Acta Orthop. Belg., 2015, **81**, 594-599

PERSPECTIVE

Arthroplasty Registries, Patient Safety and Outlier Surgeons : the case for change

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Joint registries were created to follow-up on the failure rate of different types of joint replacements. Since the only end-point is revision to another implant the registries are missing out today on essential data informing us about patients' outcome. Ideally, a modern and complete registry should capture 3 strata of data : 1) patient reported outcomes including both function and activity levels from before and after surgery, 2) morbidity including infection rates and mortality related to surgery, and 3) the cost of consecutive revision surgery. A modern knee specialist offering conservative solutions for defined problems enabling return to higher level activities may be reported as an outlier surgeon by registries today.

Keywords : Joint Registries ; total knee replacement ; unicompartmental knee replacement ; patient safety.

INTRODUCTION

Once again, I am a joint registry outlier, and proud of it. The chief executives of the hospitals I work in have their usual autumnal problem. A letter comes to them from the National Joint Registry of England and Wales, denouncing the outlier in their midst, telling them that they have a surgeon operating in their hospital whose performance ranks him as an outlier. Their motives may be pure, they must speak for themselves on that matter, but history may not view their brand of witch-hunting so kindly. For the registry they represent cares not about patient welfare at all, simply about pieces of metal and plastic. They report surgeons for doing what is best for their patients, denouncing them if they step out of the line that they have drawn in their own sandpit.

For more than a decade I have been as conservative as I possibly can be. Over the last 24 years, I have gradually extended my conservative surgery, but have not changed much in the last 5 years. Learning from Cartier (*7*), Argenson and Aubaniac (*1*), Confalioneri (*8*) and Romagnoli (*18*), I have been doing what I can to keep people in one piece, avoiding total knee replacement unless strict conditions were met. If you look at the NJR figures, (which are publically available at http://www.njrsurgeonhospitalprofile.org.uk/SurgeonProfile? gmccode=2582830) you see from my numbers (Fig. 1a,b), that I am not really high volume, only around 180 knees a year, however, total knees are only 10% and have been that way for more than 3 years. All patients know that I will only cut out the very minimum, but that if more maintenance works needs to be done, then I will do it. What is not publically available, is my

