The Critical Role of Registries in Documenting the Outcomes of Hip Preservation Surgery

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Introduction

The evidence relating to the efficacy of joint preserving surgery of the hip is lacking. Whilst several case series and cohort studies have been published, these are generally of a low standard. Most come from single centres and are lacking in a control treatment or placebo group [1–3]. However, despite their limitations, these trials, along with significant papers from Ganz [4, 5] and Villar [6], demonstrate the safety of hip arthroscopy with particular reference to labral repairs and surgery for femoro-acetabular impingement.

Recognising the inadequacy of data available, the Non-Arthroplasty Hip Register (NAHR) was created to collect data on the outcome of hip conditions not treated by arthroplasty. The Registry was unanimously supported by the Membership of the British Hip Society and went live in March 2012. The NAHR has been constructed so that any hip condition can be studied for the lifetime of the patient on a unique pathway passing between treating clinicians. It was appreciated that collecting these data will allow us to understand the natural history of various hip pathologies and the effect of surgical treatments. A Registry can prove the efficacy of our treatments so that patients will benefit and purchasers of healthcare will continue to fund them in the future.

Within the NAHR, clinicians are able to collect and display comprehensive outcome and audit data for all of their own patients using scores and outcome measures of their own choosing. Data can be entered for patients who do not undergo surgery for any specific condition so that their clinical course can be followed. Only one hip "pathway" can be started for a left or right hip in any individual so patients are not lost if they move between clinicians. If the patient has consented for their data to be collected, only an arthroplasty or the patient's demise will close their record.

To improve compliance of data collection, the National Institute for Health and Care Excellence (NICE) published in their Interventional Procedure Guidance on Arthroscopic (IPG 408) and Open (IPG 403) Femoro-Acetabular Surgery for Hip Impingement Syndrome that clinicians should submit details to the NAHR. For the condition of femoro-acetabular impingement, clinicians may choose to facilitate collection of only an initial Minimum Data Set (as they do with the NJR). The Registry may then collect additional outcome data, as needed. In addition, the NAHR provides clinicians with the ability to enter data from any other questionnaire or outcome measure as part of their own individualised patient database.

Who Benefits from the Creation of the NAHR?

If we can define the indication for all types of non-arthroplasty hip surgery everyone benefits:

The Patients. Patients will only undergo surgery if it is likely to reduce their pain, improve their function (ability to undertake activity and work) and/or prevent the progress of arthritis of the hip ultimately necessitating a hip replacement. Patients who will not benefit from hip preservation surgery (open or arthroscopic) are spared the risk of an operative procedure, the risk of exacerbation of their symptoms and acceleration of their joint degeneration.

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The Purchasers of Healthcare. Funding will be targeted on patients who will benefit from a surgical procedure. Funds will not be used where the outcome clearly does not justify the use of the available resources.

Surgeons. Surgeons will be able to define which patients will benefit from surgery and what details of the operative procedure will lead to a good result. The surgeon will have validated outcome data available to them.

Practicalities of the NAHR

The Non-Arthroplasty Hip Register (NAHR) was initially launched in 2012 with a major streamlining exercise undertaken in November 2013 to improve surgeon participation. Whilst many arthroscopic and hip preservation surgeons were enthusiastic about its development in principle, many already had their own databases and were, unsurprisingly, unwilling to duplicate data entry. It was therefore decided to use the infrastructure already existing in almost every hospital in England and Wales for collection of data for the National Joint Registry for England, Wales and Northern Ireland (NJR). It was reasoned that this decision would lead to increased enrolment of patients by minimising the necessity for surgeon involvement in the process of data collection.

In addition, a Minimum Data Set (MDS) was defined. Preoperatively, this included a specific hip function measure (iHOT-12) and a general health measure (EQ-5D) [7]. This also corresponded to the National Health Service (NHS) Patient Reported Outcome Measures (PROMS) programme for hip and knee replacement patients [8]. Paper forms were redesigned to help with this process (see Appendix). Whilst it may seem outdated to develop a paper-based system, the availability of hardware for electronic data entry varies immensely between hospitals, particularly in clinic and theatre environments. Whilst the advent of tablet devices is often hailed as the convenient solution to preoperative data collection, maintenance and theft of these devices remains a major problem. Clearly the NAHR can be used entirely without paper forms for those institutions with durable electronic systems in place. However, collection of post-operative outcome data is electronic, and patients are currently invited by email to complete outcome questionnaires at 6 and 12 months after their operation through direct linkage to the online forms.

