Clin Orthop Relat Res (2023) 00:1-3
DOI 10.1097/CORR.0000000000002711

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

CORR Insights

Published online: 23 May 2023

CORR Insights®: Did a New Design of the Oxford Unicompartmental Knee Prosthesis Result in Improved Survival? A Study From the Norwegian Arthroplasty Register 2012-2021

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Where Are We Now?

The development of orthopaedic implants has a long history of improvements and setbacks. Implant designers and manufacturers respond to the performance and failures of existing implants to change features and try to improve outcomes. Revision is the most common outcome used to assess the success or failure of an implant, and arthroplasty registries have been developed around the world to track the frequency of this event. Using the Norwegian Arthroplasty Registry, Skåden et al.'s paper in this issue of *Clinical Orthopaedics and Related Research®* [15] evaluates a design change of the Oxford unicompartmental knee arthroplasty (UKA), one of the most commonly used UKAs in many registry reports. The Oxford UKA is a mobile-bearing prosthesis that has been through several design iterations in the past. This report examines the Oxford Partial, which has cemented (Oxford Partial Cemented, or OPC) and uncemented (Oxford Partial Uncemented, or OPU) versions, and compares the results with those to the Oxford III, an earlier iteration. The Oxford III was redesigned in part to address concerns about loosening of the femoral component by adding a peg to improve fixation. The study found no improvement in revision rates, but did find some differences in the reasons for revision, with a reduction in femoral loosening but an increase in polyethylene-related failures and periprosthetic fractures.

Implants undergo design changes for multiple reasons, such as to address performance concerns or market pressures. The process of approval for these changes varies from country to country and is often limited to a superficial comparison to a similar or "predicate device," with little to no clinical testing of the new version before distribution. Therefore, it is an important function of arthroplasty registries to track the performance of these new implants in patients. This paper is one example of a registry performing that important function. Previous work has demonstrated that none of the new hip and knee implant versions introduced in Australia over a 5-year period were better than their benchmark prostheses, and in fact, 29% had worse survivorship [1]. A more recent study comparing specific implant design changes found that only 6 of 11 new implant designs had better survivorship, and two were worse [8]. If a new, and usually more expensive, implant does not provide a substantial improvement for the patient over the previous version, it should not be promoted [7].

Where Do We Need To Go?

The field of orthopaedics tends to focus on implants, and revision is the most common measure of performance of those implants. While there are well-established registries with comprehensive coverage in some countries, other

This CORR Insights® *is a commentary on the article* "Did a New Design of the Oxford Unicompartmental Knee Prosthesis Result in Improved Survival? A Study From the Norwegian Arthroplasty Register 2012-2021" *by Skåden and colleagues available at:* DOI: 10.1097/CORR.0000000000002671.

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markets have no registry or limited coverage. Because of the cost and complexity of direct, post-market surveillance of implants, few studies are being done, and most of the information available about the performance of new implants is in the form of developer-led and or manufacturer-funded single-site studies. Unfortunately, these often do not reflect real-world performance of these devices. In a study specifically looking at the Oxford UKA [5], the authors found that studies by individuals other than implant developers reported a much higher revision risk than did studies by implant developers. The difference is even more pronounced when they evaluated data from national registries: There, the revision risk was more than four times that reported in clinical research published by implant developers. Studies of other implants have demonstrated similar findings [11, 12]. Based on that, future studies need to ensure that they minimize the potential expertise bias and selection bias introduced by relying exclusively on developer surgeons. Instead, studies of new implants need to include sequential cases from surgeons at multiple sites and with a varying volume of practice. Cases also need to be completely tracked, either by the investigators or in a comprehensive registry, to reduce the fragility of the results. It would only take the revision of a few patients who had been lost to follow-up to completely change the results of many analyses [2]. Only with a more representative sample and complete follow-up will the results of implant survivorship studies more accurately reflect the results of an implant that has been released to the wider market.

Design changes to address one issue can also have unintended consequences. Perhaps attempting to reduce loosening by adding pegs and increasing commensurately the number of holes in the bone and the amount of bone resection explains the increasing number of revisions for fracture. Many examples exist of implants with apparently minor design changes that led to other serious problems [6]. Because of that, future research might focus on premarket, in vitro testing of new designs before regulatory approval rather than relying on assumed non-inferiority with a predicate device. Barring that unlikely change in the regulatory environment, tracking all cases of new or redesigned implants should be undertaken by the surgeons who decide to use the new, unproven device.

How Do We Get There?

Not all new implants are released or adopted in all countries. Some designs show up in one registry report alone, and those results may or may not reflect the outcomes that would be experienced in different hands. In the US, the growth of the American Joint Replacement Registry (AJRR) is promising, but it only collects information on a subset of arthroplasties performed in the US and relies on CMS data for survivorship analysis, so it cannot yet reliably report on results in patients younger than 65 years. Surgeons in the US, especially those considering using a new, unproven implant, should ensure that all of their cases are entered into a registry for tracking. Required participation for reimbursement may be necessary and has been successful in other registries. In Michigan, comprehensive coverage has been accomplished in the Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI) through collaboration with the primary insurer in the state [3].

When surgeons and hospitals are making implant purchasing decisions, they should assess the available data and not automatically adopt new designs based on marketing, developer studies, manufacturer claims, or surgeon preference without strong supporting evidence. Unfortunately, new designs often supplant the previous version, and by the time there is enough data to determine whether the new design is superior, the older version is no longer available. This industry lifecycle provides marketing opportunities for manufacturers and consulting and development opportunities for surgeons, but may increase risks or costs for patients instead of improving care. The newer version of the Oxford device studied in this paper [15] came to the market in 2009 and began being used in Norway in 2012. The prior device, the Oxford III, stopped being used in Norway in 2017. Despite no demonstrated survivorship benefit with the new design, the option to return to the previous design does not exist. This wholesale shift affects patients and healthcare costs across the world where this implant is being used.

Several alternatives exist for improving the release of new implants onto the market. One proposal has been a measured release of implants to the market, beginning in a country or region with a high-quality arthroplasty registry with comprehensive coverage of the population [10]. This would allow for careful tracking of implant performance and could also incorporate patient-focused factors such as patient-reported outcomes measures (PROMs). Registries can have earlier signal detection than the typical outcomes studies due to larger numbers and comparable data for other implants. Recently, efforts have begun on registry-nested studies, which utilize the infrastructure of a registry to perform a randomized controlled study [9, 14, 16]. Limited releases in registry regions and nested studies, building on the infrastructure of the registries, can begin to address some of

the difficulties discussed. Patients are tracked as long as they remain in the coverage area of the registry, so all patients from all surgeons can be included and signal detection for early problems can be performed. New implants should be evaluated in this systematic way before wholesale release on the market to avoid some of the disasters of the past. Given projected increases in arthroplasty volume around the world, we cannot assume the costs of all new changes without a demonstrated benefit to the patient [4, 13].

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