Treatments for Femoroacetabular Impingement

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September 2013

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Acknowledgements

I would like to thank Professor D. Griffin, Mr G. Andrew and Professor C. Hutchinson who supervised me through this research degree. During the project obstacles that I thought might be insurmountable were crossed with ease under the guidance and support of Professor Griffin. I would also like to thank the many study collaborators involved at various stages in this work, they are:

Dr J Brown, Dr M. Fernandez, Dr S Freshney, Professor N Foster, Ms A Realpe, Dr A Adams, Mrs R Hobson, Professor S. Petrou, Professor M. Costa, Professor R. Buchbinder, Mrs S. Duggan, Dr J Achten, Professor J Donovan, Dr N Parsons, Dr H. Parsons, Mr I. Hughes, Mr D. Robinson.

The University Hospital Coventry and Warwickshire and University of Warwick who co-sponsored much of the work included in this thesis have as institutions provided an invaluable depth of support to research degree students such as me – thank you.

Finally, I would like to thank the many patients who have taken part in this work. May your contributions help improve your own and the care of future generations of patients with hip symptoms.

Declaration

This thesis is submitted to the University of Warwick in support of my application for the degree of Doctor of Philosophy. It has been compiled solely by me and has not been submitted in any previous application for any degree.

The work presented (including data generated and data analysis) was carried out by me except in the cases outlined below:

Chapter 2: Randomisation sequence for patients with bilateral SCFE, completed by Dr H. Parsons. Dr J. Brown helped with data collection. Dr S Freshney undertook independent radiograph measurements for comparison to my own.

Chapter 3: Dr J. Brown provided independent assessment of the references reviewed. Dr N Parsons and Professor R Buchbinder provided input for the analysis plan.

Chapter 4: Dr M. Fernandez provided independent assessment of the references reviewed.

Chapter 5: The members of the core study group: Professor N. Foster, Mr D. Robinson and Mr I Hughes helped to develop the “best conservative care” protocol. Ms A. Realpe and Dr A Adams developed a new name for the protocol “Personalised Hip Therapy (PHT)”.

Chapter 6: Assistance with data collection was undertaken by Mrs R. Hobson and Mr M. Shehata.

Chapter 7: Transcription of interviews was undertaken by Ms A. Realpe, who helped with the thematic analysis and also collaborated on the project.

Chapter 8: Development of the patient information material was aided by Mrs R. Hobson, Ms A. Realpe, Dr. A Adams. The sample size calculation was carried out by Dr N. Parsons. Assistance with patient follow-up was provided by Mrs R. Hobson and Ms J. Stokes.

Chapter 9: Assistance with patient follow-up was provided by Mrs R. Hobson and Ms J. Stokes. The members of the core study group: Professor N. Foster, Mr D. Robinson and Mr I Hughes helped determine per protocol delivery of care.

Chapter 10: The sample size calculation was carried out by Dr N. Parsons.

Parts of this thesis have already been published:

Peer reviewed journals

1. Wall PDH, Brown J, Wyse M, Griffin D. An Introduction to Hip Arthroscopy part one: Surgical anatomy and technique. Orthopaedics and Trauma 2011; 25:6: 441-447.
2. Wall PDH, Brown J, Griffin D. An introduction to hip arthroscopy part two: indications, outcomes and complications. Orthopaedics and Trauma 2012; 26:1: 38-43.
3. Wall PDH, Brown JS, Freshney S, Parsons H, Griffin DR. Hip shape and long term hip function: A study of patients with in-situ fixation for slipped capital femoral epiphysis. Hip international: the journal of clinical and experimental research on hip pathology and therapy. 2013; 23:6: 560-564.
4. Wall PDH, Fernandez M, Griffin DR, Foster NE. Nonoperative treatment for femoroacetabular impingement: A systematic review of the literature. PM&R. 2013; 5:5: 418-426
5. Wall PDH. Ask the author. PM&R. 2013; 5:5: 427-428
6. Wall PDH, Brown JS, Costa M, Buchbinder R, Griffin DR. Surgery for femoroacetabular impingement. Published Protocol. Cochrane Database of Systematic Reviews. DOI: 10.1002/14651858.CD010796.
7. Clohisy JC, Kim Y-J, Lurie J, Glyn-Jones S, Wall P, Wright R, Spindler K, Lohmander S. Clinical Trials in Orthopaedics and the Future Direction of Clinical Investigations for Femoroacetabular Impingement. Journal of the AAOS 2013;21-Supplement 1:47-52.
8. Griffin DR, Wall PDH, Realpe A, Adams A, Parsons N, Hobson R, Achten J, Fry J, Costa M, Petrou S, Foster NE, Donovan J. UK FASHIoN: Feasibility study of a randomised controlled trial of arthroscopic surgery for hip impingement compared with best conservative care. Full study report submitted September 2013 to the Health Technology Assessment Programme.

Conference podium presentations

1. American Academy of Orthopedic Surgeons (AAOS) Femoroacetabular Impingement Research Symposium May 2012. FASHIoN Trial – Feasibility study of a trial of Arthroscopic Surgery for Hip Impingement versus best conservative care.
2. International Society for Hip Arthroscopy (ISHA) October 2011. Non-operative treatment of femoroacetabular impingement: Design of a fair comparator for a multi-centre national randomised trial of arthroscopic surgery.
3. International Society of Orthopaedic Surgery and Traumatology (SICOT) Prague September 2011. Does an effective non-operative treatment exist for femoroacetabular impingement? A systematic review of the literature.
4. Oswestry Research Day, May 2013. Design of a nonoperative treatment strategy for Femoroacetabular Impingement.
5. Oswestry Research Day, May 2011. Does an effective nonoperative treatment exist for Femoroacetabular Impingement?
6. European Paediatric Orthopaedics Society Annual Meeting (EPOS) Helsinki April 2012. Long Term Hip Function after Surgery for Slipped Capital Femoral Epiphysis Surgery - A 15 Year Follow up Study.

Conference poster presentations

1. University of Warwick Annual Research Symposium, May 2013**.** Treatments for femoroacetabular impingement.
2. Oswestry Research Day, May 2013**.** Workload of surgery for femoroacetabular impingement within the NHS 2011/2012.

Abbreviations

AMED	Allied and Complementary Medicine Database
AVN	Avascular Necrosis
CDC	Consensus Development Conference
CE	Centre Edge angle of Wiberg
CI	Confidence Interval
CRF	Case Report Form
CSG	Core study group
CT	Computed Topography
CINAHL	Cumulative Index to Nursing and Allied Health
CONSORT	Consolidated Standards of Reporting Trials
DDH	Developmental Dysplasia of the Hip
DG	Damian Griffin
DR	David Robinson
EMBASE	Excerpta Medica Database
FAI	Femoroacetabular Impingement
FASHIoN	Feasibility study of a trial of Arthroscopic Surgery for Hip Impingement compared with best coNservative care
GRADE	Grading of Recommendations Assessment, Development and Evaluations
HTA	Health Technology Assessment
IHOT-33/12	International Hip Outcome Tool – 33/12
ISRCTN	International Standard Randomised Controlled Trial Number Register
IH	Ivor Hughes
IQR	Inter Quartile Range
MCID	Minimally Clinical Important Difference
MD	Mean Difference
MF	Miguel Fernandez
MHHS	Modified Harris Hip Score

MPR	Multi Planar Reformation
MRA	Magnetic Resonance Arthrography
MRC	Medical Research Council
mRCT	metaRegister of Controlled Trials
NGT	Nominal Group Technique
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NNTB	Number Needed to Benefit
NNTH	Number Needed to Harm
NSAID	Non-Steroidal Anti-Inflammatory Drugs
OA	Osteoarthritis
ONS	Office for National Statistics
OPCS	Office of Population Censuses and Surveys Classification of Interventions and Procedures
PROM	Patient Reported Outcome Measure
PHT	Personalised Hip Therapy
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PW	Peter Wall
R&D	Research and Development
RB	Rachelle Buchbinder
RCT	Randomised Controlled Trial
SF	Sara Freshney
SCFE	Slipped Capital Femoral Epiphysis
SD	Standard Deviation
SMD	Standardised Mean Difference
SoF	Summary of Findings
THA	Total Hip Arthroplasty
TR	Trained Recruiter

UHCW	University Hospital Coventry and Warwickshire
UK	United Kingdom
USA	United States of America
WOMAC	Western Ontario and McMaster Universities Arthritis Index

Abstract

The hip is a ball and socket joint in which the femoral head (the ball) articulates with the acetabulum (the socket). In a condition called femoroacetabular impingement (FAI) the hip has a shape abnormality and is no longer perfectly spherical. The hip shape abnormality FAI provokes premature impingement between the femoral head and rim of the acetabulum leading to pain and in the longer term osteoarthritis. Slipped capital femoral epiphysis (SCFE), an adolescent hip disease, is thought to be one cause of FAI. However, a cohort study of patients with SCFE presented in this thesis found no evidence of an association between worsening hip shape, function and pain. Factors other than abnormal hip shape may therefore have an important role in the development of hip symptoms in both SCFE and FAI.

Systematic reviews presented in this thesis highlight that surgery or physical therapy can be used to treat FAI but the true clinical effectiveness of either treatment is not known. At least 100 surgeons undertook 2399 surgical procedures in the year 2011/12 in the UK National Health Service for FAI of which 80% were done arthroscopically. A qualitative interview study amongst 14 of these surgeons showed that many would like to engage in a RCT measuring the clinical effectiveness of their surgery. To test recruitment to such a RCT a pilot RCT comparing hip arthroscopy versus nonoperative care for FAI was undertaken. Forty-two out of 60 (recruitment 70%) eligible patients were recruited. Twenty one patients were allocated to nonoperative care, and 81% received per protocol treatment, with no evidence of serious adverse events. The work in this thesis should now facilitate a RCT to be undertaken in an area (treatment for FAI) where no RCTs have previously been conducted.

Words=289/300

Research Training

During my period of study I have undertaken the following research training:

University of Warwick in house training

i.	Post Graduate Certificate in Transferable Skills at the University of Warwick	
	a. Research Ethics	Mar 2013
	b. Team Development and Networking	July 2012
	c. Envisioning and Enabling Innovation	May 2012
ii.	Epidemiology and Statistics Postgraduate Course	Nov 2011
iii.	Good Clinical Practice Training	Oct 2011
iv.	EndNote X4: The Beginners Guide	June 2011

Research conferences attended

i.	Oswestry Research Day, UK	May 2013
ii.	AAOS) FAI Research Symposium, Chicago	May 2012
iii.	European Paediatric Orthopaedics Society Annual Meeting (EPOS), Helsinki	April 2012
iv.	International Society for Hip Arthroscopy (ISHA) Annual Meeting, Paris	Oct 2011
v.	International Society of Orthopaedic Surgery and Traumatology (SICOT) Prague	Sept 2011
vi.	Oswestry Research Day, UK	May 2011

Chapter 1 Introduction

1.1 Declarations

Aspects of this chapter have been published:

Wall P, Brown J, Wyse M, Griffin D. An Introduction to Hip Arthroscopy part one: Surgical anatomy and technique. *Orthopaedics and Trauma 2011; 25:6: 441-447*

Wall P, Brown J, Griffin D. An introduction to hip arthroscopy part two: indications, outcomes and complications. *Orthopaedics and Trauma 2012; 26:1: 38-43*

1.2 Thesis aims and objectives

The aims of this thesis are:

1. To explore the correlation if any between abnormal hip shape and long term hip specific quality of life in the context of slipped capital femoral epiphysis (SCFE); which is thought to be one mechanism by which patients can develop cam type femorocacetabular impingement (FAI).
2. Design a randomised controlled trial (RCT) to measure the clinical effectiveness of FAI surgery by:

a. Establishing a suitable nonoperative treatment comparator.

b. Exploring equipoise within the FAI surgical community in order to understand any barriers to a full RCT and subsequent recruitment.

c. Estimate the size and scale of a full RCT by:

   i. Estimating the number of FAI surgeons and their individual workload within the National Health Service (NHS).

   ii. Estimating the recruitment rate of patients by undertaking a pilot RCT.

1.3 Hip: structure, embryology and function

The human hip joint is classified as an enarthrodial joint (ball and socket joint) and forms the connection between the pelvis and lower limb.[1] A femoral head (the ball) articulates with the

cup shaped acetabulum (socket). Traditionally anatomists described the femoral head as spherical (hence the name ball and socket joint).[1] More recent research suggests that the femoral head is not infrequently aspherical in shape. However, the use of the expression "ball and socket joint" continues.[2,3]

During foetal development the hip joint forms from a single mass of scleroblastema which is first evident at six weeks between the cartilage structures of the femur and acetabulum.[4,5] The bony structure, cartilage, muscles and tendons are all formed from mesoderm. The joint space of the hip forms at 11 weeks at which point the femur and acetabulum are well formed. The acetabulum becomes progressively shallower during fetal life but after birth it begins to deepen again.[6] The acetabulum is formed by the union of the pubis, ilium, and ischium, all of which have both primary and secondary ossification centres.[7] The secondary ossification centres all appear during the first decade of life and have fused by 17 to 18 years of age.[4]

The ilium, ischium and pubis make up the innominate bone. The rim of the acetabulum is surrounded by the labrum, which is a triangular section of fibrocartilage. The labrum is thought to have two important roles:

i. It deepens the acetabulum and provides a seal to counter distraction of the femoral head and improve joint stability.[4]

It contains and controls synovial fluid in the central compartment (see page 24) of the hip as the joint is loaded.[4] At its inferior margin the labrum becomes the transverse ligament. The labrum can vary considerably in size particularly in association with diseases that alter hip shape. For example in developmental dysplasia of the hip (DDH), a childhood hip disease, the labrum often becomes hypertrophied as a result of inadequate coverage of the femoral head by the acetabulum and subsequent excessive weight bearing forces through the lateral aspect of the acetabulum and increased loading of the labrum.[8] In addition damage to the labrum – such as tears – are strongly associated with early joint degeneration.[9] The capsule of the hip is a tough fibrous layer that attaches to the acetabulum just peripherally to the labrum and transverse ligament. From this attachment the capsule extends like a sleeve

circumferentially and attaches to the neck of the femur. The capsule therefore provides some additional stability to the hip joint by virtue of its connection to both the acetabulum and femur. The part of the acetabulum covered with articular cartilage is called the lunate surface – see Figure 1.1 and Figure 1.2.

