The United Kingdom
Knee Osteotomy Registry

The First Annual Report 2018



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CONTENTS

- 1. Chairman's Introduction
- 2. Aim of Registry
- 3. Background
- 4. Results from Current data 1 Dec 2014 – 1 Dec 2017
 - 4.1 Cohort
 - 4.2 Age at Surgery
 - 4.3 Gender distribution
 - 4.4 Operated Side
 - 4.5 Indication
 - 4.6 BMI
 - 4.7 Surgeons' Profile
 - 4.8 Preoperative Radiographs
 - 4.9 Co-morbidity
 - 4.10 Arthroscopic Findings
 - 4.11 Osteotomy Procedure
 - 4.12 High Tibial Osteotomy
 - 4.13 High Tibial Osteotomy Devices
 - 4.14 Distal Femoral Osteotomy
 - 4.15 Day One Mobilisation
 - 4.16 Oxford Knee Score
 - 4.17 EQ Visual Analogue Scale
 - 4.18 EQ-5D
 - 4.19 Knee Injury and Osteoarthritis
 Outcome Score
- 5. Summary
- 6. Future Plans

FIGURES

- Figure 1: Age distribution of patients
- Figure 2: Gender distribution of patients
- Figure 3: Operated side
- Figure 4: Indications for osteotomy surgery
- Figure 5: BMI distribution
- Figure 6: Surgeon cases distribution
- Figure 7: Kellgren and Lawrence grade
- Figure 8: Osteotomies performed
- Figure 9: High Tibial Osteotomy Devices
- Figure 10: Day One Mobilisation
- Figure 11: The average pre-operative, 6 months, 1 year and 2 years post-operative Oxford Knee Scores
- Figure 12: The average 1 year and 2 years post-operative EQ VAS scores
- Figure 13: The average 1 year and 2 years post-operative EQ-5D scores
- Figure 14: The average 1 year and 2 years post-operative KOOS scores

TABLES

- **Table 1:** Arthroscopic findings graded by the Outerbridge classification
- **Table 2:** The average, minimum and maximum 6 months, 1 year and 2 years post-operative Oxford Knee Scores
- **Table 3:** The average, minimum and maximum 1 year and 2 years post-operative EQ VAS

1. CHAIRMAN'S INTRODUCTION

Osteotomy around the knee is increasingly employed by surgeons looking to offer joint preserving surgery for younger patients. These younger patients occupy a treatment gap when arthritis is mild or moderate, because unicondylar arthroplasty is contraindicated without bone on bone contact. These patients have often been told to wait until they are candidates for total knee arthroplasty without receiving symptomatic relief. A well-executed knee osteotomy can delay disease progression and treat unicompartmental arthritis with pain relief and durable restoration of function. However, when compared to unicondylar and total knee arthroplasty, osteotomy has been criticised for exposure to the risks of failure and revision surgery; a reproval that fails to observe the greater functional benefit from retaining native knee kinematics and ignores that primary arthroplasties are also threatened by revision. There are several osteotomy devices available which provide sufficient stability to facilitate a medial opening wedge on the tibia. Such opening wedges are easier to control during the procedure offering increased surgical confidence in the achieved correction. As surgical techniques for osteotomy have evolved, the previous long-term follow-up studies now analyse the results of already out-dated procedures. Emerging papers using modern osteotomy techniques report encouraging survivorship.

There is clearly a requirement to provide robust evidence of patient outcomes using modern techniques, as justification for knee osteotomy against surgical alternatives. The UK Knee Osteotomy Registry (UKKOR) has been established to provide this evidence with a focus on improving the quality of patient care by monitoring outcomes. The specific goals at the outset were to:

- Define patient selection criteria with greater clarity.
- Identify devices and surgical techniques that give the best results.
- Use stratified outcome data to influence the choice intended alignment correction.

We are indebted to the example shown by the National Ligament Registry (NLR) as the other knee specific registry. UKKOR has unashamedly chosen to follow the same model, employing Amplitude Clinical to host the data platform. The behavioural changes required to collect this data are becoming familiar to knee surgeons who also contribute to the NLR. UKKOR has required external funding, received gratefully as sponsorship from companies with a stake in osteotomy surgery. Sponsoring companies will have access to performance data on their own products but not their competitors. In addition BASK have been supportive of the project and provided a generous priming grant.

