
<th>Standard TKA n=53</th>
<th>(P) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at surgery, mean (SD), y</td>
<td>66.6 (9.0)</td>
<td>68.6 (7.9)</td>
<td>.222</td>
</tr>
<tr>
<td>Female gender (%)</td>
<td>53.4</td>
<td>56.6</td>
<td>.849</td>
</tr>
<tr>
<td>BMI, mean (SD), kg/m²</td>
<td>31.3 (5.3)</td>
<td>30.5 (4.9)</td>
<td>.388</td>
</tr>
<tr>
<td>ASA (% grade 3/4)</td>
<td>37.9%</td>
<td>41.5%</td>
<td>.846</td>
</tr>
<tr>
<td>Operative time, mean (SD), min</td>
<td>86.8 (17.0)</td>
<td>86.1 (16.2)</td>
<td>.839</td>
</tr>
</tbody>
</table>

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; TKA, total knee arthroplasty.
but still substantial improvement in the OKS functional component (coated TKA 56%, standard TKA 54%; Figure 3).

**DISCUSSION**

With a growing number of TKAs and a high prevalence of contact allergies to metals, there is a need for hypoallergenic implants. Although correlation between hypersensitivities diagnosed by epicutaneous skin testing and deep-tissue hypersensitivities is still a matter of debate, guidelines recommend the use of alternative implant materials in patients with a metal hypersensitivity. Ceramic femoral components can be used, but these implants are expensive, and their application is more demanding. Therefore, in most patients with a metal hypersensitivity, coated standard implants are used. In addition to demonstrating reduction of metal ion release, these coatings demonstrated superior abrasive properties and reduction of polyethylene wear. However, there have been reports about less favorable clinical results. Blistering of the coating caused by differences in stiffness between implant and coating has been reported. Therefore, it is not known whether these costly implants are beneficial for patients.

In this study, midterm results demonstrated significant functional improvement in both groups comparable to literature results of TKA. Only few studies comparing coated and standard implants could not demonstrate better results for coated TKA. Survival was excellent in both groups, with a calculated 5-year-survival of 100% in the coated and 98.1% in the standard TKA group, respectively. In the National Joint Registry, the cumulative risk of revision was 2.15% after 5 years for cemented TKA, and 3.7% for TKA in patients with osteoarthritis in the Australian National Joint Replacement Registry. Although the current authors did not observe any problems during midterm follow-up with the novel coating, longer term results are necessary to evaluate possible advantages such as reduced polyethylene wear.

This is, to the knowledge of the authors, the largest series comparing coated and uncoated TKA in a randomized controlled setting. Limitations include the exclusion of patients with a history of metal hypersensitivity, and therefore, the target population for coated implants. According to guidelines, standard patients with a history of metal hypersensitivity should receive a coated implant and therefore could not be randomized.

In conclusion, the current authors observed no problems with the new coating during midterm follow-up and no differences between both groups with regard to implant survival and patient-reported outcome.

**REFERENCES**


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