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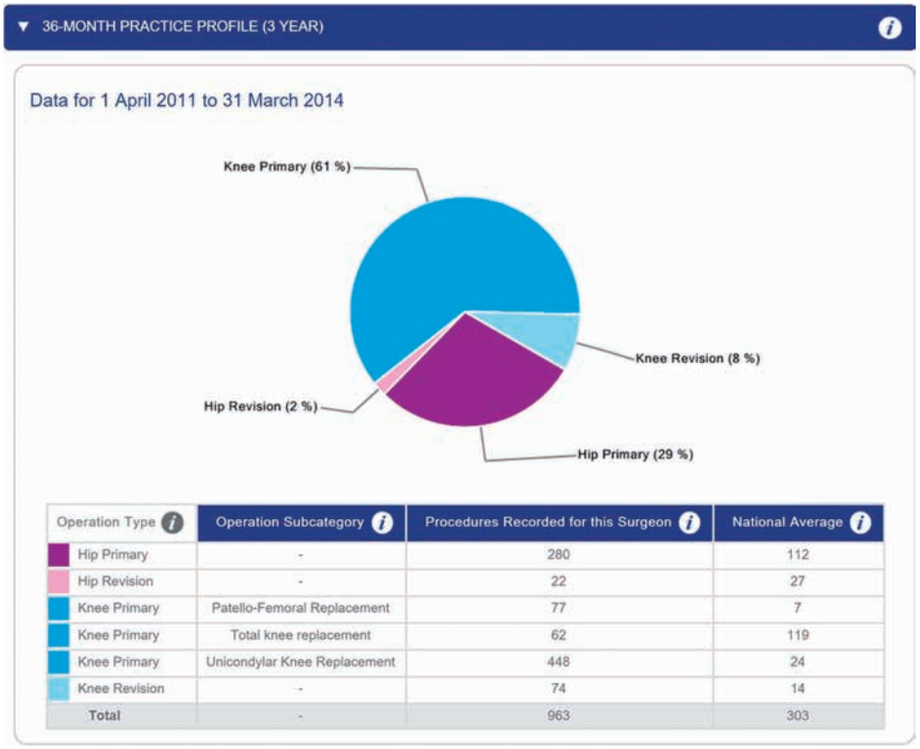
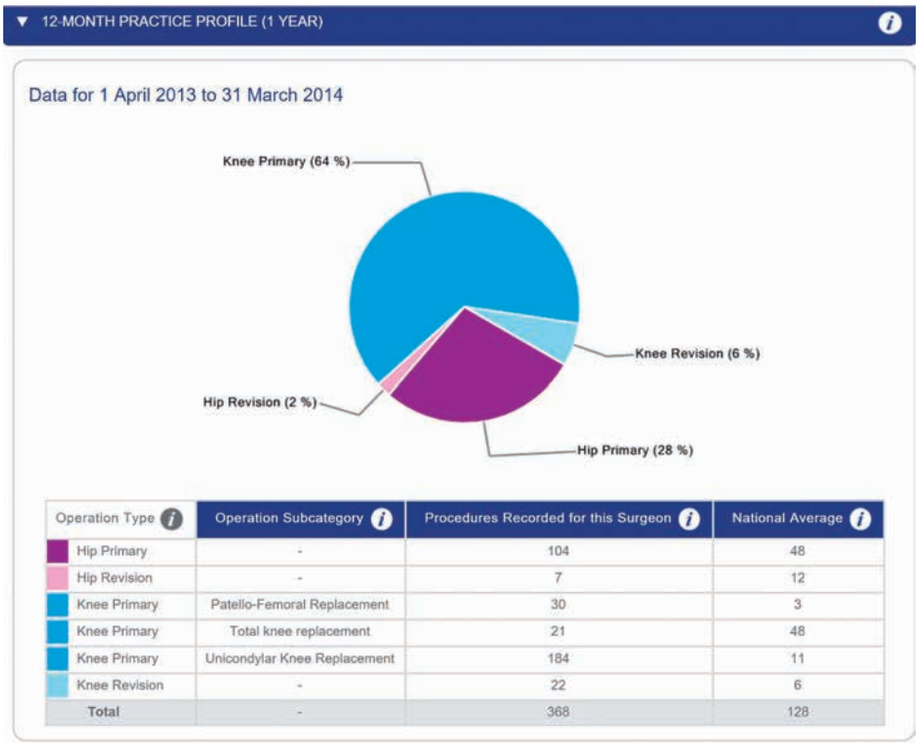
No benefits or funds were received in support of this study. The authors report no conflict of interests.



Operation Type	Operation Subcategory	Procedures Recorded for this Surgeon	National Average
Hip Primary	-	280	112
Hip Revision	-	22	27
Knee Primary	Patello-Femoral Replacement	77	7
Knee Primary	Total knee replacement	62	119
Knee Primary	Unicondylar Knee Replacement	448	24
Knee Revision	-	74	14
Total	-	963	303

a



Operation Type	Operation Subcategory	Procedures Recorded for this Surgeon	National Average
Hip Primary	-	104	48
Hip Revision	-	7	12
Knee Primary	Patello-Femoral Replacement	30	3
Knee Primary	Total knee replacement	21	48
Knee Primary	Unicondylar Knee Replacement	184	11
Knee Revision	-	22	6
Total	-	368	128

b

Fig. 1. — Publically available data on arthroplasty practice profile showing my 3 year and 1 year profile. Note it does not mention my osteotomy numbers (11 last year), nor my arthroscopy numbers (4 last year).

revision rate. The NJR gets this, and this is where things get interesting. If I am only doing 10% total knees, what are my revision rates like ? Unsurprisingly, my total knee revision rate is exactly average, and my uni revision rate is a little higher than average, as you can see from the Standardised plots (Fig. 2a,b). However, as the revision rate for UKA is higher than that for TKA, if you do more than the average number of UKA, you become an outlier (Fig. 2c). In registry terms, my 'failure' rate of re-operation, has avoided total knee replacement in over 75% of patients. So a primary total knee, with the thinnest polyethylene insert is a failure for me, but a success for the surgeon who only ever cuts peoples knees out entirely in spite of the relatively poor safety record of this procedure (*12,13*).