The inclusion of patient reported outcome measures is vital to increase any registries' sensitivity to define success. The outcome measures chosen include the Oxford Knee Score (OKS), the Knee Injury and Osteoarthritis Outcome Score (KOOS), EuroQol (EQ5D) and the Activity Participation Questionnaire (OKS-APQ) from Oxford. Patient co-morbidities will be quantified with the self-administered co-morbidity questionnaire. We hope that patients will be persuaded to participate because they can see their charted progress after surgery. Surgeons too can judge their own performance by analysing the data from their patients to reflect upon practice. In this day and age patients often migrate between dwellings but they tend to keep an email address and mobile phone number, so these pieces of information are thus critical to facilitate automated patient follow-up.

UKKOR is working alongside the BOA Trauma and Orthopaedic Registries Unified Structure (TORUS) group towards cementing the necessary infrastructure necessary to support the emerging orthopaedic registries. We are grateful to Minoo Esat and Julia Trusler for their ongoing work with this project.

The registry was launched on the podium at the Knee Osteotomy MasterClass in November of 2014 and we now have sufficient data to compile this first report. The steering committee remain grateful to our industry sponsors and above all the surgeons and their patients who have taken their time to contribute to the process because without them, there would be no registry. We hope that the following report is a useful summary of progress to date.

David Elson,

UKKOR Steering group chairman

2. AIM OF REGISTRY

Knee osteotomy surgery is a re-emerging operative technique becoming increasing accessible in the UK. Its main benefit is reduced pain and improved function in combination with joint preservation.

A variety of factors may impact upon the successful outcome of osteotomy surgery, ranging from correction accuracy to post-operative mobilisation.

UKKOR aims to:

- Collect relevant demographic and radiographic data.
- Identify the current and emerging trends in practice.
- Provide outcome data and associated complication rates.
- Improve the standard and quality of care in the UK.

Currently, there is a lack of information regarding the number of procedures, functional outcome and complication rate following osteotomy around the knee in the UK. UKKOR aims to address this gap, creating a national resource to collect and analyse data and to report findings in a clear way.

It is hoped that this will:

- Help both surgeons and patients to understand the outcome of osteotomy surgery.
- Help support cases of best practice.
- Identify techniques and devices that do not perform well.
- Inform commissioners and national bodies about the value and benefits of osteotomy surgery.

The UKKOR Steering Group, and in consultation with our surgeon users, have identified some early research questions for exploration over the coming years. The research questions will be expanded in future consultation with our user group, to help focus UKKOR on providing the answers to the most pressing questions that arise surrounding osteotomy surgery. The identified, early research questions are:

- The relationship between patient characteristics and subsequent outcomes, to inform patient selection criteria.
- The identification of devices and techniques which give the best outcomes
- The use of stratified outcome data to direct the intended alignment correction of an osteotomy.

3. BACKGROUND

UKKOR, developed in 2014, was launched November 2014. It has been designed by surgeons to evidence and understand the impact and outcomes of osteotomy surgery around the knee for the benefit of future patients. The exciting approach to data collection requires the support of surgeon users throughout the UK. At the time of writing in December 2017, we have 49 registered surgeons contributing data to the Registry. This is a glowing endorsement of UKKOR at this early stage and speaks of the benefit that these early-adopting surgeons see in the Registry. We hope that in future years these numbers will increase because additional surgeons will experience the benefit of a free, easy to use tool for collecting patient data. In addition, a new generation of future orthopaedic surgeons will be encouraged to make osteotomy surgery around the knee a core part of their practice.

UKKOR is a simple, user-friendly web based platform that collects various demographic, radiographic, operative and outcome data from osteotomy operations around the knee. UKKOR is easily accessible through any web browser which can be accessed via computer or tablet. UKKOR aims to create the simplest possible process for surgeons and patients to use, however there is a minimum amount of input from surgeons and patients and so a balance is struck between data quality and the burden of completion. UKKOR is designed to automatically prompt patients to complete their information at scheduled times, both pre- and post-operatively. In December 2017, we have 1,652 registered patients.

Amplitude Clinical was selected as the company to collect and host UKKOR data, given their connection to a number of other orthopaedic registries. Building upon their experience, we have developed an online, paperless, data collection model for this Registry, allowing both surgeons and patients to easily access the portal and complete their data in the quickest and simplest way possible.

The automated data collection process requires patients' email addresses, to maintain contact for ongoing contributions to data collection.