Patient-Completed Sections

The consent form outlines the purposes of the NAHR to the patient, the type of data required, an explanation of data security and confidentiality measures and a statement that patient participation in the Register is voluntary and consent can be withdrawn at any time. The patient signs their consent and completes their name, date of birth and address and, most importantly, their email address. This email is used for collecting post-operative functional scores and must be checked.

The short version of the International Hip Outcome Tool (iHOT-12) [9] was chosen to measure health-related quality of life and changes after treatment due to its brevity and the fact that it is valid, reliable and responsive to change. It has also been shown to have very similar characteristics to the longer iHOT-33, with very little information being lost with the shorter form and conveniently has twelve questions in the same way as the Oxford Hip and Knee Scores [10, 11]. Responses to each question on the iHOT-12 consist of marking a point on a 100 mm line from 0 (worst) to 100 (best). The score is the average value from the questions answered, allowing patients to omit the question on sexual activity. The mark on the line is measured with a ruler, although this is considered impractical for most units. Data entry is therefore facilitated by the addition of a feint ruler below the dark line, although this may lead to digit preference by the patient. Each value is then entered into the NAHR and the mean value is automatically calculated. When patients complete their 6- and 12-month post-operative iHOT-12 scores online, they use an on-screen slider.

The European Quality of Life 5-Dimensions questionnaire (EQ-5D-5L) was chosen as a standardised general health instrument as it is well established, quick to administer and acceptable to the patient [12, 13]. The EQ-5D is designed for patients to describe and value their health by generating a single summary index value (utility) by quantifying a preference for his or her health state. The EQ-5D instrument consists of five items (dimensions) to describe the respondent's own health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Respondents can value their health in each dimension at five severity levels, which significantly increase reliability and sensitivity (discriminatory power) while maintaining feasibility and potentially reducing ceiling effects in comparison to the three ordinal levels of the original EQ-5D-3L. The second measurement component of the EQ-5D is a Visual Analogue Scale (EQ VAS) for the patient to rate their own health. The format of the EQ-5D-5L is easily reproduced for the online version for both initial data entry and for the patient to complete for their 6- and 12-month post-operative outcomes.

Despite the simplicity and brevity of these outcome measures, patient compliance for completing post-treatment questionnaires can be variable, with particularly low completion rates in young men, an important demographic group in hip preservation surgery. The NAHR allows easy identification of patients who have not completed their forms and can therefore be reminded by telephone or further email. Ensuring patients understand the purpose of the NAHR as they consent to their data being included is a vital step. One

would also hope that evolving technology of both the data entry interface for mobile devices, combined with biometric security measures will improve convenience of completing electronic questionnaires.

Surgeon-Completed Sections

Patient demographic data are easily acquired with use of patient identifier labels and the email address is included by the patient on the consent form, although the operation presents a good opportunity to check patient data. The NHS number is readily available for NHS patients and is often on the identifier label. This number is also used in the NJR and is vital for linkage of patients between the two Registries. For private patients, the NHS number may be obtained from the patient's primary care provider if it was not included in the patient's original referral letter.