The well trained and well intentioned knee arthroplasty surgeon today should be able to perform medial or lateral unicompartmental replacement, or bi-uni (medial and lateral combined), or uni-pfj (medial or lateral combined with patellofemoral joint (pfj)). Less frequent combinations are uni-acl combined, osteotomy-uni combined, with the very occasional bi-uni-acl. He or she should be able to undertake TKA, but from the data on candidacy for total knee, he may only need those skills in a minority of cases (*20*). This strategy is highly conservative, with very low medical complication rates, and allows the patients to know that their body is being preserved if at all possible. When cost-effectiveness is the key, then this strategy is both safe and cost-effective (*16*).

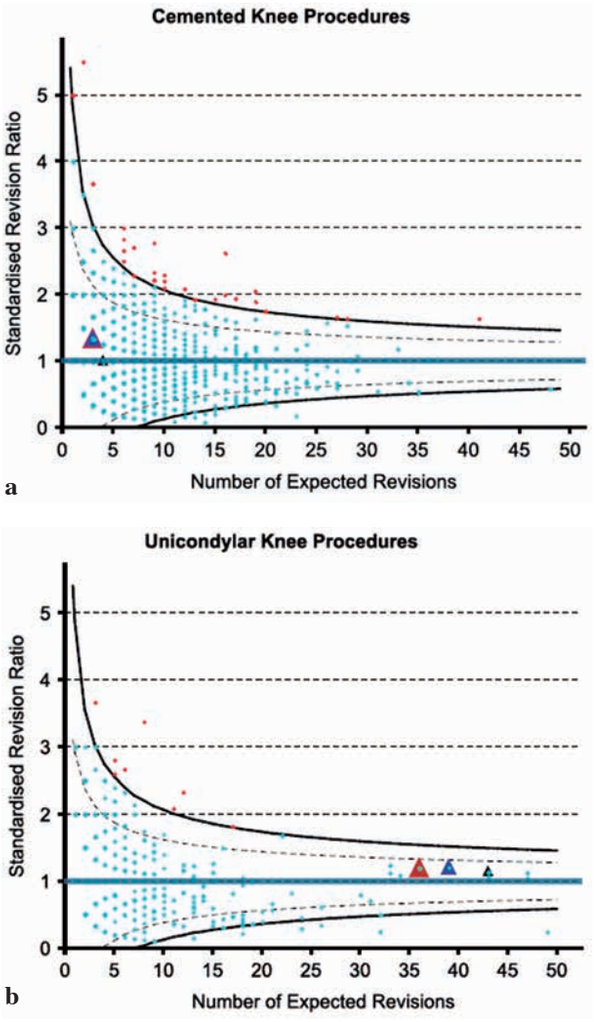
Patients seeing such a surgeon will also know that if there is a problem, it can be fixed. So the 18stone man whose personal trainer had him doing lunges after his uni-pfj is a failure in the NJR as his patella button fractures, but the fix is a small thing. The tennis and squash playing man who came back for a left medial uni 7 years after his bilateral lateral unis is a success on many levels, leading a highly active and enjoyable life. He has been playing tennis and squash for 7 years, was 'revised' in January 2015, and is back on the court again (Fig. 3). He is a failure, by registry standards. If he had been given a hinged knee, that prevented him from any sport at all, it would be a 'success', particularly so if he died early from heart disease brought on by inactivity !

This is because death is a success for the NJR, while in proper registries which care about patients, it is of course the ultimate failure. By determinedly and persistently focussing solely on revision of the device, the NJR gets some things right, but as many things completely wrong. Anyone can be admitted to the NJR, regardless of disease severity and co-morbidity, and only device-related surgical procedures are reported as failures. In their looking glass world, the NJR like every other joint registry are unable to reflect on poor functional outcomes that do not result in revision of the device, but from the patient's point of view are highly regrettable.

Set up to give warning of poorly performing devices, with operations leading to exchange of device as the main focus, the registries are now commonly abused to compare operations that have widely different thresholds for second surgery. This focus can lead to perverse results : a joint replacement with a problem that can be fixed, curing the pain and restoring the patient's quality of life, is a failure owing to its revision, whereas a painful joint replacement that cannot be revised, condemning the patient to a lifetime of stiffness and pain, is recorded as a success in registry terms. Thus, TKRs are reported as successful despite the fact that between 10% and 30% of patients who are not revised are no better or even worse after TKA (*9,10*). By perversely and determinedly refusing to use functional thresholds for 'failure' the registry persists in peddling the nostrum that no re-operation is success.