Figure 1.1: View of central compartment of hip joint during hip arthroscopy (Source: Wall et al[10])

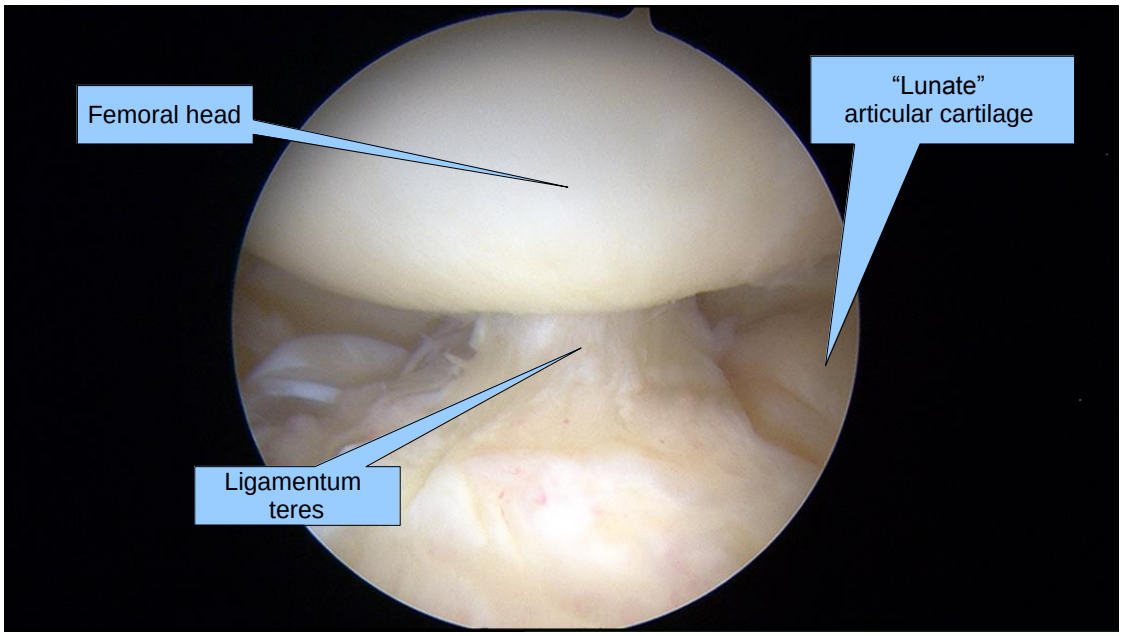
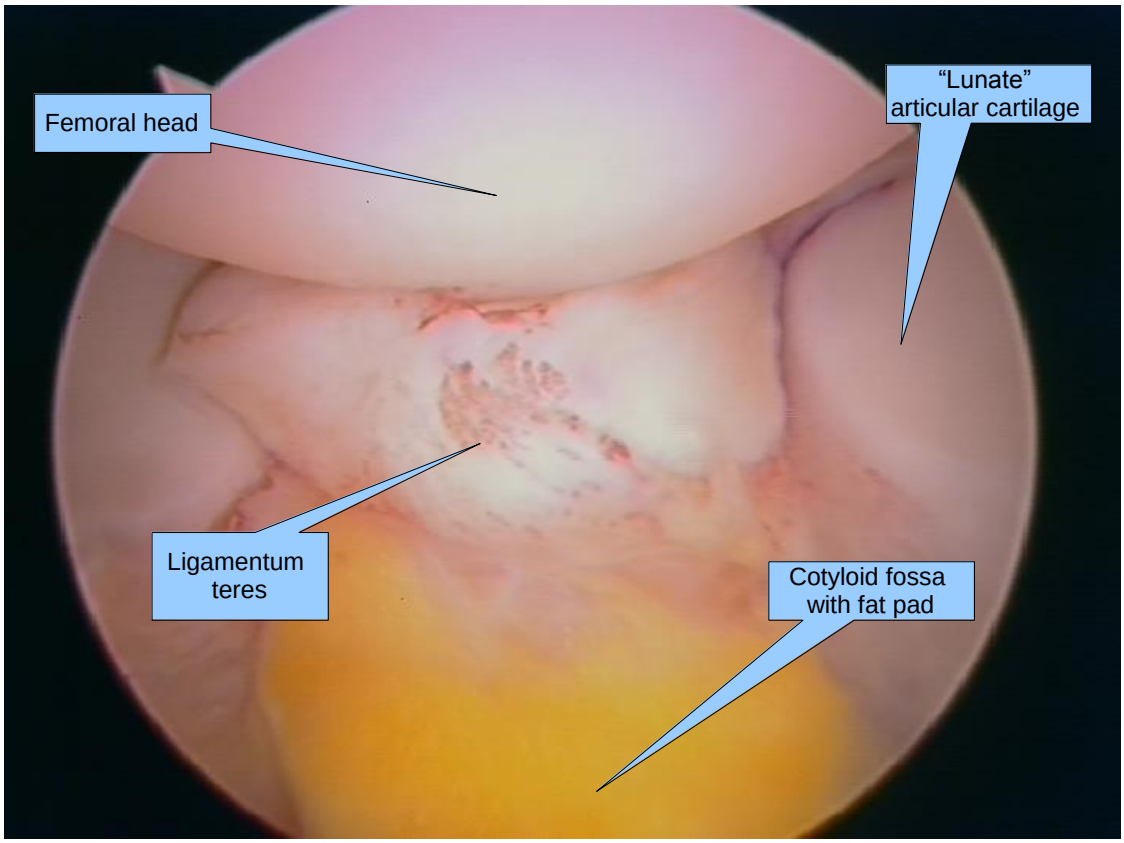


Figure 1.2: Further view of central compartment of hip joint during hip arthroscopy (Source: Wall et al[10])



The cartilage overlying the lunate surface forms a horseshoe-shaped configuration and extends from the postero-inferior aspect to the antero-inferior aspect of the acetabulum. In the middle of the acetabulum and therefore contained within the horseshoe of cartilage is the cotyloid fossa.[10] The cotyloid fossa does not contain any articular cartilage but instead has within it a pad of fat. The cotyloid fossa is also the site of attachment for the ligamentum teres, which is a large strap like structure that connects the femoral head to the acetabulum. The attachment is in the base of the cotyloid fossa and close to the posterior attachment of the transverse ligament – see Figure 1.1 and Figure 1.2. The ligamentum teres is slightly broader and typically covered in synovial membrane at its connection to the acetabulum. The other attachment of the ligamentum teres is to a pit or fovea in the centre of the femoral head.

The following three ligaments, which are distinct thickenings of the capsule of the hip provide additional stability to the joint:

i. the iliofemoral ligament which lies anteriorly and connects the femur to the ileum;
ii. the pubofemoral ligament which lies anteriorly and connects the femur to the pubis and
iii. the ischiofemoral ligament which lies posteriorly and connects the femur to the ischium.

These all form direct connections between each of the bones that constitute this part of the pelvis.

The use of hip arthroscopy (keyhole surgery - see section 1.11) has revealed the following additional clinically relevant anatomical areas of the hip joint:

i. The central compartment the space between the surface of the femoral head and the acetabulum, limited by the labrum. This compartment comprises the hips articular surfaces and labrum - see Figure 1.3 and Figure 1.4, which are Magnetic Resonance Arthrography (MRA) views of the hip joint.

ii. The peripheral compartment refers to the remainder of the hip joint within the intracapsular space but both lateral and peripheral to the labrum. It includes the area along the junction of the femoral head and neck – see Figure 1.3 and Figure 1.4.

Figure 1.3: Coronal section of hip joint using MRA (Source: Wall et al[10])

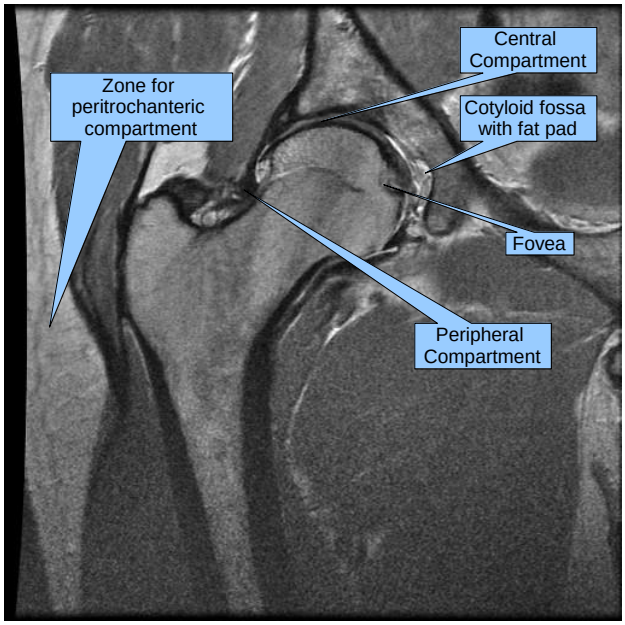
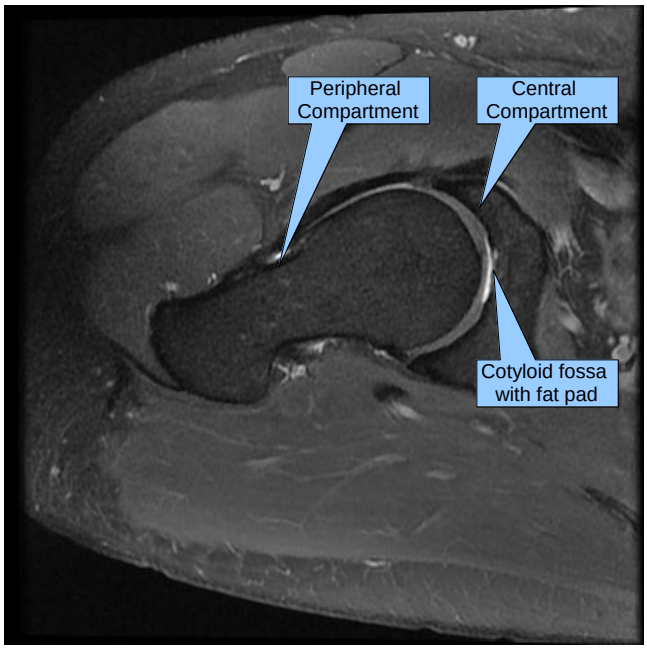


Figure 1.4: Axial section of hip joint using MRA (Source: Wall et al[10])



The hip joint is designed to support the entire weight of the upper body whilst allowing movement to occur between the pelvis and lower limb during activities such as walking, running and climbing. The forces that cross the hip joint are large with up to three times body

weight transferred across the hip during normal walking and this increases to seven times with fast walking.[11]

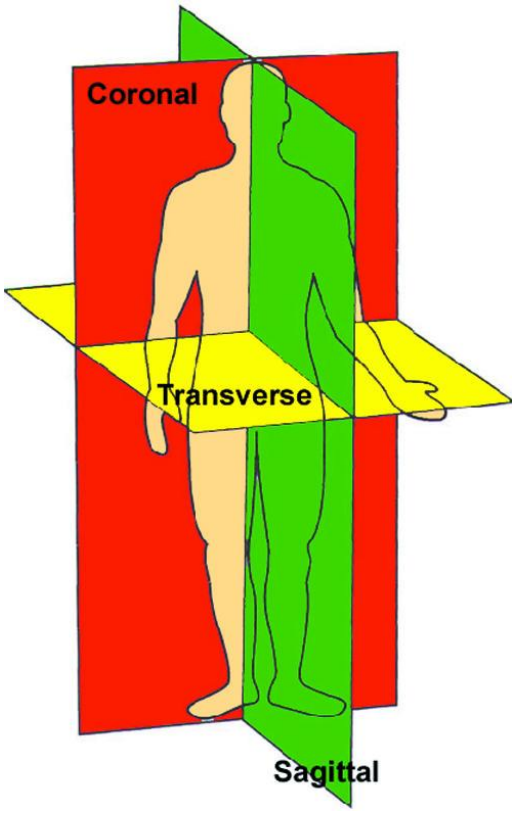
The hip joint allows movement in three anatomical planes – see Figure 1.5:

i. Sagittal; allows flexion and extension.

ii. Coronal; allows abduction and adduction

iii. Transverse; allows internal and external rotation

Figure 1.5: Anatomical planes (Source: Cook et al[12])



Ranges of movement for the hip joint can vary markedly but for the purpose of this thesis the following published parameters have been used:[13]

i. Flexion; 0 degrees to between 100° and 135°

ii. Extension; 0 degrees to between 15° and 30°

iii. Abduction; 0 degrees to between 40° and 45°

iv. Adduction; 0° to 25°

v. Internal rotation; 0° to between 30° and 40°

vi. External rotation; 0° to between 40° and 60°

1.4 Osteoarthritis of the hip

Osteoarthritis (OA) is one of the most common types of arthritis and the hip is one of the joints most frequently affected.[14] OA is typically defined as a clinical syndrome which affects a joint, with subsequent pain and loss of function.[15] The pathology underlying OA involves structural changes within the joint. However, it is not uncommon for patients to have evidence of structural change without any symptoms.[15] The structural changes involve loss of hyaline articular cartilage, subchondral changes (both sclerosis and cysts), reduction in the normal joint space, and evidence of new bone formation (osteophytes). Many of these structural features described can be evaluated with radiological imaging, which is the rationale for imaging being used to confirm a diagnosis of OA.[16] One method described by Tonnis et al for assessing radiological evidence of OA, which will be used later in this thesis, is described in Table 1.1.

