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Clinical Results of Oxidized Zirconium Femoral Component in TKA. A Review of Long-Term Survival

Review Article

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Abstract *Background:* Oxidized zirconium (OxZr) femoral component for total knee arthroplasty (TKA) have been introduced in an attempt to reduce polyethylene wear and secondary osteolysis and improve longevity of implants.

Questions/Purposes: We reviewed clinical studies in literature evaluating OxZr femoral component for TKA. The aim of this review was to evaluate the clinical outcome and survival rate of TKA with an OxZr femoral component. *Methods:* A review of the existing literature was undertaken to collect data on the OxZr femoral component in order to provide a better understanding of its performance. Of 34 studies published in the literature, 8 met the eligibility criteria and were included in the final analysis. *Results:* Findings indicated that the mean Knee Society knee score improved in all series from preoperative to postoperative evaluation. The post-operative Knee Society knee score reported range from 84 to 95 and mean postoperative Knee Society functional score range from 74 to 90. The revision rate with this implant is low with up to 12.6 years of follow-up, with three revisions in total. The survival rate ranged from 100–98.7% at 5–7 years to 97.8% at 10 years. *Conclusions:* Excellent clinical outcome and high survival rate

has been demonstrated for OxZr femoral component in TKA. No adverse reaction has been described for this new material.

Keywords knee · TKA · tribology · oxidized zirconium · polyethylene wear · osteolysis

Introduction

The total knee arthroplasty (TKA) is one of the most revolutionary and successful surgical procedures of modern orthopedics, through which is possible to relieve pain, restore joint function, and improve quality of life [1, 16]. However, polyethylene (PE) wear and osteolysis still remains one of the major causes of failure in long-term survival of TKA especially in younger, athletically active patients and in those with suboptimal component alignment [5, 6, 10].

In order to reduce the aforementioned complication and improve the longevity of the implants, oxidized zirconium (OxZr) was introduced as an alternative bearing for femoral components in TKA. Preliminary studies in vitro have indicated excellent mechanical properties for this material with a high resistance to roughening and a reduction of PE wear when compared to cobalt-chromium (CoCr) femoral component for total knee replacement [2–4, 18]. However, it is well known that preclinical laboratory testing of materials has limitations, sometimes leading to catastrophic failure, and that proof for all new technologies must come from clinical trials. The literature contains many studies which have reported clinical results of OxZr femoral component for TKA [7–9, 11–15, 17].

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The purpose of this study was to summarize the current data of clinical studies evaluating OxZr femoral component for TKA. In particular, the first aim of this study was to evaluate the clinical outcome for TKA with OxZr femoral component, as defined by the Knee Society score reported in literature. The secondary purpose was to assess the survivorship and analyze causes of failure of primary TKAs with a femoral component made of oxidized Zr.

Methods

Using PubMed, Embase, Cochrane, and Medline, a review of the medical literature in indexed peer-reviewed journals was done using the following search terms: “oxinium” or “zirconium,” “knee,” and “arthroplasty/ies.” Articles were evaluated in full text by at least two independent reviewers, and their results were cross-checked by an independent reviewer who was blind regarding their results and revision rates. Studies were included if they contained “revision for any cause” or “clinical results,” or “survival rate.” We excluded in vitro studies, retrieval analysis, case studies, and studies that focused solely on a specific reason for the revision (e.g., re-revision, mechanical failure, infection, or aseptic loosening).

By the time of the final search of the literature in September 2015, 34 published studies that utilized an OxZr femoral component for TKA were identified, of which 26 did not meet the inclusion criteria for this review. Therefore, eight articles were included in the current analysis [7–9, 12–15, 17] (Table 1).

Seven of eight studies reported clinical results as Knee Society knee scores and one as WOMAC and SF 12 scores. All studies reported implant survival data. Implant survival findings in our analysis were either derived directly from Kaplan-Meier data or extrapolated from revision data.

Results

An improvement over time in Knee Society knee scores was noted in all studies reporting this outcome. The mean post-operative Knee Society knee score was 89.8 (range, 84 to 95) and mean postoperative Knee Society functional score was 82.16 (range, 74 to 90).