The automated and continuing nature of the follow up process is appealing as it and requires little further effort from the surgeon.

Understanding the outcomes following any operative procedure requires careful analysis of relevant factors.

UKKOR collects information on a range of demographic and surgical factors, including type of operation, deformity analysis, wedge distances, devices and post-surgery mobilisation. The Patient Report Outcomes Measurements (PROMs) chosen are: Oxford Knee Score (OKS), Oxford Knee Score Activity & Participation Questionnaire (OKS-APQ),

EQ Visual Analogue Scale (EQ-VAS), EQ-5D and Knee Injury and Osteoarthritis Outcome Score (KOOS). These selected PROMs will facilitate comparison with existing national and international cohorts and reflect the outcome measures currently being used.

Backed by support from industry partners, UKKOR's Steering Group oversees the data collected by the Registry and will produce an annual, independent report. The Steering Group also takes responsibility for the future direction of research and manages data request from external partners. UKKOR will continue to work with, and be supported, by Amplitude, experts in collecting clinical outcomes data.

4. RESULTS FROM CURRENT DATA 1 DEC 2014 – 1 DEC 2017

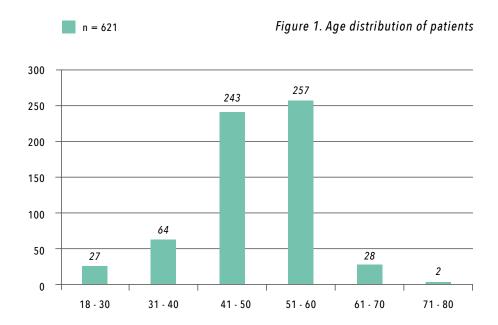
4.1 Cohort

A total of 1776 cases of osteotomy surgery were registered in the United Kingdom Knee Osteotomy Registry between 1 December 2014 and 1 December 2017. A total of 1652 patients were entered into the Registry in this period, suggesting a number of bilateral or revision cases. Of these, 621 patients have undergone surgery (34.97%) and 1155 (65.03%) are either waiting for surgery or have no operative data entered on the registry.

4.2 Age at Surgery

The average age for patients undergoing osteotomy surgery was 48.7 years. The age at surgery ranged from 18.3 years to 79.9 years. 70% of all patients were between 40-55 at the time of surgery. Figure (1) demonstrates the number of patients who had osteotomy surgery in different age groups. This reflects a younger cohort than reported by the NJR (National Joint Registry, 14th Annual Report 2017) for

total knee replacements (70 years old), unicompartmental knee replacements (64 years) and patellofemoral replacements (58 years). Primary knee arthroplasty in younger groups is associated with a higher risk of revision arthroplasty (NJR 14th Annual Report 2017) which may influence the selection of joint preserving of knee osteotomies for these younger patients.



4.3 Gender distribution

The percentage of men and women who have undergone osteotomy surgery were 72.4% and 27.6% respectively. The average age for a man who had osteotomy surgery was 49.2 whilst for women it was 46.8. Figure (2) demonstrates the split between male and female patients.

4.4 Operated Side

The left knee was operated on 51% of patients who underwent osteotomy surgery whilst the right knee was operated on in 49% cases (Figure (3)).

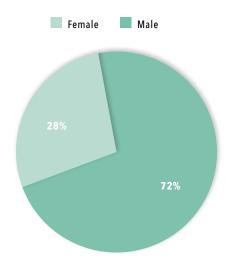


Figure 2. Gender distribution of patients

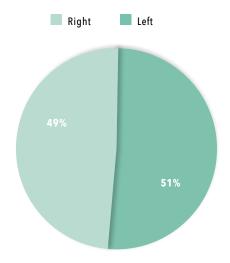
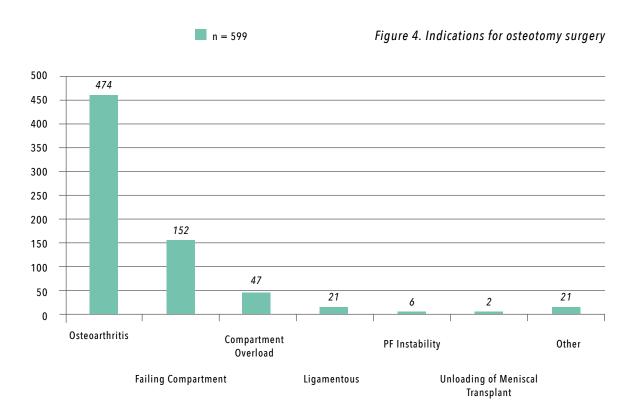