Table 1.1: Tonnis grading system for OA of the hip[17]

Tonnis Grade	Radiographic Description (using anterior posterior pelvic radiograph only)
0	No signs of osteoarthritis
1	Slight narrowing of joint space, slight lipping at joint margin, slight sclerosis of femoral head or acetabulum
2	Small cysts in femoral head or acetabulum, increasing narrowing of joint space, moderate loss of sphericity of femoral head
3	Large cysts, severe narrowing or obliteration of joint space, severe deformity of femoral head, avascular necrosis

The prevalence of structural changes consistent with hip OA found on radiological imaging is reported to be 27% amongst adults ≥45 years of age.[14] However, of this group the prevalence of symptomatic hip OA (evidence of symptoms and structural change on radiological imaging) is much lower and has been reported as 9.2%.[14]

The majority of hip OA is so called ‘primary / idiopathic’, for which the cause is unknown. Studies have shown that primary OA of the hip has a strong hereditary (genetic) component but the mechanism by which genetic predisposition leads to disease is not known.[18,19] Surgery for hip OA is typically reserved until other non-operative treatments no longer provide adequate relief of symptoms.[15] In 2011, 80,314 total hip replacements were undertaken in the

United Kingdom, of which 93% were reported as being performed to alleviate the symptoms of OA.[20]

1.5 Young adult hip pain

Over recent years the management of hip pain in young adults has evolved considerably.[21,22] A small proportion of young adults with pain have established OA, inflammatory arthritis, avascular necrosis (AVN), fractures or preexisting childhood hip disease (such as DDH), and their care sometimes includes surgery.[22] However, until recently the majority of patients had no specific diagnosis and received multidisciplinary medical care, provided by a combination of physiotherapists, rheumatologists, orthopaedic surgeons, sport and exercise medicine physicians, and general practitioners.[21] Over the last ten years however, there has been increasing recognition of the syndrome of femoroacetabular impingement (FAI), which may account for a large proportion of the previously undiagnosed cases of hip pain in young adults and subsequent so called primary OA.[21,23]

1.6 Femoroacetabular Impingement: background

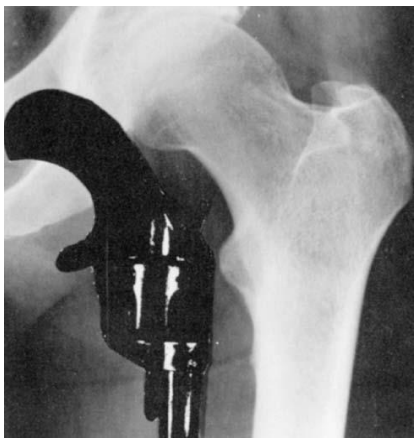
The association between an abnormal hip shape and early onset degenerative hip disease (OA) has been known for some time.[24-26] DDH a condition, that prevents the hip joint from forming a normal shape in childhood and leads to a lack of acetabular coverage of the femoral head, is associated with and thought to be a risk factor for OA.[27]

In 1966 Murray hypothesised that the majority of so called “primary” hip OA resulted from “minimal anatomical variations” and that these “correspond to the more gross abnormalities of acetabular dysplasia (DDH) and of the adult deformity resulting from epiphysiolysis (SCFE described later in 1.8.2)”.[26] He suggested that: “their presence postulates an abnormal joint mechanism and the resulting incongruity of the articular surfaces makes the development of degenerative change more likely than in a joint having a normal anatomical structure.” He tested his theory by reviewing pelvis radiographs from 50 patients with no hip symptoms and no evidence of OA and compared these to 200 patients with primary hip OA. He assessed both cohorts of patients using established radiographic criteria for acetabular dysplasia which

included a Centre Edge (CE) angle of Wiberg and acetabular depth (see section 1.9). He also described a new radiographic measure - “femoral head ratio” – to determine cases of so called “tilt deformity” which he believed represented an abnormal relationship of the femoral head to the femoral neck. In 10% of the control population and 39% of patients with hip OA there was evidence of “tilt deformity”. Similarly in 3% of the control population and 25% of patients with hip OA there was evidence of subtle acetabular dysplasia. He concluded that “65% of so called primary hip OA is in reality secondary to a pre-existing asymptomatic abnormality.” He recognised that acetabular dyplasia was a “forme fruste” of DDH and that its association with hip OA was nothing new. However he highlighted that “tilt deformity as a precipitating factor in the development of OA of the hip has received astonishingly little comment”. Murray was referring to the dearth of publications in this field and only one other similar published account by Law (1952) which stated that: “I am of the opinion that quite a number of cases placed in the primary OA group are really the result of a slight degree of slipping of the upper femoral epiphysis (SCFE see section 1.8.2), which did not cause symptoms or signs during adolescence, and which were masked by hypertrophic changes in the joint later.”[28] Law apparently went on to test this theory but never formally published the results other than in personal communications.[26]

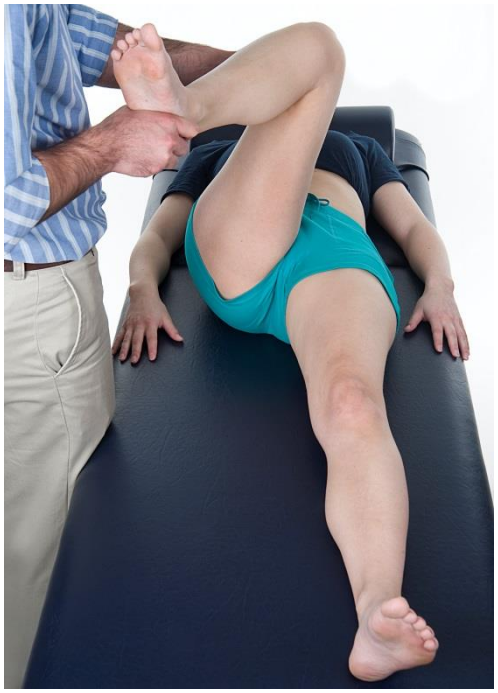
The work by Murray was closely followed by Stulberg et al in the 1960 and 1970s who noticed that up to 40% of patients who develop hip OA have evidence of a so called “pistol grip deformity” on plain radiographs prior to presentation with symptomatic OA – see Figure 1.6.[24]

Figure 1.6: "Pistol grip deformity" (Source: Stulberg et al[24])



It was not until 2001 when Ganz et al described a technique for safely dislocating the hip joint without compromising the blood supply to the femoral head (Avascular Necrosis-AVN), that the concept of subtle hip shape malformations and hip pain and early OA progressed further. Ganz et al published results for 213 procedures over a 7 year period and gave no reported cases of AVN. By using either this open approach or hip arthroscopy +/- Magnetic Resonance Arthrography (MRA – see section 1.10), Ganz and colleagues began investigating patients with evidence of intra-articular hip and labral pathology. They began to describe a population of young patients with hip pain but no evidence of overt OA.[29] These patients had subtle hip shape abnormalities (other than known shape malformations such as DDH) which they collectively described as FAI (see Figure 1.8 and Figure 1.9). Associated with these shape abnormalities they noticed characteristic patterns of soft tissue injury (labral and chondral lesions - see Figure 1.10 and Figure 1.11) within the hip joint.[23] Since the early descriptions by Ganz et al, FAI is now generally thought of as a syndrome that results from subtle shape malformations of the hip combining to cause premature impingement between the femoral neck and anterior rim of the acetabulum during the terminal phases of hip motion leading to soft tissue injury. FAI is thought to occur most frequently when the hip joint is in a combined position of flexion, adduction and internal rotation. This is known as the FADIR position (Flexion, ADduction and Internal Rotation) also demonstrated by the anterior impingement test (see Figure 1.7[30,31]).

Figure 1.7: Typical position of impingement (FADIR test)

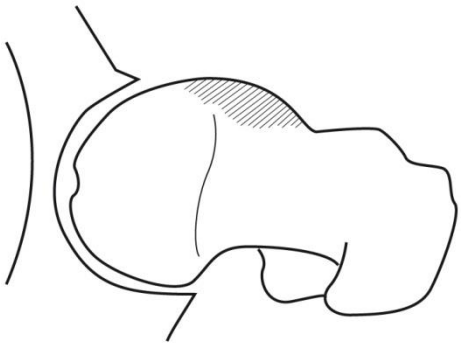


FAI seems to cause both hip pain (possibly attributable to associated soft tissue injury) and reduced ranges of hip movement, probably due to the mechanical block the shape malformation exerts on the hip joint in certain ranges of movement. Ganz et al suggested that these hip shape abnormalities consistent with FAI and the resultant soft tissue injury leads to early degenerative disease of the hip.[23] The evidence is that FAI and OA are associated and many surgeons believe that FAI is actually a risk factor for subsequent OA.[23,32-34]

Ganz et al described three types of FAI shape malformation of the hip joint:[23]

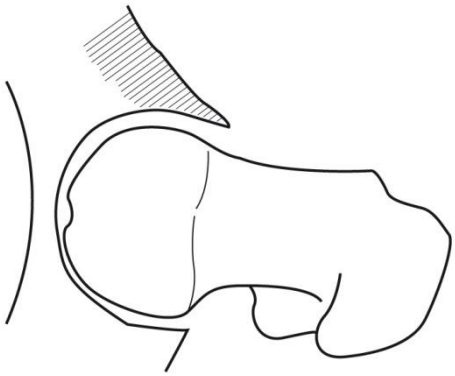
a. Cam type which involves an asphericity of the femoral head and or widening of the femoral neck (see Figure 1.8). The “pistol grip deformity” Stulberg described back in 1975 is similar to what Ganz et al called “cam type FAI” in 2001. [24,35]

Figure 1.8: Axial Line drawing of hip with cam deformity



b. Pincer-type which is an abnormal version of the femur or acetabulum leading to over-coverage of the antero-superior acetabular wall or an acetabulum that is deep (coxa profunda or protrusio) leading to global over coverage of the femoral head (see Figure 1.9)

Figure 1.9: Axial line drawing of the hip with pincer deformity



c. Mixed type hip impingement; a combination of cam and pincer types.

Anyone of these three malformations can lead to excess contact forces between the proximal femur and the acetabular rim during the terminal motion of the hip leading to lesions of acetabular labrum (see Figure 1.10) and the adjacent acetabular cartilage (see Figure 1.11).[30]

Figure 1.10: Hip arthroscopy view of a labral tear due to cam type FAI (Source: Wall et al[36])

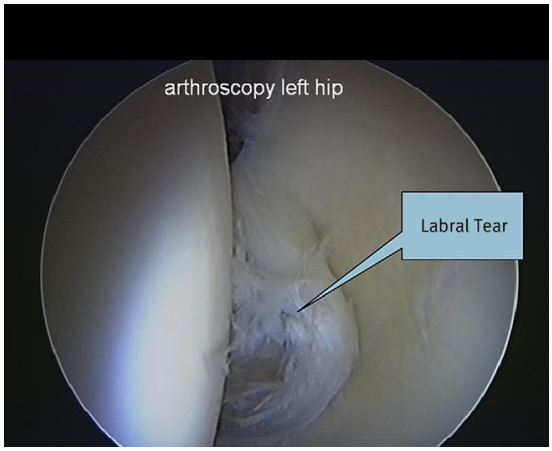
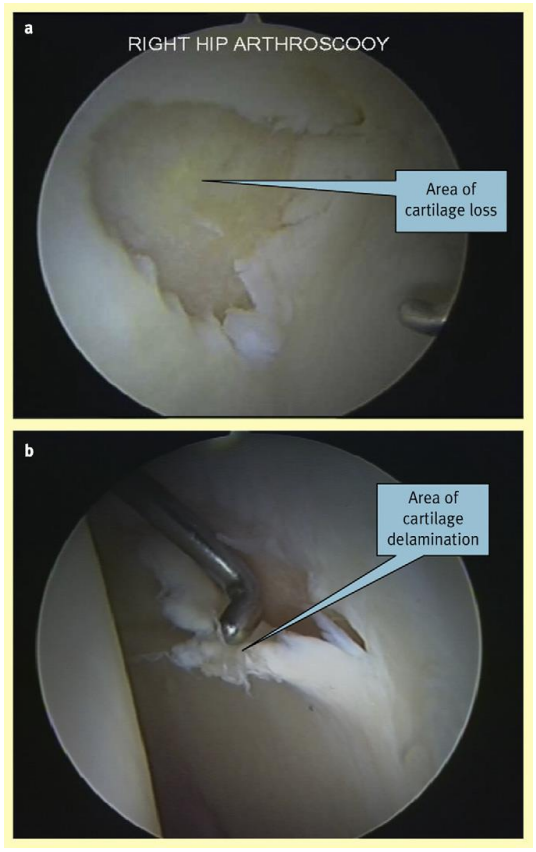
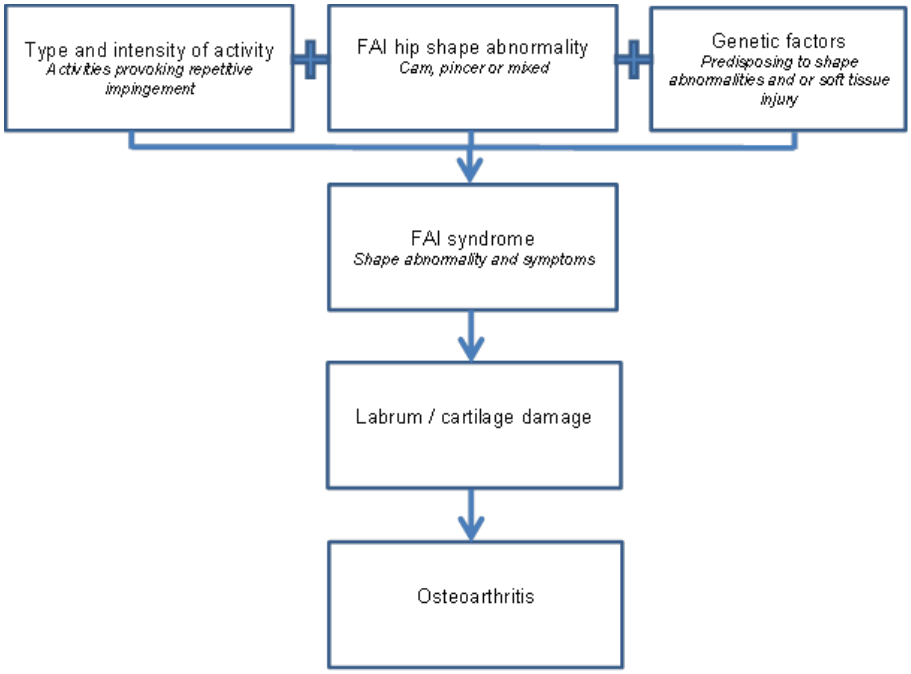


Figure 1.11: Hip arthroscopy view of cartilage damage due to cam type FAI (Source: Wall et al[36])



Ganz et al thought damage to either the labrum or cartilage as a result of FAI leads to progressive hip joint degeneration and OA[23]. The association between FAI and OA may be expressed in the following way see Figure 1.12.