What are the endpoints for arthroplasty which really matter ?

Death is a very firm endpoint, of great relevance to patients. It is also a surrogate for more common risks of intraoperative complications, stroke, myocardial infarction, thromboembolism, blood transfusion, and admission to critical care. All these are substantially more common after big operations than after small ones. Quite literally, Total knee replacement kills people, and in significantly greater numbers than UKRs. Every dead patient can no longer face revision, guaranteeing excellent 'survivorship' of that device. Every patient who has a stroke, or a myocardial infarction, swells these



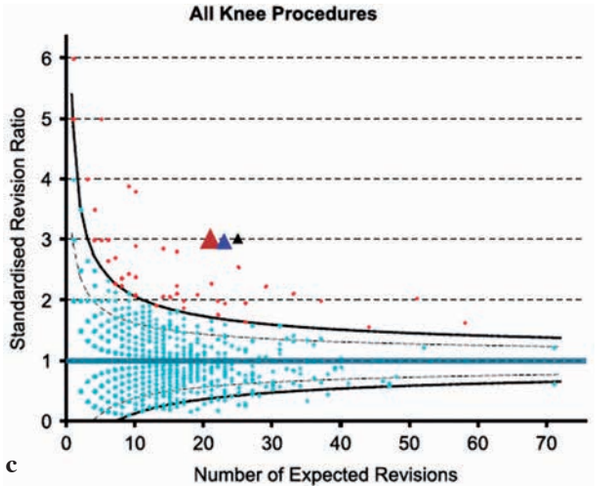


Fig. 2. — The Standardised Revision Ratios for for my knee practice in the last 3 years. a) for total knees, b) for unicompartmental knees, and c) for all knees.

ranks as these people are not going to wear out their device, nor are they going to be referred to back for attention to their painful knee. The perverse logic that allows the NJR to count these deaths as success is epitomised by the NJR paper reporting on the 'success' of hinged knee replacements, whose 10% mortality rate within 2 years draws no comment from the authors (*2*).

Infection, the most serious and costly local complication, is the one that all of us dread. Yet the operation that has one third of the infection rate (*13*) is given no recognition by the NJR. Revision for an infected UKA is never nice, of course, but in my experience never needs more than a primary TKA in reconstruction terms, while an infected TKA can be a pretty big deal (*3*). But in their looking glass world, the NJR counts them just the same.

Fracture is a device specific problem : an excessive tibial resection, or a sagittal saw nick in the posterior cortex may result in an early peri-prosthetic fracture following a UKA. And some designs may be more prone to this than others. So it is a feature that should be considered seriously, by registries looking at devices, and they may give us information that will drive device choice and design. However peri-prosthetic fracture is much more likely following TKA, with the pronounced osteopaenia that develops with a stiff total knee. However those supra-condylar fractures that are seen quite regularly on trauma lists seldom or never reach the registries, as no device is changed, even if the fracture has been caused by the stiffness of the procedure. The management of these fractures is a discipline in itself, usually undertaken in the trauma theatres, by trauma surgeons, who run courses on how to treat the problem (*4*). Supracondylar femoral fractures in adults are rare injuries, almost only seen following TKA, but the incidence and severity of the problem are not recognised by the Registries, as no implant is exchanged.

Wear is a paradoxical problem. For some devices, such as the Brigham, high wear was the cause of its withdrawal (*15*), and for others, such as the Oxford, low wear is the reason for its success (*17*).

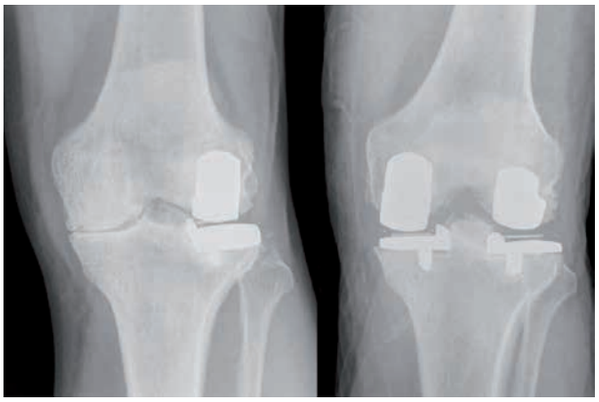


Fig. 3. — 8.5 years after lateral uni when aged 53, a tennis and squash player returns for a medial uni. 7 months postop, the patient now aged 62 has an OKS of 39 and is playing squash. The registry records this as a failure.