The diagnostic categories listed on the MDS form are fairly comprehensive and multiple diagnoses may be chosen. Due to difficulties in diagnosing the subtypes of femoroacetabular impingement (FAI) and the resulting inter-observer variation, it was agreed to use the simple umbrella term of FAI to include cam, pincer and combined types, which also includes the associated labral and chondral lesions. The options of "Undiagnosed hip pain" and "Hypermobility" were also included for hips with normal bony structure and normal findings at arthroscopy. The MDS form is completed by describing where, when and who performed surgery, as well as patient weight and height, and whether surgery was performed arthroscopically, open, or a combination of both (e.g. central compartment arthroscopy followed by mini-open femoral neck osteoplasty, or pelvic osteotomy). The details of the operation collected for the MDS are only those which are unambiguous. Whilst, at first viewing, these terms may seem to lack detail, they have been chosen to enable early patient outcomes to be established for all three surgical approaches for FAI and open surgery for hip dysplasia. The strength of a Registry is in its scale and inclusiveness and it was felt important to ensure engagement of the surgical community with a simple, unambiguous, practical dataset rather than a more inclusive one which can be subject to misinterpretation.

The optional Extended Data Set (EDS) was included for surgeons, particularly those without their own existing databases, to include additional surgical details to provide individual activity data, i.e. how often chondral microfracture is performed per year. This information can be useful for planning services and is certainly more detailed than available in most generic hospital systems. Whilst this does allow some basic analysis, the EDS is not yet designed to be sufficiently detailed to allow scientific comparison between different techniques, such as whether labral repair is superior to labral debridement. This is because it is impossible to control for the myriad of other factors, many of which are not yet fully understood, that affect the outcome of hip preservation surgery, and which can only be answered with proper scientific trials. It is hoped, however, that the EDS will continue to develop and will shortly contain a means for quantifying the severity and extent of chondral damage.

Additional Features of NAHR Database and Surgeon Reports

Whilst the "front end" of the NAHR is designed to correspond with the paper forms for ease of data entry, the inherent flexibility of the data collection software allows entry of data in addition to the MDS and EDS. This includes data collected by a variety of hip outcome instruments, including the UCLA activity score [14], the modified Harris Hip Score (HHS) [15], the Non-Arthritic Hip Score (NAHS) [16] and the Hip disability and Osteoarthritis Outcome Score (HOOS) [17]. The system also allows the clinician to enter information describing the type and timing of previous radiological studies and surgical procedures as well as data derived from imaging studies.

The NAHR automatically generates reports for surgeons based on diagnosis and surgical approach showing the preoperative, 6- and 12-month scores for cohorts of patients having surgery in sequential 6-month periods. This quickly gives surgeons feedback on the extent and type of their hip preservation practice as well as their clinical outcomes. Reporting tools within the NAHR allow surgeons to further interrogate their own data by fields in both the MDS and EDS, e.g. male patients having arthroscopic cam resection and labral debridement within a particular date range. This allows the NAHR to serve as an online database, enabling the surgeon ready and secure access to his/her own patient data using multiple devices with a robust back up.

The NAHR as a Research Tool

Recent data obtained from the Hospital Episode Statistics database in the UK suggest that hip arthroscopy grew by 450 % between 2001 and 2011 (Fig. 106.1) [18].

This rapid expansion is likely to be reflected in other countries such as the United States where an estimated 100,000 hip arthroscopies were conducted in 2012. This highlights the need for better quality evidence in determining the efficacy of hip arthroscopy, which now appears to be widely practiced outside the confines of specialist centres. Groups such as the IDEAL Collaboration have demonstrated that the pathways for introducing new surgical procedures are deficient, and that many procedures and devices are widely used without adequate evidence [19]. This group has suggested a phased introduction of new technologies (Table 106.1).