Figure 1.12: Potential theory for association between FAI and OA



1.7 Femoroacetabular impingement: pathobiomechanics

The pattern of damage caused varies depending upon the subtype of FAI involved. Beck et al reported on 244 hips that had undergone “Ganz type” surgical hip dislocations for intra-articular hip pathology.[37] Preoperative pelvic radiographs (both anterior-posterior and cross table lateral views) were reviewed to determine which patients if any had evidence of either cam or pincer type FAI. During surgery the state of the labrum and acetabular cartilage and femoral cartilage was recorded and the location of any damage noted. Beck et al found that in all hips with cam type the acetabular cartilage was damaged anteriosuperiorly and that the cartilage had separated from the labrum, but the labrum itself was still well attached to the bone. In pincer type there was more circumferential damage with only a “narrow strip” of acetabular cartilage involved. In pincer type where the cartilage was damaged there was also damage to the labrum which was frequently ossified. Based upon these findings they suggested that there were likely to be two quite distinct pathomechanical consequences of cam and pincer type FAI. Beck et al and now others have proposed that in cam type an inclusion injury (“or outside in pattern”) occurs whereby the abnormal femoral head with increasing radius jams into the acetabulum during forceful hip motion (typically flexion).[25,37] The impact stretches and pushes the labrum outwards and leads to a compressive and

shearing force on the cartilage as it is pushed centrally particularly at the labro-chondral junction.[4,31,37] As a result areas of cartilage delamination develop where it peels away in layers and from the underlying bone.[31,38] In pincer-type impingement, it has been suggested that the femoral neck abuts the labrum (impaction type FAI) compressing it between the femoral neck and rim of the acetabulum.[4,31,37] This force is transmitted to the acetabular cartilage but only to a limited degree and the labrum acts as the primary bumper. Repeated micro trauma to the labrum leads to intra-substance fissuring and cyst formation and can result in ossification of the labrum, which further deepens the socket and exacerbates the impingement.[4,31,37]

One proposed mechanism by which patients with FAI feel pain relates to activation of the nerve endings which run within the non-articular portion of the labrum where it attaches to bone. Therefore, labral tears, degeneration and separation can all elicit pain.[4,37] However, the mechanism by which cartilage lesions elicit pain if at all is less clear in much the same way as the mechanisms of pain in OA remain unclear.[39]

1.8 Femoroacetabular Impingement: aetiology and epidemiology

A description of the epidemiological characteristics of FAI is incomplete, primarily because the condition has only recently been formally described in published literature over the last decade. However, several epidemiological studies were published on FAI in 2010:

Hack et al published a cross-sectional study of 200 asymptomatic patients (aged 21-50). Patients underwent an MRI of both hips. They found that 14% of patients had at least one hip with cam type FAI morphology. In addition 24.7% of men compared to 5.4% women had evidence of cam morphology.[40]

Reichenbach et al published a cross-sectional study of 244 asymptomatic young (mean age 19.9 years) male recruits to the Swiss army and found the prevalence of cam type FAI to be 24% (95% CI 19-30%).[41]

Gosvig et al published a cross-sectional study of 3620 subjects in Copenhagen, Denmark.[42] Subjects had a plain pelvis radiograph, which was used to identify evidence of hip shape malformations and were asked whether they had experienced frequent and recurrent deep

pain in the groin during the last 12 months. The results showed:

i. Radiographic evidence of acetabular dysplasia in 4.3% men and 3.6% of women. Of these 22% of the men and 16% of the women had evidence of groin pain.
ii. Radiographic deep acetabular socket (coxa profunda and/or protrusion acetabuli) in 15.2% of men and 19.4% of women. Of these 11% of the men and 13.1% of the women had evidence of groin pain.
iii. Radiographic pistol grip deformity in 19.6% of men and 5.2% of women. Of these 16.1% of the men and 18% of women had evidence of groin pain.

They also found that 12.6% of the men and 15% of women with no evidence of hip shape abnormality had groin pain. There was no significant difference ($p=0.13$) in the prevalence of reported groin pain between the two groups (those with hip shape abnormality and those without hip shape abnormality).

There are an increasing number of publications concerning FAI. However the concept of FAI is controversial. To my knowledge there are no published references that formally voice this controversy, but scepticism does pervade amongst the Orthopaedic and wider community. For example I delivered a presentation at the Annual Oswestry Research Day Meeting 2013 (a meeting attended predominantly by Orthopaedic surgeons, Rheumatologists, laboratory scientists and physical therapists) on aspects of my thesis (treatments for femoroacetabular impingement). At the end of my presentation during questioning the meeting convenor – sensing a mix of opinions amongst the crowd - asked the audience to show hands if they believed that FAI did not truly exist as a clinical entity; a sizeable (approximately 30%) proportion raised their hands. This is informal anecdotal evidence but similar post presentation feedback was received at international and national meetings during the course of my research. Comments such as “this is surgeons creating work for themselves” were not uncommon opinions often voiced with vigour! The mixture of FAI proponents and sceptics I believe highlights the lack of adequate research and understanding within this subject area. However, in terms of evaluating treatment options for FAI it does represent a potential barrier whereby some clinicians (often surgeons) are strong believers (for some their livelihood relies

on it) reluctant to offer their patients anything other than surgery while others regard treatment of a “fictitious” syndrome as pointless and when surgery is involved, potentially harmful.

1.8.1 The nine Bradford Hill principles of disease causality

In 1965, Bradford Hill described a methodology for establishing disease causality:[43] It is helpful to apply the nine principles described in his research to understand the possible relationship between FAI hip shape malformations causing hip pain and the later onset of OA.

i. **Strength of association**

“To take a very old example, by comparing the occupations of patients with scrotal cancer with the occupations of patients presenting with other diseases, Percival Pott could reach a correct conclusion because of the enormous increase of scrotal cancer in the chimney sweeps”.

Applying work published by Gosvig et al suggests the strength of association between hip shape abnormality and hip pain is weak; with no significant difference in prevalence of hip pain between those with FAI like hip shape malformations and those without.[42] Unfortunately the authors do not present a power calculation for their research and type 2 statistical error remains a possibility. The research also included those with hip shape malformations associated with DDH in the analysis making it difficult to establish if there is any true association with hip pain. However, given the reported prevalence of hip shape abnormality in the general population (approximately 20% of men with cam type FAI) and the lower prevalence of hip pain (approximately 7% in the young adult population[44]) there are likely to be other extraneous factors other than hip shape malformations contributing to symptomatic FAI. The research presented so far suggests that abnormalities of hip shape consistent with FAI are so common that they should be considered as spectrums of normality and that the shapes described as FAI are merely an incidental finding amongst patients that have hip pain. However, Ochoa et al, found that the prevalence of FAI type shape abnormalities amongst patients with hip related complaints is as high as 87%.[45] Overall the research seems to suggest that the strength of association between FAI shape abnormalities and hip pain is not strong, but in patients with hip pain in the absence of other known causes of hip pain

(rheumatoid arthritis, septic arthritis etc.) the prevalence of FAI type shape abnormalities is high.

The association between hip shape abnormalities and OA is, however, clearer. Gosvig et al found that both a pistol grip deformity (cam type FAI) and a deep acetabulum (pincer type FAI) were associated with an increased risk of OA – risk ratio 2.2 and 2.4 respectively. Similarly Kim et al found an association between acetabular retroversion (pincer type FAI) and OA ($r=0.46$, $p<0.01$).[32]

ii. **Consistency**

"Has it been repeatedly observed by different persons, in different places, circumstances and times?"

The concept of FAI syndrome is consistent in the published literature. Many case series of patients (the majority whom have undergone surgical intervention) have been published in which authors describe patients with FAI as having: hip shape malformation, evidence of soft tissue injury (chondral or labral lesions), hip pain and evidence of early degenerative disease.[46-48]

iii. **Specificity**

When discussing amongst workers:

"If, as here, the association is limited to specific workers" (in a nickel refinery) *"and to particular sites and types of disease" (rates of nasal and lung cancer) "and there is no association between the work and other modes of dying, then clearly that is a strong argument in favour of causation."*

There are already other well proven causes of both hip pain and OA. Therefore, an exclusive link between hip shape and hip pain or OA is unrealistic. Bradford Hill acknowledged this and reiterated that when specificity is present the causal link is likely to be very strong, but in most cases of disease particularly multifactorial disease, specificity is rarely present.

iv. **Temporality**

"Which is the cart and which the horse? This is a question which might be particularly relevant with diseases of slow development."

There are no current published accounts of a temporal relationship between FAI hip shape

abnormalities and subsequent hip pain. However, Gregory et al explored the temporal relationship between hip shape and subsequent OA.[33] The authors use an established cohort of patients (the Rotterdam study[49]) and analysed plain pelvic radiographs of patients, using a shape analysis model. The initial cohort had no evidence of OA. This was then divided into those that subsequently developed OA and those that did not. A particularly shape characteristic (mode 6 shape – which correlates well with cam type FAI) was found to be associated with subsequent OA and need for THA.

v. Biological gradient

"If the association is one which can reveal a biological gradient, or dose-response curve, then we should look most carefully for such evidence. For instance, the fact that the death rate from cancer of the lung rises linearly with the number of cigarettes smoked daily, adds a very great deal to the simpler evidence that cigarette smokers have a higher death rate than non-smokers."

There are no well described biological gradients for FAI. For example there is no evidence that a more severe cam type FAI deformity increases the risk of, or severity of, hip pain and or OA. However, this may in part be a reflection of an inadequate quantification of shape abnormality. The most routine measurement of cam type FAI is the alpha angle which is determined from either plain hip radiographs or cross-sectional imaging, but this measurement provides very little detail about the volume or extent of the shape abnormality.[50,51]

vi. Plausibility

"It will be helpful if the causation we suspect is biologically plausible."

Perhaps the most compelling aspect of FAI is the strong mechanical argument that bony hip shape abnormalities such as cam and pincer type FAI can lead to soft tissue injury in and around the hip joint, particularly to the labrum and articular cartilage. A better understanding of the structure and function of the labrum has helped support the plausibility of FAI. The labrum is innervated with nerve fibres around its attachment to the non-articular zone of the acetabulum and therefore injury to it is typically painful.[4] In addition the labrum is thought to act as a high pressure seal for synovial fluid around the hip and therefore it is entirely

plausible that damage to this seal by bony impingement might lead to early hip joint failure and subsequent OA.[4]

vii. Coherence

"The cause-and-effect interpretation of our data should not seriously conflict with the generally known facts of the natural history and biology of the disease."

The concept of FAI is coherent with the current understanding of hip pain and OA. For example it is well established that gross shape abnormality of the hip such as that seen after malunited hip fractures or Legg-Calve-Perthes disease leads to hip pain and stiffness and subsequent OA.[27] The FAI model really describes a spectrum of hip shape abnormality that is less severe than this but the implications of which are a risk of hip pain and subsequent OA.

viii. Experiment

"Occasionally it is possible to appeal to experimental, or semi-experimental, evidence. For example, because of an observed association some preventive action is taken. Does it in fact prevent?"

There are numerous case-series and now systematic reviews of these case series detailing the favourable outcome of surgery for FAI in terms of reduced hip pain and improved hip function.[48] See Chapter 3 for a review of the available RCT level evidence examining treatments for FAI.

ix. Analogy

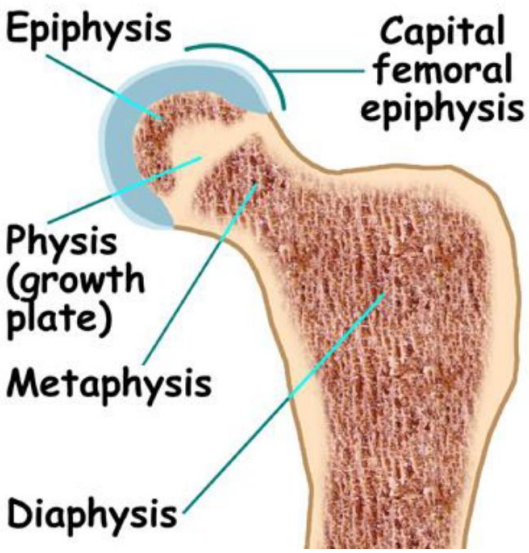
"In some circumstances it would be fair to judge by analogy. With the effects of thalidomide and rubella before us we would surely be ready to accept slighter but similar evidence with another drug or another viral disease in pregnancy."

DDH is a condition that leads to a hip shape abnormality (see section 1.3 and 1.5). DDH hip shape is different to FAI-like shape malformations but nevertheless DDH is associated with hip pain and a risk of subsequent OA.

1.8.2 Slipped Capital Femoral Epiphysis and cam type FAI

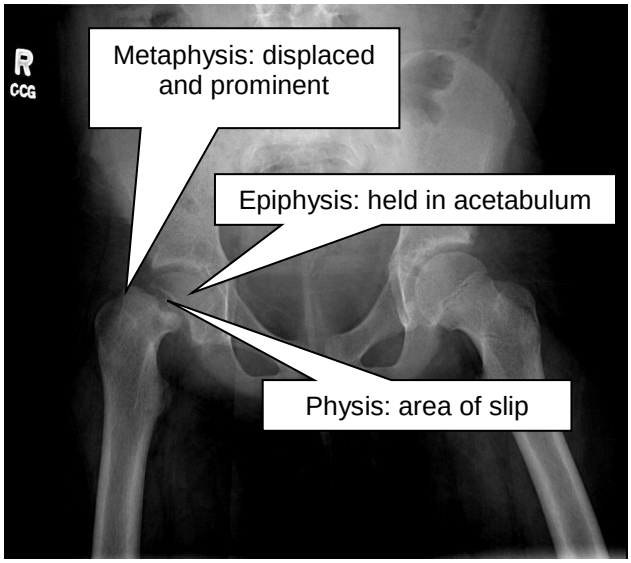
Leunig et al identified a possible link between Slipped Capital Femoral Epiphysis (SCFE) and the cam type FAI deformity (described in section 1.6).[25] Many researchers now believe that SCFE is one mechanism by which patients could develop cam type FAI.[52] SCFE is a rare hip disorder (prevalence approximately 0.71 to 10.8 per 100,000 children) that presents in adolescence.[53] The adolescent femoral head and neck which is still growing is made up of an epiphysis (the rounded end or femoral head), a physis (the growth plate) and a metaphysis (the widening of the femoral neck which connects to the diaphysis or shaft of the femur) – see Figure 1.13.