Figure 3. Operated side

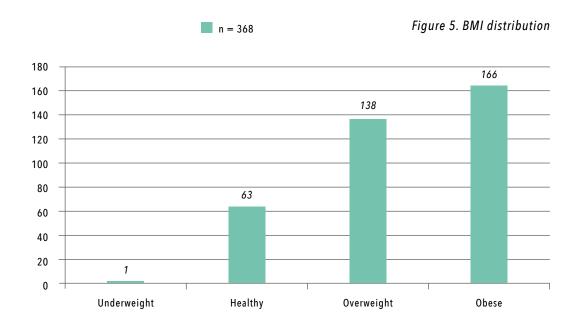
4.5 Indication

Figure (4) describes the indications listed for patients who underwent osteotomy surgery. The indication was collected in 599 cases, with osteoarthritis being by far the most common indication (79.1%).



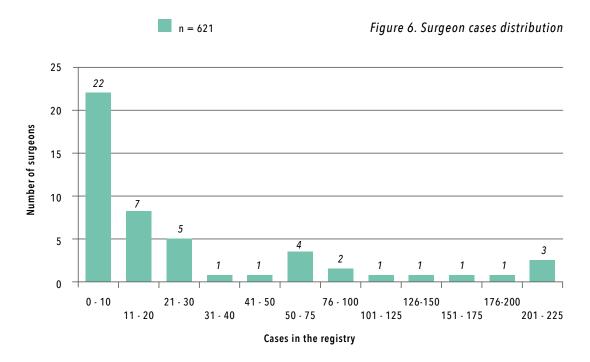
4.6 BMI

BMI was recorded on 368 patients. The average BMI was 30.1. Male average BMI was 29.8 and Female average BMI was 30.9. Figure (5) shows the distribution of the patients BMI.



4.7 Surgeons' Profile

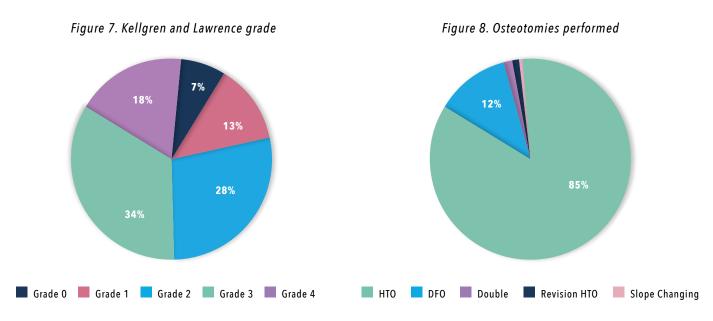
At the time of writing in January 2018, 49 surgeons have registered their patients on UKKOR. Figure (6) demonstrates the number of surgeons in relation to the total number of recorded osteotomies they have recorded in UKKOR.



4.8 Pre-operative Radiographs

UKKOR collects data on pre-operative radiographs to determine the extent of the deformity prior to the operation and to understand the damage to the knee. A total of 339 pre-operative radiographic forms have been collected. The average

pre-operative Mikulicz point was 34.8%. The surgeon's intended correction average was 55.1%. Figure (7) details the Kellgren and Lawrence grade of the knee before surgery, with grade 3 being the most commonly observed.



4.9 Co-morbidity score

A total of 429 Self-Administered Comorbidity Questionnaire (SCQ) were collected. The average SCQ score is 2.23, ranging from 0 to 16.

4.10 Arthroscopic Findings

In the cases where an arthroscopy accompanies the osteotomy procedure, Outerbridge classification of joint cartilage breakdown is collected as shown in Table (1) below. Further to this, 108 cases reported the ACL normal and 18 reported the ACL as insufficient.

Table 1: Arthroscopic findings graded by the Outerbridge classification

n-130	PFJ	МС	LC
Average	1.72	3.2	0.8
GO	41	9	76
G1	9	5	24
G2	37	12	10
G3	24	19	4
G4	16	84	12

4.11 Osteotomy Procedure

A total of 620 osteotomy procedures were recorded in UKKOR. Figure (8) clearly details that High Tibial Osteotomy (HTO) is by far the most common operation performed.