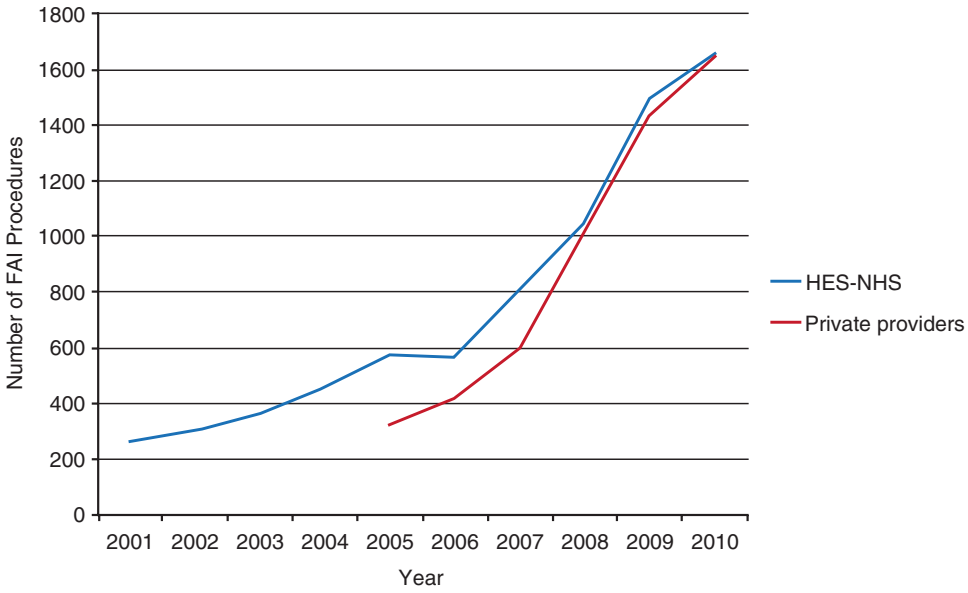

Fig. 106.1 Temporal trend in arthroscopic FAI surgery (2001–2011)

Table 106.1 The stages for introducing new surgical technology (based on the IDEAL collaboration framework) [19]

IDEAL framework				
Stage 1: idea question	Stage 2a: development	Stage 2b: exploration	Stage 3: assessment	Stage 4: long-term study
Can the procedure or device achieve a specific physical or physiological goal?	What is the optimal technique or design, and for which patients does it work best?	What are the outcomes of most widespread use? Can consensus equipoise be reached on a trial question?	How well does the procedure work compared with current standards of care?	What are the long-term effects and outcomes of the procedure?
Aim				
Proof of concept	Safety, efficacy	Efficacy	Comparative effectiveness	Quality assurance
Patient base				
Single to few	10s	100s	100s+	100s+
Optimal study design(s)				
First-in man study; structured case report	Prospective development study	Prospective collaborative observational study (Phase IIS) or feasibility randomised controlled trial (or both)	Randomised controlled trial	Observational study or randomised trial nested within a comprehensive disease-based Registry
Example of procedure at this stage				
Stem cell-based tracheal transplant for tracheal stenosis	Peroral endoscopic myotomy for oesophageal achalasia	Single incision laparoscopy for abdominal surgery	Minimally invasive oesophagectomy	Banding and bypass surgery for morbid obesity

The orthopedic community has begun to make significant steps towards evaluating the different types of arthroscopic procedures. The American Academy of Orthopaedic Surgeons conducted an international symposium on hip arthroscopy in 2012, led by a group of international experts. Its aim was to determine the best mechanism for evaluating this new technology and the findings of the conference were published in a series of proceedings [20–22]. The main conclusions focused on current practice and the best mechanism for evaluating this new technology. The heterogeneity of current practice was highlighted with the recognition that several different procedures are being performed, including FAI surgery, labral treatments and procedures designed to treat osteoarthritis. There is often considerable variability in the way in which the procedures are performed and patients often undergo more than one procedure simultaneously, which makes evaluation of new surgeries difficult. The authors identified FAI surgery as the principal target for evaluation, as it has the potential to slow osteoarthritis progression in the hip. The symposium provided recommendations on the design, outcomes and non-operative control for a future RCT.

The National Institute for Clinical Excellence (NICE) has also called for further evaluation of hip arthroscopy (with particular reference to FAI surgery). There are two potential ways of achieving this; either by using a well-constructed Registry or by performing a randomised controlled trial. The rest of this section will seek to summarise the current and ongoing efforts to gather evidence of efficacy in hip arthroscopy and FAI surgery.