Figure 1.13: Cross-section of proximal femur showing the physis (Source: www.orthopediatrics.com)



The underlying pathology of SCFE is disruption through the proximal femoral physis allowing the metaphysis to displace superiorly and anteriorly, while the epiphysis remains in the acetabulum (see Figure 1.14).[54]

Figure 1.14: Pelvis radiograph of pelvis showing SCFE of right hip



Southwick reported a method for quantifying the severity of SCFE by referring to amount of angulation that results at the hip following a SCFE. Southwick describing an angle subtended between the epiphysis and femoral shaft taken from a frog lateral radiograph.[55] These angles can be categorised into mild – less than 30°, moderate – 30° to 50° and severe – greater than 50°.[55,56]

Historically a substantial proportion of patients with SCFE undergo in-situ fixation for the full spectrum of SCFE severity.[56] However, more recently there is some controversy about the best treatment even amongst patient with mild SCFE.[52,54] The main reason for this controversy relates to the variation in reported long term clinical outcome in terms of pain and function following surgery for SCFE and the realisation that if SCFE is a cause of cam type FAI, accepting any degree of hip shape abnormality may be detrimental in the longer term.[56-59] If SCFE is a cause of cam type FAI, then it may be expected that an increase in severity of SCFE would be associated with a deterioration in long term functional outcome. The relationship between abnormalities of hip shape associated with SCFE/FAI and the effects on hip specific quality of life are explored further in Chapter 2.

1.9 Femoracetabular impingement: radiographic measures of hip shape

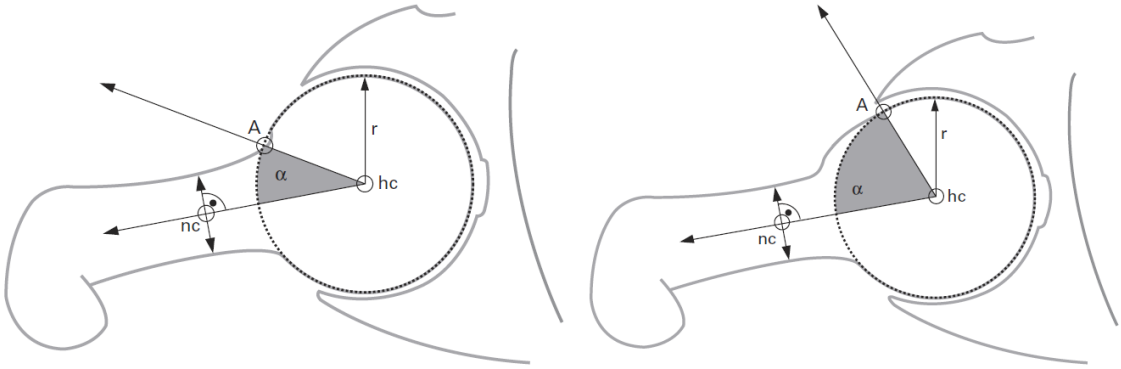
There are a number of ways of quantifying hip shape for both the femoral and acetabular side in relation to FAI, these include:

Femoral side

i. Alpha (α) angle[50]

The alpha angle is the angle subtended between two lines projecting from the centre of the femoral head: one along the line of the femoral neck and the other to a point where the femoral head is no longer spherical – see Figure 1.15

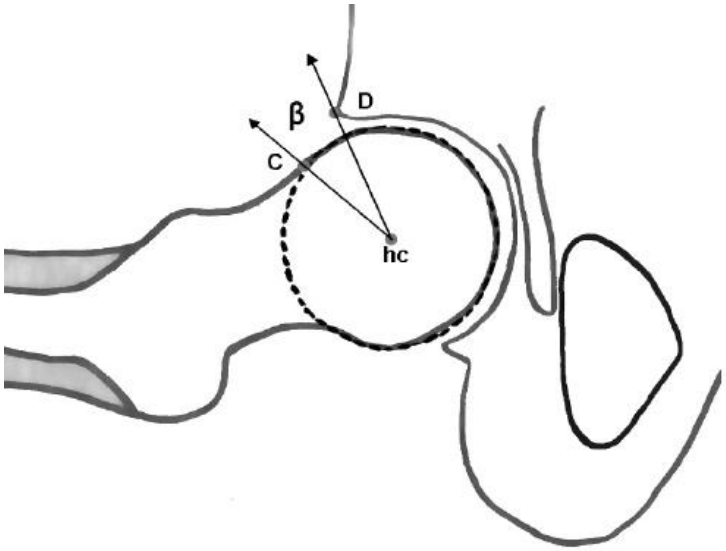
Figure 1.15: Diagramatic representation of the α angle (Source: Notzli et al 2002[50])



ii. Beta (β) angle[60]

The beta angle is the angle subtended between two lines projecting from the centre of the femoral head**;** one to the edge of the acetabulum, other to a point where the femoral head is no longer spherical (see Figure 1.16).

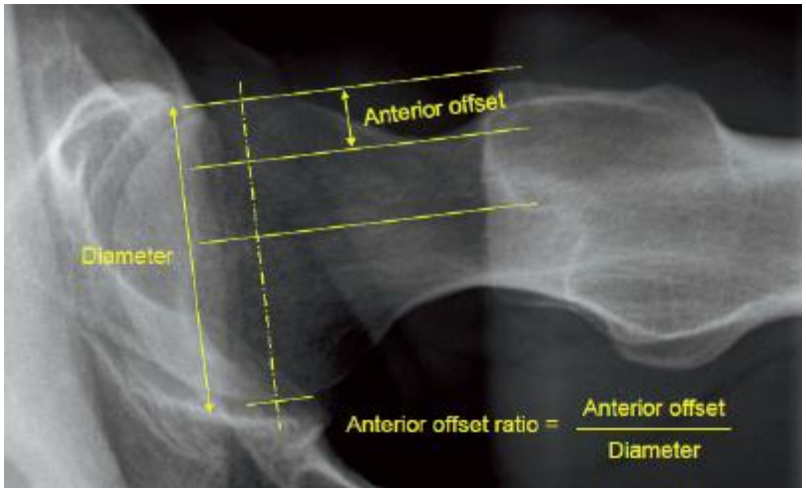
Figure 1.16: Diagramatic representation of the β angle (Source: Brunner et al 2010[60])



iii. Anterior offset[61]

The anterior offset is the perpendicular distance from the femoral neck to the outer cortex of the femoral head (see Figure 1.17).

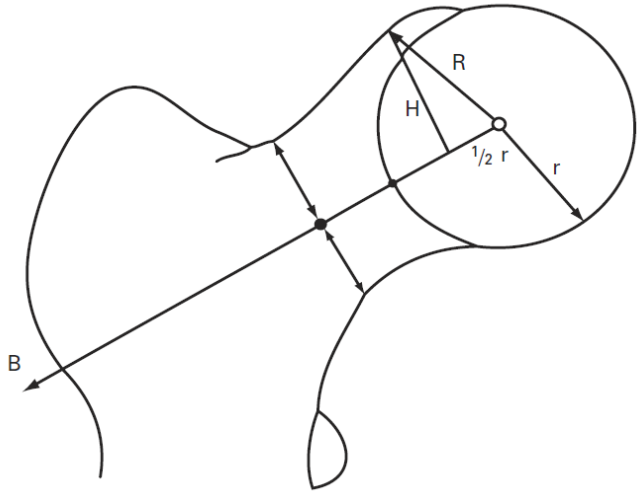
Figure 1.17: Diagramatic representation of the anterior offset / ratio (Source: Pollard et al 2010[62])



iv. Triangular offset[63]

The distance r (radius of the femoral head) is measured – see Figure 1.18. H is then measured which is the distance to the anterior cortex measured at a point ½ r along a line from the centre of the femoral head through the centre of the femoral neck (line B). Distance R, which is $\sqrt{(H^2 + (1/2r)^2)}$ is then calculated. If R is >r then it is regarded as pathological.

Figure 1.18: Diagramatic representation of the triangular index (Source: Gosvig et al 2007[63])

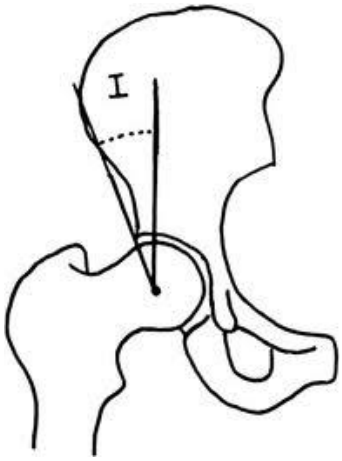


Acetabular side

i. Lateral centre edge angle (Centre edge angle of Wiberg)

The angle is formed between two lines emerging from the centre of the femoral head (see Figure 1.19): one vertical line perpendicular to the transverse axis of the pelvis and one line to the lateral edge of the dense subchondral plate of the acetabulum.

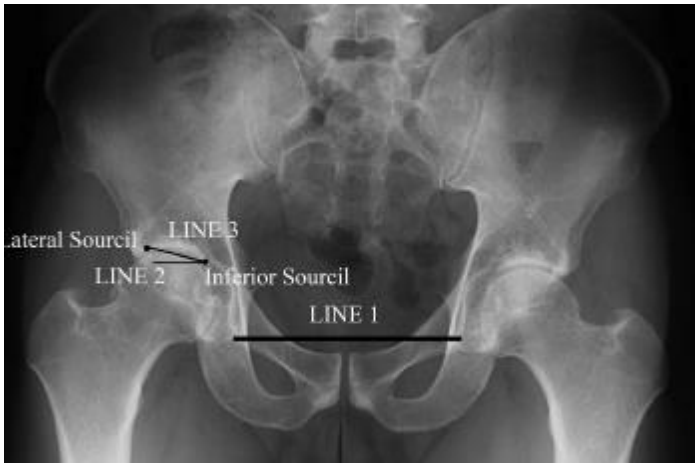
Figure 1.19: Diagramatic representation of the lateral centre edge angle



ii. Tonnis angle

The Tönnis angle is the angle formed between lines 2 and 3 (see Figure 1.20). Line 1 is a line connecting the base of the teardrops of each acetabulum. Line 2 is a horizontal line parallel to line 1 so that it intersects the inferior point of line 3. Line 3 runs from the inferior point of the sclerotic acetabular sourcil and the lateral margin of the acetabular sourcil.

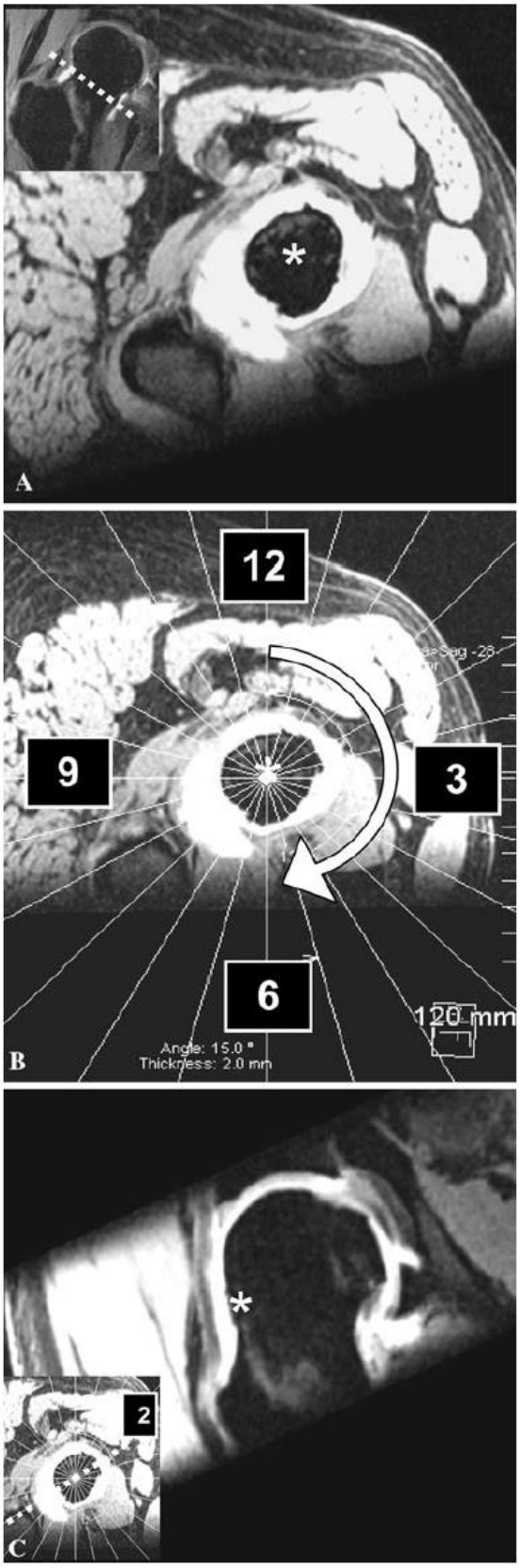
Figure 1.20: Diagramatic representation of the Tonnis angle (Source: Clohisy et al)[64]



1.10 Femoroacetabular Impingement: cross-sectional imaging

The radiographic measures described in section 1.9 can be taken from plain radiographs of the pelvis and hip or more accurately from cross-sectional imaging such a Computed Topography (CT) or Magnetic Resonance (MR) imaging. The advantage of cross-sectional imaging is that measures such as the alpha angle can be obtained in multiple anatomical planes, thus allowing a more three dimensional perspective of FAI like shape abnormality to be appreciated. Rakhra et al described a process of using the multi planar reformation (MPR) feature of MR to generate images perpendicular to the long axis of the femoral neck using the centre of the femoral neck as the axis of rotation, with images generated at 15 degree intervals (see Figure 1.21).[65] The result is radial MPR images oriented orthogonal to the femoral head neck junction see Figure 1.21 - image C.

Figure 1.21: Radial reformatting of MR images along femoral neck (Source: Rakhra et al)[65]



The same MPR process with radial reformatting along the axis of the femoral neck can also be achieved with CT imaging.