Yet a bearing that is worn out, only ever wears out if it feels good. The TKAs of the last 30 years all have had substantial wear rates, as the contact are has been pretty small. Wear is predicted and inevitable. It should not be considered a failure, just the result of having a good life. Surgeons who report series of total knees, using old polyethylene, with no wear need to look at their patients and their operative skills. An active person with a total knee, who wore out their own knee already once, is highly likely to do the same to the artificial knee, unless it is so stiff and uncomfortable that the patient has not been able to use it. Here is one further wrinkle : once a bearing has worn down by one or two millimetres, the joint starts to become unstable. By being a good doctor, if the surgeon fixes that, simply exchanging the bearing, as one would caring for a car, or bicycle, then he or she runs the risk of becoming an outlier. By fixing a problem, it is a failure, by leaving it to disrupt the bone implant interface and provoke a real problem is the successful strategy according to the NJR.

Loosening is the largest catch-all cause of revision on the registry, and should rightly be interrogated. It can and should be interrogated together with implant failures of all sorts. Implant-related operations occur later and are substantially more common after UKR (subhazard ratio (SHR) 2·12, 95% CI 1·99-2·26) at 8 years (*13*). These failures, mainly loosening and implant failure caused by overuse, and were usually treated by a primary TKR. When the same problems of loosening or implant failure resulted in reoperation after TKR, they were often treated by larger so-called revision devices involving stems and augments. Yet there is no tariff for these operations – a simple total knee replacement is considered the same weight as a stemmed, wedged, augmented superstabilised device that costs a multiple, and may well require further surgery soon.

Under-reported revisions are a substantial embarrassment for all registries, in particular since a large retrieval centre reported that 39% of the devices they received were not registered as revisions on the NJR (*19*). This under-reporting of failure undermines the confidence with which the registry conclusions are made.

Pain is perhaps the one symptom, upon which we should all be able to agree. Yet quite the opposite applies : as John Goodfellow noted in his elegant skewering of the New Zealand Registry almost 20 years ago (*11*), the threshold for revision is determined by the ease of the procedure. So a problem that can be fixed will be fixed, resulting in a failure. While if the pain cannot be addressed, then it is a success. And as the threshold for revising a painful total knee is understandably high, they are more successful than UKAs which can be revised rather easily. So the elephant in the room of the NJR is the over 20% of patients whose knees which remain stiff and sore and seldom used (*5,6,14*), but remain unrevised, and are 'successes' in the NJR. No recognition is given by the NJR to this silent and substantial group of people.

Statistics : what should the registries be doing ?

A patient focussed registry not a device focussed one is possible, but would produce completely different results : death or serious complications are 'failures', and second surgery which gets patients back on the golf course is just a service procedure. What is to be done to achieve that aim ? A revolution is needed, and would be surprisingly easy. Patients should be able to reclaim their registry entry. By simply writing some code, every

patient could upload their own health state to a modern registry, as often as they like. They could also upload their preop and postop imaging, which could be 'read' by computer code for objective measures of disease severity. Then the 'survival' curves could be transformed into living curves, based upon objective measures of disease severity, and how patients feel, not whether they have device exchange or not. In a world where almost everyone coming to joint replacement has a smart phone (or a younger relative with one), and almost everyone uses online retailers who know everything about us, it should be both possible and and easy to capture extensive data at close to no cost at all. This way we would really know how patients are, and have registries of which we can be rightly proud.

CONCLUSION

National joint registries were created to follow up the failure rate of implanted medical devices. They are losing their focus today. Implant registries are only capable of capturing revision as an end point. They completely miss the failed but unrevised TKAs, and the iceberg of surgery-related morbidity and mortality. Patient's functional gain, and the lifetime societal cost are not considered. A modern joint registry system should combine function, survival and cost to reflect the real value of arthroplasty.

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