Ongoing and Planned RCTs

RCTs are the gold standard for determining the efficacy of new treatments or interventions. Their principal advantage over cohort studies is the ability to strictly control the study population, the intervention and to also use a comparator group. This means that all patients entering a study may be accurately phenotyped and should receive the same intervention as all other patients participating in each arm of a study. However, surgical RCTs are very costly, require significant feasibility and pilot work, and are often hampered by recruitment problems due to surgical equipoise (i.e. the belief that the new operation and the alternative treatment are equally likely to be effective). Despite these limitations, in 2014 there were four RCTs of arthroscopic FAI surgery worldwide that were *recruiting* subjects (Table 106.2) registered on ClinicalTrials.gov and one ongoing feasibility study registered on the ISRCTN website. Three of the trials are running in North America and one in the United Kingdom. Most compare hip FAI surgery with a non-operative control, whilst one study compares FAI surgery with a "placebo" procedure (Table 106.2). These trials all use a patient-reported outcome as their primary outcome and are generally pragmatic in nature, with the aim of reflecting current practice. Only one trial (FAIT) has a published feasibility study [23]. This is a parallel 2-arm multicentre RCT. The first phase of this trial has demonstrated that patients are interested in the ability of FAI surgery to improve pain in the short term as well as prevent/slow osteoarthritis in the long term. This means that trials should address both questions.

The NAHR as a Tool for Assessing the Efficacy of Hip Arthroscopy

The Non-Arthroplasty Hip Register may also be a potential tool for evaluating the efficacy of hip arthroscopy and FAI surgery. In theory, a successful Registry, such as the NJR of England and Wales [24] captures more than 80 % of the current practice in a clinical area. In such a scenario accurate comparisons between commonly performed procedures can be made in terms of device failure, complications and for different surgical approaches. A Registry therefore has the potential to draw accurate conclusions on the efficacy of procedures, provided those procedures are performed frequently. The NJR of England and Wales is an excellent example of a highly successful Registry which enables current practice and the efficacy of different designs of hip and knee arthroplasty to be accurately evaluated, and allows for early identification of failing prostheses.

Limitations of Registries and the Need for Data Linking

Despite these obvious strengths, registries also have some limitations. The biggest of these is the need to capture large volumes of procedures in order to draw statistically meaningful conclusions. This means that both the numbers of operations performed and the proportion of surgeons contributing must be high. This has been a particular problem with new devices in the NJR, which are typically implanted in small numbers initially, making outliers difficult to identify [25]. This is best illustrated by the recent issues with

Table 106.2 Details of the four recruiting RCTs of arthroscopic FAI surgery worldwide registered on ClinicalTrials.gov

Study source: ClinicalTrials.gov	Intervention/comparator	Primary outcome	Location/country	Start date
Femoro-acetabular impingement trial (FAIT)	Surgery vs. non-operative control Cohort size: 120 (300 2nd phase) Number of centres: 9	Hip outcome score at 12 months	University of Oxford	04/2013
Femoro-acetabular impingement randomised controlled trial (FIRST)	Surgery vs. "placebo" surgery Cohort size: 50 Number of centres: 1	Hip outcome score at 24 months	McMaster University, Canada	09/2012
Hip arthroscopy versus conservative management of femoro-acetabular impingement	Surgery vs. non-operative control Cohort size: 140 Number of centres: 1	Unknown (in feasibility phase)	University of Western Ontario, Canada	04/2011
A physical therapy program versus surgery for femoro-acetabular impingement: randomised clinical trial	Surgery vs. physiotherapy Cohort size: 60 Number of centres: 1	Hip outcome score at 24 months	Madigan Army Centre, United States	03/2013

metal on metal implants which were identified in cohort studies in 2008 and only appeared as outliers in the NJR in 2011 [26–28].

At present less than 4000 hip arthroscopy procedures are performed in the UK every year. Even with 100 % compliance it would be difficult to draw statistically meaningful conclusions for all but the most general outcomes, given the heterogeneity of the procedures performed. Nevertheless, looking at the current expansion in the numbers of hip arthroscopies and the frequency of pathologies such as FAI and labral tears in the population, the NAHR is likely to be of great value in the near future. In particular, the non-operative data collected by the NAHR are likely to be useful in comparing the results of surgery with non-operative interventions. This may be of particular value, given that the NAHR also collects cost-utility measures, such as the EQ-5D.