1.10.1 CT imaging

Additional features of FAI that may be identified from CT include ossification of the labrum along the acetabulum in the zone of impingement and sclerosis and subchondral cyst formation which may be features of both FAI and early onset joint degeneration.[66]

1.10.2 MR Imaging

MR provides high resolution imaging of the labrum, cartilage and joint space as well as depicting the regional soft tissues.[67] Several MR techniques have been described including:

i. conventional MR Imaging;

ii. direct MR Arthrography (D-MRA) which involves an intra-articular injection of contrast medium;

iii. indirect MR arthrography (I-MRA) where the contrast medium is administered by peripheral intravenous injection.[68]

D-MRA is currently the preferred imaging technique for detecting intra-articular hip pathology associated with FAI such as labochondral separation and labral tears.[68-70]

1.11 Femoroacetabular Impingement: management options

1.11.1 Surgical options

The “Ganz” approach by dislocating the hip joint without damaging the blood supply to the femoral head allowed the development of open surgical techniques to correct the shape abnormalities of FAI. The aim of surgical treatment is to reshape those parts of the hip joint which appear to be responsible for premature femoral abutment against the rim of the acetabulum. This is achieved by re-profiling the rim of the acetabulum (in pincer-type FAI) and/or reshaping the femoral head/neck (in cam-type FAI).[71] Good clinical results were initially reported for the “Ganz” open surgical approach.[48,72] Beck et al reported a mean improvement in the Merle d’Aubigne Score of 2.4 points with 68% patients reporting a clinically good or excellent outcome in their case series of 19 patients with a mean follow-up of 4.7 years.[46]

The “Ganz” approach is a major operation and involves a trochanteric osteotomy in order to dislocate and expose the hip joint. The post-operative rehabilitation, is, long and patients typically have to use crutches while the osteotomy heals. In order to try and minimise the invasiveness of open surgery some surgeons have adopted a “mini-open” approach.[73] This involves surgical intervention on the anterior aspect of the hip joint, and the risk of damaging the blood supply to the femoral head is low. However, while theoretically less invasive and without the need for a trochanteric osteotomy the technique only provides limited access to the anterior aspect of the hip joint. It is therefore inappropriate for correcting anything other than localised anterior shape abnormalities.

It must be questionable whether the outcomes of such relatively extensive open surgery are sufficiently positive to justify the risks. As a result hip arthroscopy is rapidly becoming a favoured alternative technique in the management of FAI. It was not until the 1990’s that hip arthroscopy became well established with the advances in imaging and arthroscopic equipment.[10] The technique remains a challenge due to the bony and soft-tissue anatomy of the joint and the surgery typically requires a general anaesthetic and muscle relaxant. This allows the hip joint to be distracted when traction is applied to the leg and provides space in the hip joint for the arthroscopic instruments. Small portals are then inserted under image intensifier guidance into the hip joint. An arthroscope can then be passed through these portals into the hip joint allowing visualisation of the joint and the FAI shape abnormalities. Surgical instruments are then passed through other portals allowing the surgeon to undertake FAI surgery.[10]

Studies suggest that the results for arthroscopic FAI surgery are favourable.[36] Byrd and Jones reported a median improvement of 21.5 points in mean Harris Hip Score at 2-year follow-up, in a consecutive group of 100 patients who had shape corrective surgery for FAI.[74] This group included 63 cam-type, 18 pincer-type and 23 mixed-type FAI. Philippon et al reported a mean 26-point improvement at a minimum follow-up of 2 years, although ten

patients had a THR at a mean of 16 months.[75] Almost all patients had associated labral and chondral injuries. Arthroscopic management of FAI in athletes produced excellent results, with 95% of professional athletes able to return to their previous level of competition.[74] Arthroscopic FAI surgery has also shown some success in a series of 40 patients above the age of sixty.[76] The overall results of these studies are promising but most have relatively limited follow-up.

The current evidence suggests that the outcomes from hip arthroscopy for FAI are comparable to open surgical techniques, but the risk of complications for open surgery is greater than those undergoing arthroscopic surgery.[77]

1.11.2 Nonoperative care

There is a strong and compelling argument that FAI is a mechanical disorder secondary to a hip shape abnormality and it follows therefore that symptoms should not improve unless the shape abnormality is corrected.[23] For this reason many authors and surgeons dismiss nonoperative treatment.[78] However, given the risks of surgery, insufficient detail about the natural history of FAI and lack of good quality evidence for surgery this may be inappropriate. There is in fact some mechanical explanations by which nonoperative care could influence FAI. For example if a patient's adopted pelvic inclination could be reduced then this may reduce the effective anterior coverage of the hip and may reduce anterior impingement.[79] There is already some evidence that this can be achieved by physical therapy and has been used in the treatment of lower back pathology.[80]

Kennedy et al observed the gait patterns of patients with FAI and a control group.[81] The FAI group had a significantly lower peak hip abduction ($p=0.009$) and an attenuated pelvic frontal ROM (pelvic roll $p=0.004$). The authors suggest that limited pelvic roll may be secondary to limited mobility at the lumbo-sacral joint. Physical therapy based treatment strategies could attempt to address these issues and may help patients' symptoms.

Interestingly in 1993 prior to FAI being formally recognised and reported in the literature, Cibulka et al undertook a randomised study of two different physiotherapy regimes for

treating hip pain in runners (20 patients) without evidence of arthritic changes.[80] One group received mobilisation to the involved hip while the other group had a manipulative technique known to affect sacroiliac joint dysfunction. Patients were evaluated with a pain questionnaire which showed significantly (p=0.016) less pain at follow up in those patients treated with sacroiliac manipulation. It is reasonable to hypothesise that a proportion of these patients would have had FAI if not a substantial proportion given the demographics of the patients (i.e. age 15-35, athletic population, no established cases of OA). The study result would give further strength to an argument that forceful mobilisation (ROM exercises) of a hip with FAI may be counterproductive but other physical therapy techniques that improve mobility at the joints in the region of the hip (i.e. sacroiliac and lumbosacral) could be beneficial.

There is evidence to suggest that nonoperative treatments in the form of physical therapy, activity modification and simple analgesia can alleviate symptoms and potentially postpone or even negate the requirement for FAI surgery.[82] There is however a need to clarify the quantity and quality of evidence including determining the most appropriate methods of nonoperative care (see Chapter 4).

Chapter 2 Hip shape and long term hip specific quality of life: an analysis of Slipped Capital Femoral Epiphysis (SCFE)

2.1 Declarations

This work has been presented at an international conference:

April 2012*:* European Paediatric Orthopaedic Society Annual Meeting (EPOS) Helsinki. Long-term hip function after surgery for slipped capital femoral epiphysis surgery

This work has been presented as a poster at a national conference:

May 2012: Oswestry Research Day. Long-term hip function after surgery for slipped capital femoral epiphysis surgery

This work has been published:

Wall PDH, Brown JS, Freshney S, Parsons H, Griffin DR. Hip shape and long term hip function: A study of patients with in-situ fixation for slipped capital femoral epiphysis. Hip international: the journal of clinical and experimental research on hip pathology and therapy. DOI: 10.5301/hipint.5000075.

This work was co-sponsored by University Hospital Coventry and Warwickshire and the University of Warwick.

This work was granted research ethics approval 11/WM/0228 from the regional ethics board.

2.2 Introduction

It has been suggested that a substantial number of cases of SCFE are reflected in subsequent diagnoses of cam type FAI.[25,52,54] The impingement in such instances occurs between the more prominent femoral head neck junction (cam type deformity) and the anterior rim of the acetabulum in the extremes of functional hip movement, particularly in flexion adduction and internal rotation.[25,83,84]

In order to evaluate how alterations in hip shape as a result of SCFE in adolescence may influence long term function, a cohort study was undertaken of patients who had previously undergone in-situ fixation for SCFE. The aim was to establish if the radiological hip shape associated with both SCFE and cam type FAI had any effect on long term hip specific quality of life. In a secondary analysis, the effect of time since surgery on long term hip specific quality of life was explored. Obtaining a better understanding of the possible relationship between FAI like hip shape and hip specific quality of life would also help to clarify the role, if any, of interventions for FAI that address factors other than hip shape (such as the role of physical therapy).

2.3 Objectives

Establish if there is a strong correlation between long term hip specific quality of life and the radiological hip shape associated with SCFE and cam type FAI.

2.4 Methods

The purpose of the study was to explore the correlation between hip specific quality of life and hip shape measured using Southwick angle (as described by Southwick[55,56] see Chapter 1) and alpha angle (as described by Notzli et al[50] see Chapter 1).

2.4.1 Sample size

A sample size calculation for the study was done using R (http://www.r-project.org). The sample required to detect a negative or positive correlation coefficient ≥0.5 (medium to strong correlation) with 80% power, and significance at the 0.05 level was 23 patients.

Hip specific quality of life was assessed using the IHOT-33 patient reported outcome tool. IHOT-33 is a validated patient reported outcome tool to measure health-related quality of life in young, active patients with hip disorders.[85] The tool uses a visual analog scale from 0-100. A total score of 0 is the worst possible outcome and 100 is the best possible outcome. All patients aged 18-50 who had undergone SCFE surgery in our own institution from 1970 onwards were identified by screening operative logs. The following inclusion criteria were applied:

i. Patients who had in-situ fixation for SCFE
ii. Patients with pre and post-operative radiographic imaging
iii. Patients able to understand written English
iv. Patients with up to date contact details available

A number of potential confounding variables were identified prior to the study that may independently affect the long term hip specific quality of life. These included subsequent hip shape changing surgery (e.g. femoral osteotomy); total hip arthroplasty (THA) and complications (e.g. penetration of the fixation into the hip joint, osteonecrosis and chondrolysis). Therefore the following additional exclusion criteria were applied:

i. Patients undergoing further hip surgery except removal of metalwork (e.g. femoral osteotomy and THA)
ii. Patients with evidence of screw penetration on post-operative imaging
iii. Patients with documented evidence of chondrolysis or osteonecrosis

All recruited patients provided informed written consent. All patients were sent a postal questionnaire which included the IHOT-33. Patients who did not respond to the first questionnaire were sent one reminder. In cases of bilateral SCFE where both hips met the eligibility criteria patients were asked to complete a questionnaire for each hip independently. Hip shape measures were taken from the immediate post-operative radiographs (within 5 days of surgery) these included:

i. Southwick angle on both hips using frog lateral projection. In order to take account of normal variance the unaffected hip Southwick angle was measured and subtracted from the effected hip. In cases of bilateral SCFE an angle of 12° was subtracted.[55]

ii. Alpha angle on index hip using frog lateral projection.

iii. Tonnis grading for radiological evidence of OA.[17]

When follow-up imaging was available the most recent frog lateral projection was used to obtain a further lateral alpha angle on the index hip. All measures were taken by two researchers (PW and SF). The average of the two results was taken as the final radiographic result for each of the variables.

Patients with complete data for the primary analysis were then matched 1:1 by age and sex to a cohort of control patients with no history of childhood SCFE. Control patients were derived sequentially from an upper limb fracture clinic within the host institution and invited to complete the IHOT-33 questionnaire.

2.4.2 Statistics

IBM SPSS version 21 for Windows was used for the statistical analysis.[86] In patients with bilateral SCFE (i.e. those who completed a questionnaire for each hip), one hip was selected at random for analysis per patient thereby ensuring independence of the variables between each unit of analysis. Correlation analysis between independent variables (Southwick angle, lateral alpha angle, time since surgery and IHOT-33 score) was done using Pearson's correlation coefficient. Differences in outcome between cases and controls was analysed using a Student's T-test. The level of statistical significance (p-value) was set at 0.05. Multiple linear regression was used to model the IHOT-33 score, when controlling the variables of side of SCFE, gender, days since first surgery, Southwick angle and lateral alpha angle.

2.5 Results

A total of 47 patients (60 hips comprising 13 bilateral and 34 unilateral cases) with a history of SCFE surgery were identified on first screening of records from our institution. Six patients (11 hips) were excluded for the following reasons:

i. One hip underwent revision in-situ fixation.
ii. Eight hips had a proximal femoral osteotomy at some stage (in 5 cases osteotomy was the initial treatment).
iii. Two hips underwent THA.
iv. Three of the excluded patients also lacked of up to date patients contact details or adequate radiological imaging and would have been excluded on those grounds alone.

There were no reported cases of subsequent chondrolysis or avascular necrosis. There were 38 patients (46 hips) who met the eligibility criteria. We obtained follow–up data for 32 patients (38 hips), 83% follow-up. Ten patients (20 hips) had bilateral SCFE, but only 12 of these hips were eligible for inclusion. Two patients refused to take part and 4 did not return questionnaires. All included cases were chronic (symptoms >3weeks).[87] The mean follow up was 13.5 years (SD 6.7), with a minimum of 6.6 and maximum of 25.6 years follow up.

The inter observer reliability of the radiographic measures taken between the two observers is shown in Table 2.1.

Table 2.1: Inter-observer reliability of radiographic measures taken

	Intra-class correlation single measures (two-way mixed effects model)
Southwick angle	0.961
Lateral alpha angle	0.960

A comparison of characteristics and hip specific quality of life between the cases and controls is shown in Table 2.2.

Table 2.2: Characteristics of SCFE cases and control data

Category	**Number of patients**	**Mean age at follow up (SD)**	**Sex**	**Mean IHOT-33 at follow up (95% CI)**	**Between IHOT-33 category p-value**
Case	32	25.9 (6.7)	16 F, 16 M	71.8 (63.1-80.6)	p<0.01
Control	32	26.7 (5.7)	16 F, 16 M	96.1 (94.6-97.6)	

The correlation analysis between the measures of hip shape (Southwick angle and lateral alpha angle), time since surgery and IHOT-33 outcome are shown in Table 2.3.

Table 2.3: Correlations between Southwick angle, lateral alpha angle, time since surgery and IHOT-33. *significant result at p<0.05, **significant result at P<0.01

	Southwick angle	Mean lateral alpha	Time since first surgery	IHOT-33 Score
Southwick angle	1	.438**	.126	-.179
Mean lateral alpha	.438**	1	.166	.030
Time since first surgery	.126	.166	1	.202
IHOT-33 Score	-.179	.030	.202	1

Multiple linear regression was used to model the IHOT-33 score, when controlling the variables of Southwick angle and years since surgery (see Table 2.4). For these continuous variables the coefficient is the change made by one unit increase.

Table 2.4: multiple linear regression analysis modelling IHOT-33 scores

Variable	Coefficient	p-value
Years since first surgery	0.248	0.176
Southwick angle	-0.210	0.249

All 32 patients included in our study had a Tonnis grade of 0 on the initial imaging of the hip under investigation. Follow up frog lateral imaging was available for 23 patients. The mean time to the follow-up imaging was 2.6 years (SD 1.9). The mean change between initial alpha angle and follow-up alpha angle was -2.3 degrees (95% CI -8.8-4.2). For all 23 patients with follow-up imaging the Tonnis grade was ≤1 for the index hip under investigation.