Revision rate for any reason was evaluated from this analysis. The mean survival rate from 5 to 7 years of follow up was 99.74%. Only one study reported survival at 10 years of follow up with 97.8% of survival rate. The only reason for failure was aseptic loosening. Innocenti et al. [13] reported 2 of 98 cases of revision for aseptic loosening of the femoral component. Holland et al. [8] reported 1 of 199 cases of aseptic tibial component loosening.

No complications related to the implant or to the Oxinium material were reported in all the studies.

Discussion

OxZr femoral component for TKA has shown promising result in some laboratory analyses with better wear properties than CoCr when articulating with ultra-high molecular weight polyethylene. These findings promise a reduction of PE wear and secondary osteolysis and an improvement in long-term survival of knee joint arthroplasties. The clinical performance of OxZr implants was investigated by several authors documenting excellent survival rate and clinical outcome. From our analysis, survival rate of TKA with OxZr femoral component is 99.74% at 5–7 years with high Knee Society scores achieved.

However, some limitations were identified and need to be considered when interpreting these data. First, most of the studies were a nonrandomized study of selected rather than consecutive cases with a potential for patient selection bias.

Table 1 Summary of reported clinical results

Author	Year	Study design	Knees (number)	Follow-up (years)	Clinical results	Survival
Laskin [15]	2003	RS (randomized OxZr vs. CoCr)	73	2	KS 92 FS 74	100%
Innocenti et al. [13]	2010	RS (Ox only)	98	6.2 (5–7)	KS 84 FS 86	89.7%
Hui et al. [9]	2011	RCT (OxZr vs. CoCr bilateral TKA)	40	5	KS 89	100%
Kim et al. [14]	2012	RCT DB (OxZr vs. CoCr bilateral TKA)	331	7.5 (6–8)	KS 95 FS 79	100%
Holland et al. [8]	2013	RS (Ox only)	199	5.2	WOMAC 34.5	99.5%
Hofer et al. [7]	2014	RS (Ox only)	109	5.9 (5–10)	KS 92 FS 81	100%
Park et al. [17]	2014	RS (Ox only)	71	5.2 (4.2–7.3)	KS 92 FS 90	100%
Innocenti et al. [12]	2014	RS (Ox only)	98	11.3 (10–12.6)	KS 84 FS 83	97.8%

KS Knee Society knee score, FS Knee Society functional score, WOMAC The Western Ontario and McMaster Universities Arthritis Index, RS retrospective series, RCT randomized controlled trial, RCT DB randomized controlled trial, double-blind

Second, a control group was not available in all these studies for direct comparison, so we could not show that a conventional CoCr femoral component would have the same results. Finally, the follow-up is of relative short duration. Most of the studies reported results at 5 years of follow up, and that is an important end point to detect any unexpected adverse events related to this new material. However, to demonstrate the potential clinical benefit of OxZr femoral component in reducing PE wear and increasing survival of TKA, more investigations with longer follow up are needed.

Clinical results comprising prospective cohort studies, prospective randomized controlled studies, and registry data showed no significant differences in patients with conventional CoCr implants and OxZr implants. Analyses of synovial fluids and evaluation of amount and size of PE particles showed no differences between OxZr and CoCr femoral components [9, 14].

In conclusion, OxZr femoral component is promising in order to reduce PE wear and thus increase survival of TKA implants. The results of the current review demonstrate safe use of this new material with no adverse reaction and excellent clinical results and survival rate. Further study with longer follow up is required to confirm this trend and demonstrated the advantages in using this material for TKA.

Compliance with Ethical Standards

Conflict of Interest: Fabrizio Matassi, MD, Christian Carulli MD, Luigi Sirleo, MD, and Andrea Cozzi Lepri, MD have declared that they have no conflict of interest. Roberto Civinini, MD, reports personal fees from Smith & Nephew, outside the work. Innocenti, MD, reports personal fees from Smith & Nephew, outside the work.

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