Linking datasets may also provide a method for improving compliance and the quality of data entered into a Registry, especially during the early phases of development. In much the same way as the HES and National PROMs databases enhance the NJR, the NAHR dataset may be enhanced or validated using data uploaded on a periodic basis from cohort studies and RCTs. This gives the added advantage of being able to compare outcomes from two different, but complementary, data sources and may help to refine the data analysis methodology of the NAHR. In particular, this may be useful in refining the statistical methods used to detect outliers within smaller Registries.

Summary

There is a real excitement that the culture of data collection is changing in UK orthopedics. There is a growing appreciation amongst surgeons that the best way to improve the quality of patient care is for the profession to collaborate in order to organise, collect and interpret quality outcome data. The Non-Arthroplasty Hip Register is one such Register collecting longitudinal data. Other Registries have already made a significant contribution to improving the quality of care for patients including the National Hip Fracture Database (NHFD), the Trauma Audit and Research Network (TARN) and the National Joint Registry for England and Wales (NJR). Several others, more recently launched, include the National Knee Ligament Register, the British Spine Register, several paediatric pathways and a hand surgery audit.

Data within orthopedic Registries are complex and require context and interpretation by clinicians.

The drive towards transparency of outcomes will inevitably accelerate allowing scrutiny of data by patients and those who purchase healthcare. There is an imperative for orthopedic surgeons to engage and help define the culture surrounding the collection and use of data within our areas of specialist interest.

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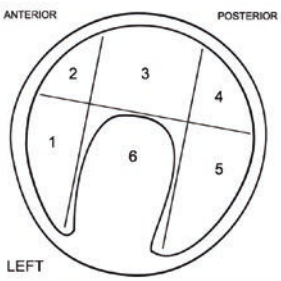
Appendix

SURGEON

EXTENDED DATA SET (OPTIONAL) – OPERATION DETAILS

Acetabulum					
Labrum Debridement	☐	Labrum Resection	☐	Labrum Repair	☐
Rim Recession Simple	☐	Rim Recession – labral reattachment	☐	Sub-spinous resection	☐
Cartilage Debridement	☐	Microfracture	☐	Cartilage Reattachment	☐
Graft/ACI	☐	Other	☐		

Location and severity of **single worst** area of acetabular cartilage damage
(Ilizaliturri et al Arthroscopy 2008;24:534, Konan et al JBJSB 2011;93:332)



Location (tick one)		Severity (tick one)			
None	☐	None	☐	3A	☐
1	☐			3B	☐
2	☐	1A	☐	3C	☐
3	☐	1B	☐		
4	☐	1C	☐	4A	☐
5	☐			4B	☐
6	☐	2	☐	4C	☐

Severity	Extent
1 Wave Sign with intact chondrolabral junction	A Lesion less than one-third of the distance from the
2 Chondrolabral junction separation but no delamination	acetabular rim to the cotyloid fossa
3 Delamination	B One-third to two-thirds of this distance
4 Exposed bone	C Greater than two-thirds of this distance

Femur					
Cam removal	☐	Osteophyte removal	☐	Cartilage Debridement	☐
Microfracture	☐	Core decompression	☐	Graft/ACI	☐
Other	☐				

Severity of Femoral Cartilage Defect (Outerbridge)

None ☐ Normal Cartilage 1 ☐ Rough surface, chondral softening 2 ☐ Irregular surface defects <50% cartilage thickness 3 ☐ >50% loss of cartilage thickness 4 ☐ Full thickness loss

Soft Tissue					
Ligamentum Teres Debridement	☐	Ligamentum Teres Reconstruction	☐		
Loose body removal	☐	Biopsy	☐	ITB release	☐
Psoas release	☐	Gluteal tendon repair	☐	Troch Bursa debridement	☐
Pelvic osteotomy					
PAO	☐	Triple	☐	Chiari	☐
Salter	☐	Dega	☐	Pemberton	☐
Shelf	☐				
Femoral osteotomy					
Varus	☐	Valgus	☐	Derotation	☐
Shortening	☐	Troch advancement	☐	Complex	☐
Open reduction (DDH)	☐				

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