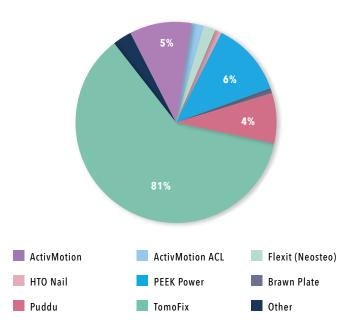
4.12 High Tibial Osteotomy

A total of 526 HTO cases were recorded. Osteotomies in a valgus direction make up 80% of those performed whilst osteotomies in a varus direction represent 20%. The average posterior wedge distance was 9.8mm (3mm-38mm) whilst the average anterior wedge distance was 8.4mm (2mm-28mm). Standard saw blades were used in 439 cases whilst Precision® saw blades were used in 87 cases.

4.13 High Tibial Osteotomy Devices

A total of 10 different HTO devices were recorded, with TomoFix being recorded as the most commonly used in 81% of the cases. Figure (9) details devices recorded.

Figure 9. High Tibial Osteotomy Devices



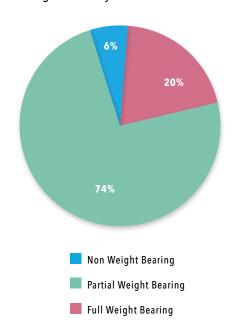
4.14 Distal Femoral Osteotomy

A total of 77 Distal Femoral Osteotomy (DFO) procedures were recorded. Varus direction osteotomies made up 92% of the recorded operations with valgus direction comprising the other 8%. The average posterior wedge distance was 7.3mm (3mm-15mm) whilst the average anterior wedge distance was 7.1mm (0mm-15mm). Standard saw blades were used in 64 cases whilst Precision® saw blades were used in 12 cases. TomoFix was the most common fixation device with 95% of the recorded cases.

4.15 Day One Mobilisation

To better understand the most successful rehabilitative process post-osteotomy, UKKOR collects data on day one mobilisation of the osteotomy. It is hoped that as this data matures in the coming years, it can be examined for any causative effect on early PROMs results. Figure (10) shows the proportion of mobilisation on day one.

Figure 10. Day One Mobilisation



4.16 Oxford Knee Score

The Oxford Knee Score (OKS) is a PROM questionnaire consisting of twelve questions covering function and pain associated with the knee. Results range from 0 (worst possible result) to 48 (best possible result). UKKOR has collected OKS data at pre-operative and six month, one year and two years post-operatively. Figure (11) details the OKS average whilst Table (2) offers minimum and maximum values for each time point. Both Figure (11) and Table (2) indicate a post-operative improvement at each time point. At one year OKS had improved by 11.7 points.

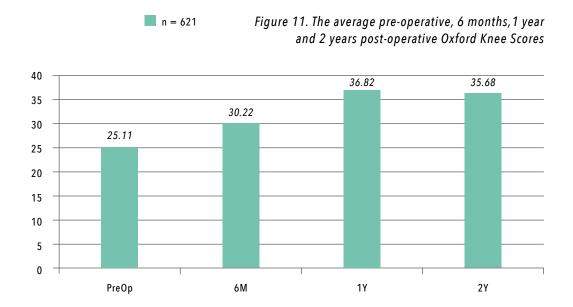


Table 2: The average, minimum and maximum 6 months, 1 year and 2 years post-operative Oxford Knee Scores

	AVERAGE	MIN	MAX
Pre O p	25.11	3	48
6M	30.22	3	48
1Y	36.82	3	48
2Y	35.68	7	48

4.17 EQ Visual Analogue Scale

UKKOR collects the EQ visual analogue scale (EQ VAS), alongside the EQ5D. This comprises of asking the patient to mark their health status on the day of data collection on a 20cm line between 0 (worst health you can imagine) and 100 (best health you can imagine). EQ VAS data pre-operatively, one year and two years post-operatively has been collected. Figure (12) details the EQ VAS average whilst Table (3) offers minimum and maximum values for each time point. Figure (12) and Table (3) indicate an initial drop in EQ VAS one year post-operatively before a return to pre-operative levels at the later time points.