2.6 Discussion

2.6.1 Summary of findings

Long term hip specific quality of life using IHOT-33 scores is significantly worse in patients who have undergone in-situ fixation for SCFE when compared to age and sex matched members of the general population with no history of SCFE (mean IHOT-33 scores of 71.8 and 95.8 respectively). There was, however, no significant (P>0.05) correlation between long

term hip specific quality of life (IHOT-33 scores) and Southwick angle or lateral alpha angle (correlation coefficient -0.179 and 0.030 respectively) amongst patients who had undergone in-situ fixation. These findings suggest that patients with a SCFE are more likely to suffer impaired long term hip specific quality of life when compared to those who have never had a SCFE. It is apparent that the initial hip shape (in terms of both severity of SCFE and FAI like cam deformity) has no strong influence on subsequent long term hip specific quality of life.

2.6.2 Methodology

The study excluded 8 patients who had undergone an osteotomy at any stage. These exclusions were necessary because of the inevitable effect such surgery has on hip shape.

To ensure the validity of the research it was necessary to check that the severest forms of SCFE were not inadvertently excluded by virtue of having had early osteotomy surgery. It was established that 5 of the 8 excluded patients had an osteotomy as the initial treatment for SCFE; a clinical decision which is likely to be based on the initial severity SCFE (shape abnormality) rather than any long standing symptoms. This left only 1 patient with severe SCFE in the study. However, there is an established view that severe SCFE leads to an "impaction" type impingement as the femoral neck abuts the acetabular rim causing an extra-articular impingement with little or no damage to the intra-articular cartilage.[52] For the above reasons this study concentrates principally on patients with in-situ fixation with either mild or moderate SCFE. There remains considerable debate about outcome and optimal management in patients with mild and moderate SCFE. These types of SCFE (mild and moderate) are thought to lead to an "inclusion" type impingement with the prominent shape abnormality entering the central compartment of the hip and thus causing intra-articular cartilage damage.[52].[52,54,58,84]

The two measures used to assess hip shape abnormality (Southwick angle and lateral alpha angle) did correlate (0.438) significantly ($p<0.05$), suggesting that both provide similar evidence of hip shape abnormality. This is helpful as the alpha angle is regarded as a

standard methodological technique for assessing evidence of cam type FAI, but the Southwick angle is not. The Southwick angle was introduced to quantify SCFE severity many years before FAI was formally described in the medical literature.

The plain radiographs used to assess hip shape abnormality are not the most advanced techniques available.[66] Cross-sectional hip imaging using Computed Topography (CT) and or Magnetic Resonance (MR) imaging is now used routinely used to aid the diagnosis of a hip shape abnormality such as FAI. The majority of the patients in this study had surgery before routine use of CT and/or MR in such cases. More importantly surgery took place at a time before FAI had been formally recognised in the medical literature. However, evidence suggests that plain radiographic measures of alpha angle as used in this study correlate well with cross-sectional imaging and are adequate for diagnosing FAI.[88] The frog lateral radiograph as used in this study is the preferred radiographic projection to assess evidence of FAI.[89] It is unlikely that the results are affected by using plain radiography alone and the intra-class reliability of the two independent measures of Southwick angle and lateral alpha angle (0.961 and 0.960 respectively) is reassuring. This suggests that the findings are reproducible and is consistent with previous studies of inter-observer reliability on frog lateral radiographs.[89]

The current measures of FAI hip shape abnormality including the measures used in this study may not accurately quantify the extent/volume of such abnormalities. For example, a small alpha angle evident in multiple anatomical planes may represent a greater volume of hip shape abnormality than a large alpha angle in fewer anatomical planes (i.e. less extensive). It has to be acknowledged that the nomenclature/methodology currently used to measure the extent of hip shape abnormality is inadequate. Until more sophisticated techniques become available to establish precise measures and location of hip shape abnormality the relationship between hip shape and hip specific quality of life may remain difficult to determine.

Many of the typical complications of SCFE and SCFE surgery such as chondrolysis, avascular necrosis and screw penetration were excluded in this study. However, because many patients with SCFE who have in-situ fixation undergo surgical removal of metalwork it was not feasible to exclude them from this study. It seems unlikely that surgical removal of metalwork has any additional influence on long term hip specific quality of life.

2.6.3 Incidental findings

A surprising secondary finding was the lack of correlation between the time since in-situ fixation and subsequent long term hip specific quality of life as reported by patients (correlation coefficient 0.202, $p>0.05$). There is some suggestion in the literature that a degree of hip remodelling occurs after in-situ fixation.[59] It is therefore possible that, given time, hip shape abnormality associated with SCFE resolves spontaneously and hip symptoms then plateau or even improve. If this does occur then it may explain the finding that initial radiological hip shape appears not to influence long term hip specific quality of life following surgery (see section 2.6.1). Interestingly, however, follow-up imaging of 23 patients (mean follow-up at 2.6 years) found no evidence of a significant change in hip shape as measured using the lateral alpha angle. This admittedly small sample contradicts the supposition that spontaneous hip remodelling occurs but is worthy of further research using larger sample.

2.6.4 Conclusions

Evidence suggest that those undergoing SCFE in-situ fixation experience worse long term hip specific quality of life than an age and sex matched control group. However, the evidence does not indicate that the initial severity of the shape abnormality necessarily indicates the severity or otherwise of long term hip specific quality of life e.g. a moderate SCFE or larger cam type morphology does not always result in a poorer long term functional outcome. This has important implications for measures (such as in-situ fixation combined with arthroscopic femoral osteoplasty) to correct shape abnormality in SCFE.[52] This study suggests that other

extraneous factors not related to hip shape may have an equally important role to play in determining long term outcomes for SCFE. This study sought to establish whether there is a medium to strong correlation between SCFE/cam type FAI and long term hip specific quality of life[90] but to detect a smaller correlation a much larger sample size would be required.

SCFE has been suggested as a cause of cam type FAI in some patients, but this remains unproven. It follows that basing this study on an assumption that SCFE and FAI are linked could be flawed but never the less it was important to explore this putative relationship.

A more robust although technically more difficult modification of the study would be to follow patients with an established diagnosis of FAI to determine both the severity of the hip shape abnormality and long term hip specific quality of life. This would remove potential uncertainties and variables such as:

i. Surgery effecting long term hip specific quality of life.

ii. SCFE as a cause of cam type FAI.

iii. Changes in adolescent hip shape due to remodelling.

Such a study presents difficulties because established practice is to favour surgery for FAI.[23,48] Once diagnosed many patients with FAI are told that surgery is the preferred solution. These factors are discussed and addressed in the remainder of this thesis.

Chapter 3 Surgery for treating femoroacetabular impingement: a systematic review of the literature

3.1 Declarations

The analysis plan was completed with input from Dr N Parsons at the University of Warwick and Professor R Buchbinder at Monash University, Australia.

This protocol for this work is published:

Wall PDH, Brown JS, Parsons N, Buchbinder R, Costa ML, Griffin DR. Surgery for treating femoroacetabular impingement: Study protocol. Cochrane Database of Systematic Reviews. DOI: 10.1002/14651858.CD010796.

3.2 Introduction

FAI surgery has evolved rapidly and at a pace far quicker than our understanding of the natural history and epidemiological characteristics of the condition.[42,64,91-93] Although some evidence exists to suggest abnormal hip shape morphology, pain and OA are associated, a true causal effect relationship has yet to be proven. It is, therefore, far from clear that surgically correcting shape will have any beneficial effect on symptoms such as pain or reduce the risk of OA. Establishing the true effect of surgery in terms of benefit and harm will help guide both clinicians and patients when considering treatment. Multi-centre RCTs are acknowledged to be the best design for evaluating the effectiveness of health care interventions as they provide robust evidence of effect.[94-97] It is clear that such RCTs comparing surgery for FAI versus nonoperative care would assist in evaluating the relative merits of the two options.[48] A systematic review was undertaken to determine if any RCT level evidence currently exists to support FAI surgery as a preferred option.

3.3 Objectives

To determine the benefit and safety of surgery for FAI.

3.4 Methods

Only studies where participants were either randomised or quasi-randomised into intervention groups were included in the review. There are no established diagnostic criteria for FAI with a diagnosis generally made on the basis of symptoms of hip or groin pain or both, restricted range of motion and a positive anterior impingement test, or both, and the presence of abnormal hip shape morphology and abnormalities of the adjacent labrum and cartilage, or both on imaging. The hip shape imaging should include cross-sectional studies, these may be: CT or MRI or MRA.[23,66] Trials with participants with FAI that conformed to the above criteria were included. Studies with patients with established OA were excluded. Studies of all types of FAI surgery were included. Surgery could be performed using open, mini-open, arthroscopic assisted mini open or arthroscopic approaches and the interventions could consist of:

i. Reshaping of the hip joint by removing bone, cartilage or both (osteoplasty, osteochondroplasty) from either the femoral head neck junction or rim of the acetabulum.
ii. Reorientating the hip joint by cutting the bones around the hip joint (osteotomy) and refixing the bones in a new orientation. The new orientation of the hip should reduce the risk of future FAI. The bony reorientation can be done for the femur, acetabulum or both.

Accepted comparators included:

i. Placebo (sham surgery)
ii. No treatment
iii. Non-operative treatment (for example physical therapy, analgesia, glucocorticoid injection, activity modification)

No studies were excluded on the basis of outcome measures. However a hierarchy was used based upon recent work and evidence supporting the use of a set of core outcomes for painful musculoskeletal conditions.[98,99]

Primary outcomes were:

i. Efficacy: proportion with reported pain relief of 30% or greater

ii. Number and type of serious adverse events (SAEs), defined as adverse events that are fatal, life-threatening, or require hospitalisation. Possible SAEs include: death; pulmonary embolism; fluid extravasation, fracture and avascular necrosis.

Secondary outcomes were:

i. Pain reported as:

Proportion with pain relief of 50% or greater

Proportion below 30/100mm on the Visual Analogue Scale (VAS)

Change in pain score on a VAS or numerical rating scale

ii. Adverse events (AEs)

iii. Hip specific function and quality of life measured using multi-domain outcome measures such as the Non-arthritic Hip Score and IHOT-33

iv. Generic quality of life, as measured by instruments such as: Short Form-36 (SF-36), Short Form-12 (SF-12), EuroQol-5D (EQ-5D)

v. Participant global assessment of treatment success

3.4.1 Search methods for identification of studies

The following electronic databases, unrestricted by date or language were searched: Cochrane Central Register of Controlled Trials (CENTRAL, via The Cochrane Library); MEDLINE (Ovid); and EMBASE (via) MEDLINE (Ovid; 1946 to present), EMBASE (1980 to present) and Cochrane Central Register of Controlled Trials (CENTRAL, via The Cochrane Library). In OVID MEDLINE, a subject-specific search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials: sensitivity-maximising version.[100] The strategy was designed in OVID MEDLINE and adapted to the other databases (see appendix A). The search terms used are shown in Table 3.1.

Table 3.1: Search terms used

Population	Intervention	Design
Femoracetabular Impingement	Surgical Procedures	randomized controlled trial
cam	cheilectomy	Randomly
Pincer	trochanteric flip	Placebo
femoro-acetabular	hueter	Controlled clinical trial
	arthroscopy	
	ganz	
	arthroscopic assisted	
	mini-open	
	Osteochondroplasty	
	Osteoplasty	
	Osteotomy	
	Operative	

Reference lists of relevant articles were also searched and trial registries (WHO International Clinical Trials Registry Platform - http://apps.who.int/trialsearch/, ClinicalTrials register - http://www.clinicaltrials.gov/, Current controlled trials register - http://www.controlled-trials.com/) were also searched to identify trials that were currently underway.

3.4.2 Selection of studies

Two researchers (PW and JB) independently selected the studies for inclusion in the review. Titles and abstracts obtained from the searchers were reviewed to determine potential eligibility and short listed if appropriate. The full text of each study in the shortlist was then reviewed to determine which studies are eligible for inclusion in the review. Any disagreement between the two authors was resolved by consensus or discussion with a third reviewer DG. Studies were translated into English where necessary.

3.4.3 Data extraction and management

Two review authors (PW and JB) independently extracted the following data from any included trials and entered it into RevMan 5:

i. Trial characteristics including size and location of the trial, and source of funding;

ii. Characteristics of the study population including age, and characteristics of FAI including: diagnosis criteria, type and duration of symptoms;

iii. Characteristics of the surgery and comparator treatment including: surgical approach used, type of FAI being addressed (cam/pincer/mixed), type of intervention used to correct the FAI (osteochondroplasty/osteotomy).

iv. Risk of bias domains as outlined in 'Assessment of risk of bias in included studies', below;

v. Outcome measures - mean and standard deviation for continuous outcomes (pain - when reported as a change in pain score, hip function or quality of life), and number of events for dichotomous outcomes (efficacy, pain - when reported as a proportion, SAEs, AEs and participant global assessment of treatment success).

If additional data was required, the trial authors were contacted to obtain this. Where data was imputed or calculated this was to be reported in the characteristics of included studies table.

3.4.4 Assessment of risk of bias in included studies

The plan was that studies included in the review would each be assessed for risk of bias using the recommended Cochrane Collaboration 'Risk of bias' tool.[101] This tool incorporates assessment of randomisation (sequence generation and allocation concealment), blinding (participants, personnel and outcome assessors), completeness of outcome data, selection of outcomes reported and other sources of bias. To determine the risk of bias of a study, it was planned to assess each criterion for the presence of sufficient information and the likelihood of potential bias. Each criterion was to be rated as 'Low risk' of bias, 'High risk' of

bias or ‘Unclear risk’ of bias (uncertain of the potential for bias, or insufficient information reported to make an assessment).

3.4.5 Measures of treatment effect

Risk ratios with 95% confidence intervals (CIs) were to be used to express the intervention effect for the following dichotomous outcomes:

i. pain, when reported as a proportion of participants within defined limits (i.e. reduction in pain of 30% or greater, 30/100 mm or less on VAS);
ii. AEs;
iii. SAEs;
iv. participant global assessment of treatment success.

Where dichotomous data from cross-over trials were combined with data from parallel-group trials, the odds ratio (OR) with 95% CI were to be calculated, rather than relative risk (RR). It was planned to calculate mean difference (MD) or, where studies used different measurement tools, standardised mean difference (SMD), both with 95% CIs, for the following continuous outcomes:

i. pain, when reported as either mean change in pain scores or mean absolute pain scores;
ii. hip function;
iii. quality of life.