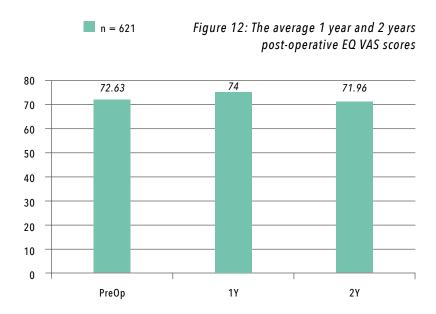
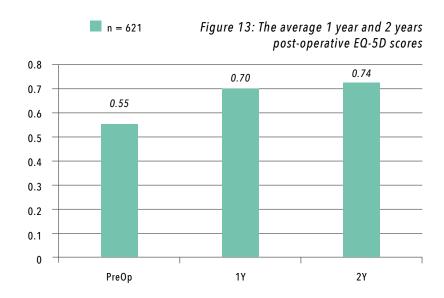


Table 3: The average, minimum and maximum 1 year and 2 years post-operative EQ VAS

	AVERAGE	MIN	MAX
PreOp	72.63	0	100
1Y	74.00	0	100
2Y	71.96	0	100

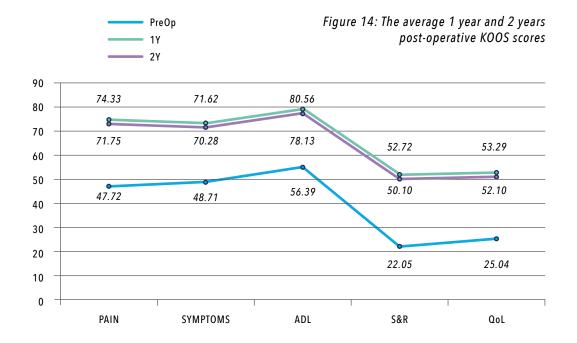
4.18 EQ-5D

The EQ-5D is a generic measure of heath for clinical and economic analysis. It allows for a description of a patient's general health across five domains, ranging from 0 to 1. Figure (13) demonstrates the mean changes in the EQ-5D, showing an improvement from the pre-operative average at all time points.



4.19 Knee Injury and Osteoarthritis Outcome Score

The Knee Injury and Osteoarthritis Outcome Score (KOOS) is a knee-specific patient reported outcome measure. It is used to evaluate five areas: pain, symptoms, activity, sport & recreation and knee-related quality of life. It consists of 42 self-administered questionnaire intended to monitor short- and long-term outcomes. Figure (14) details to changes in all five categories average scores at 1 year and 2 years post-operatively. Figure (14) shows clear improvement beyond 1 year in all five of the evaluated areas.



5. SUMMARY

Over the last 3 years, UKKOR has commenced data collection of demographics, operative techniques and functional outcomes for patients who undergo knee osteotomy surgery. A number of observations can be drawn from this report. There is a group of early adopting surgeons who have responded to the registry and continue to contribute to its growing cohort. Other findings include:

The UKKOR cohort is **younger** than the NJR cohort for arthroplasty. Men are selected more frequently than women and patients tend to be overweight or obese.

Osteoarthritis is the most common indication for knee osteotomy; where severity is most frequently Kellgren & Lawrence grade 3. However a substantial subset have grade 4 arthritis, suggesting that surgeons are confident performing knee osteotomy for more advanced pathology.

Outerbridge classification analysis reveals that the **medial compartment** is often the most damaged compartment across the cohort.

HTO is by far the most common operation performed, amounting to 80% of the cohort and TomoFix plates are the most frequently used fixation devices for HTO (80%) and DFO (95%).

Patients are most likely to be mobilised **partially weight bearing** the day after surgery.

PROMs show **improvement** in functional outcome scores at 1 year and 2 years compared to their pre-operative status.

6. FUTURE PLANS

UKKOR is aware of the need for this early data to mature whilst the registry develops into a meaningful tool for analysis. Whilst our initial findings have been encouraging there are a number of areas in which improvement is needed.

There is a concern around the current translation rate from those patients who are entered into the registry to the patients who have completed operative data. At present, patients with operative data only make up 35% of the total number of patients entered.

Efforts are underway to simplify the UKKOR operative form to increase surgeon completion rates and consultation will be held in spring 2018 to determine further ways of improving this.

Linked to this are the low data completion rates for complications, device removals and post-operative radiographs, which have not been reported here due to the small number of entries. This area has been targeted with form simplification to enhance surgeon engagement and prompt better uptake.

The aim for UKKOR for the coming year is therefore to further simplify our data collection process and to improve our reporting functions to encourage better data completion rates.

Published March 2018

The United Kingdom Knee Osteotomy Registry