3.4.6 Unit of analysis issues

It was expected that most studies would report outcomes at a number of follow-up times; for example, at 3, 6 and 12 months. It was therefore planned to extract at three time points: ≤3months; >3 and <12months; ≥12months. If there were multiple time points within each category, we planned to extract data at 3, 6 and 12 months.

3.4.7 Dealing with missing data

It was planned to seek additional information from authors of any included studies where the published information or data was incomplete. In cases where individuals were missing from the reported results, we planned to assume that the missing value had a poor outcome. For dichotomous outcomes that measured SAEs and AEs (for example number of SAEs), the number of patients that received treatment were to be used as the denominator (worst case analysis). For dichotomous outcomes that measure benefits, the worst case analysis was to be calculated using the number of randomised participants as the denominator. For continuous outcomes (for example pain) we planned to calculate the mean difference (MD) or standardised mean difference (SMD) based on the number of patients at the time point. If the numbers of patients was not presented for each time point, the numbers of randomised patients in each group at baseline were to be used. Sensitivity analysis was to be conducted to test the effect of these assumptions. Where possible, missing standard deviations were to be computed from other statistics such as standard errors, confidence intervals (CI) or p-values according to the methods recommended in the Cochrane Handbook for Systematic Reviews of Interventions.[101] If small amounts of outcome data are missing (for example standard deviations), the plan had been to consider imputing them (with appropriate sensitivity analyses) from other studies.[101]

3.4.8 Assessment of heterogeneity

For any studies judged as clinically homogenous, the degree of statistical heterogeneity between studies was to first be assessed graphically using a forest plot and more formally using the I^2 statistic, the following as a rough guide for interpretation: 0-40% might not be important, 30-60% may represent moderate heterogeneity, 50-90% may represent substantial heterogeneity, and 75-100% considerable heterogeneity.[102] In cases of considerable heterogeneity (defined as I2 ≥75%), it was planned to explore the data further, including subgroup analyses, in an attempt to explain the heterogeneity.

3.4.9 Assessment of reporting biases

In order to determine whether reporting bias was present, it was important to establish whether the protocol of the RCT was published before recruitment of patients of the study was started. For studies published after July 1st 2005, the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organisation was screened. The plan was then to evaluate whether selective reporting of outcomes was present (outcome reporting bias).

It was decided to compare the fixed-effect estimate against the random-effects model to assess the possible presence of small sample bias in the published literature (i.e. in which the intervention effect is more beneficial in smaller studies). In the presence of small sample bias, the random-effects estimate of the intervention is more appropriate than the fixed-effect estimate.[103] The potential for reporting bias was to be explored by funnel plots if ≥10 studies were available.

3.4.10 Data synthesis

If studies were found to be sufficiently homogeneous that it was clinically meaningful for them to be pooled, meta-analysis was to be performed using a random-effects model, regardless of the I^2 results. Analysis was to be performed using Review Manager 5 and forest plots produced for all analyses. Risk ratios with 95% CIs were to be used to express the intervention effect for dichotomous outcomes. For continuous data, such as patient reported quality of life measures, it was planned to calculate MD or, where studies may have used different measurement tools, SMD; both with 95% CIs. Where dichotomous data from cross-over trials were combined with data from parallel-group trials, the odds ratio (OR) with 95% confidence interval were to be calculated, rather than relative risk (RR).

3.4.11 Subgroup analysis and investigation of heterogeneity

The inclusion of intervention effects at a number of time points (e.g. three, six months and twelve months) should provide some sensitivity to the selection of an appropriate follow-up

time for assessment of the treatment effect. Where sufficient data was available, the following sub-group analyses were planned:

Cam versus pincer type FAI. These two shape abnormalities arise from different aspects of the hip joint and therefore the results of surgery may differ between these two types. Subgroup analysis will measure the result of surgery using pain as the outcome.

The subgroup analysis will informally compare the magnitudes of effect to assess possible differences in response to treatment by considering the overlap of the CIs of the summary estimates in the two subgroups - non-overlap of the CIs indicates statistical significance.

3.4.12 Sensitivity analysis

If it was necessary to exclude any studies because they appeared to differ markedly (i.e. if the outcome is different - effect goes in opposite direction) from the majority of studies then all main analyses were to be reported with and without these studies. Where sufficient studies existed, sensitivity analyses were planned to assess the impact of any bias attributable to inadequate or unclear treatment allocation (including studies with quasi-randomised designs).

3.4.13 Summary of findings tables

The main results of the review were to be presented in a summary of findings (SoF) table which would provide key information concerning the quality of evidence, the magnitude of effect of the interventions examined, and the sum of available data on the outcomes (efficacy; SAEs; pain; AEs; hip function; participant global assessment; quality of life), as recommended by the Cochrane Collaboration.[104] The SoF table included an overall grading of the evidence related to each of the main outcomes, using the Grading of Recommendations Assessment, Development and Evaluations (GRADE) approach.[105]

In addition to the absolute and relative magnitude of effect provided in the summary of findings table, for dichotomous outcomes, the number needed to treat to benefit (NNTB) or the number needed to treat to harm (NNTH) were to be calculated from the control group event rate.

3.5 Results

A breakdown of the search results and subsequent analysis is shown in Table 3.2.

Table 3.2: Search results

Database, and coverage	Search date	Number of references retrieved	Number after de-duplication
Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to July 30, 2013	July 30, 2013	105	92
Ovid Embase Classic+Embase <1947 to 2013 July 30>	July 30, 2013	75	52
Wiley Cochrane Library – CENTRAL	July 30, 2013	185	176
Clinical Trials. Gov	July 30, 2013	11	11
Totals		**376**	**331**

None of the 331 titles/abstracts reviewed met the inclusion criteria when reviewed independently by PW and JB.

3.6 Discussion

In order to participate in RCTs, surgeons need to acknowledge collective uncertainty or equipoise between treatments. For patients, the idea that there is uncertainty about the comparative effectiveness of treatments can be very difficult to accept. Lack of surgeon and patient equipoise could both be major barriers to recruitment in a RCT of surgery versus control for FAI. All of these factors may help explain why no RCTS or quasi randomised controlled trials examining the effectiveness of FAI were found. The results are in keeping with a systematic review of surgical treatment for FAI conducted by Clohisy et al in 2010[48] in which observational studies only are reported. The systematic review protocol presented in this chapter has helped outline the potential structure for a full RCT and the remainder of this thesis explores and addresses some of the major barriers to the feasibility of a RCT to measure the clinical effectiveness of FAI surgery against nonoperative care.

Chapter 4 Nonoperative treatment for FAI: a systematic review of the literature

4.1 Declarations

This work has been presented at a national and international conference:

September 2011*:* International Society of Orthopaedic Surgery and Traumatology (SICOT) Prague September 2011. Does an effective nonoperative treatment exist for femoroacetabular impingement: A systematic review of the literature?

May 2011: Oswestry Research Day. Does an effective nonoperative treatment exist for Femoroacetabular Impingement?

This work has also been published:

Wall PDH, Fernandez M, Griffin DR, Foster NE. Nonoperative Treatment for Femoroacetabular Impingement: A Systematic Review of the Literature. *PM&R,* 2013; 5:5: 418-426.

This project was facilitated by the NIHR Health Technology Assessment programme (project number 10/41/02).

4.2 Introduction

Nonoperative treatment for FAI is often dismissed on the grounds that surgery is the only effective mechanism by which the shape abnormalities of FAI can be corrected to improve patient's symptoms. There is, however, evidence that nonoperative care is being used in routine National Health Service (NHS) clinical practice for patients with FAI.[106] Although

changes in hip shape without surgery are not possible there are number of other mechanisms by which nonoperative care could theoretically help patients with FAI including:

i. Avoidance of positions that cause impingement such as flexion, adduction and internal rotation of the hip.
ii. Addressing associated soft tissue dysfunction such as muscle weakness and poor muscle control. There is evidence that FAI is associated with hip muscle weakness, while this may be primary or secondary to FAI, strengthening these muscles may improve functional outcome.[107,108]
iii. Pain relief for symptoms. Simple analgesia is already a well proven mechanism for relieving the symptoms of other chronic musculoskeletal conditions.
iv. A relative increase in the arc of anterior impingement free movement. If a patient can maintain their pelvis in a position of relative posterior tilt then it would reduce the anterior acetabular coverage of the femur and allow the femur more flexion before impingement occurs.[109] There is some evidence that pelvic inclination can be altered with exercise and this has been employed in the treatment of lower back pathology.[110]

In order to determine the quantity and quality of evidence supporting nonoperative care for FAI a systematic review of the literature was undertaken. The results were then used to help determine a suitable nonoperative treatment comparator to surgery in a RCT.

4.3 Objectives

To establish whether any nonoperative treatment options for FAI have been reported and the evidence for them.

4.4 Data Sources and Searches

A search of the published literature was performed up until June 2012 in accordance with a prospectively registered review protocol (registration no. CRD42012002456, www.crd.york.ac.uk/PROSPERO).[111] The following databases were searched: Pubmed, Ovid Medline, Excerpta Medica Database (EMBASE), Cumulative Index to Nursing and Allied Health (CINAHL), Allied and Complementary Medicine Database (AMED) and Cochrane

Library databases. The search terms used were: Femoroacetabular Impingement, Femoro-Acetabular Impingement and Hip Impingement. Medline example of our search strategy = ("femoroacetabular impingement" OR "femoro-acetabular impingement" OR "hip impingement").af (Limit to: English Language). In addition we searched the International Standard Randomised Controlled Trial Number Register (ISRCTN) and metaRegister of Controlled Trials (mRCT) for reports of on-going and unpublished trials. The references generated were then transferred to EndNote® to determine any duplicates.

4.5 Study Selection

Article titles and abstracts were independently screened by two researchers PW and MF, to look for relevant publications which satisfied the following inclusion/exclusion criteria: any systematic review, discussion paper, clinical trial or case series which discussed or evaluated a non-operative treatment for FAI. Single series case reports and abstract only publications were excluded, as were studies in which all patients were treated with FAI surgery. Where abstracts were not available or did not provide sufficient detail, the full text publication was retrieved. Adjudication from a third researcher (DG) was sought where disagreement about inclusion occurred. The full texts were then further analysed and the inclusion/exclusion criteria applied.

4.6 Data Extraction and Quality Assessment

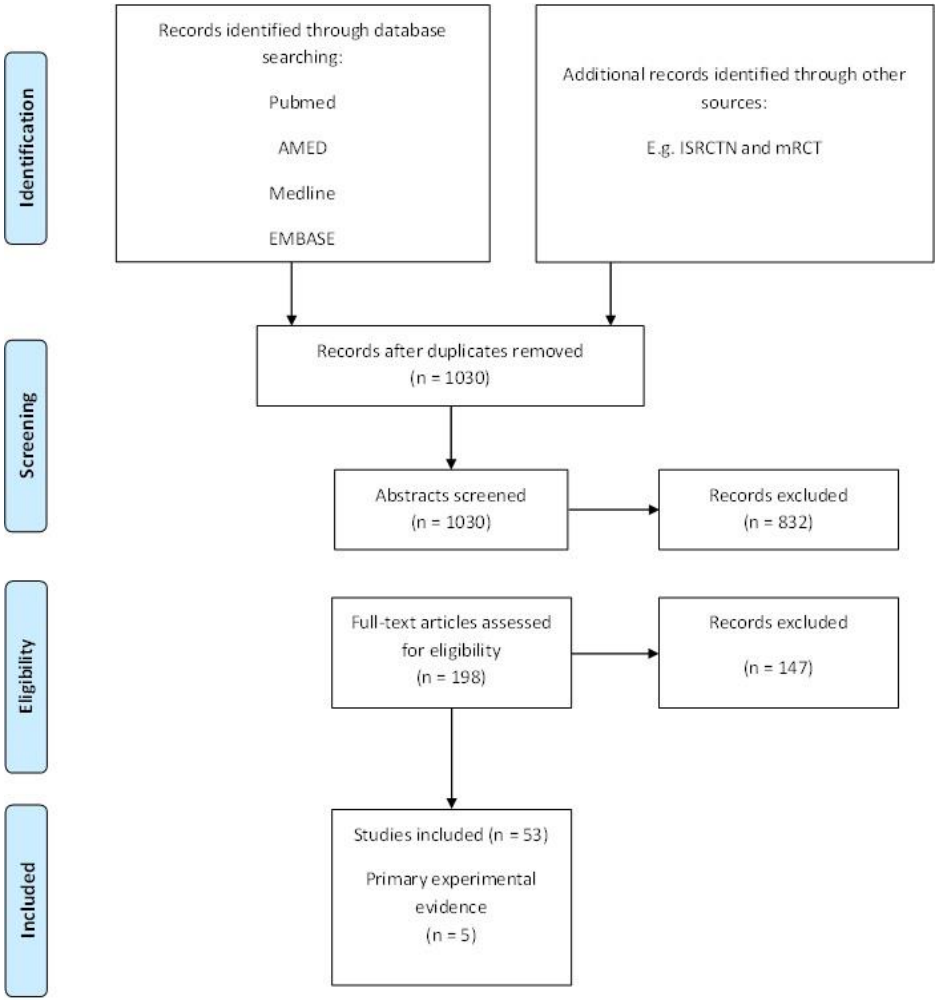
Final full texts for inclusion then underwent data extraction by PW. This was validated for all papers by MF. Where there was disagreement a third researcher (DG) was consulted. The following data was extracted: type of study, baseline patient details and diagnosis, details of non-operative treatments and comparators, reported outcomes, and follow up period. Papers were divided into those that provided primary experimental evidence about the effectiveness of non-operative treatment of FAI and review or discussion papers (i.e. expert opinion – level 5 evidence[112] and below) about FAI. For primary experimental evidence papers we used the GRADE tool to judge the quality of the experimental evidence as high, moderate, low or very low.[113] A scientific quality assessment tool specifically designed for case series was also

applied to all the experimental evidence articles.[114] If the studies were sufficiently homogeneous that it was clinically meaningful for them to be pooled, a meta-analysis was to be performed using a random-effects model, regardless of the I^2 results. For reviews/discussion papers data was put into prearranged SoF tables detailing all non-operative treatment strategies mentioned.

4.7 Synthesis

The search returned 1030 abstracts (after removal of duplicates). There were a total of 53 papers that met our eligibility criteria. There were a total of 5 papers providing primary experimental evidence about the effectiveness of non-operative treatment of FAI and 48 review or discussion papers about FAI. A flow diagram in Figure 4.1 describes the review process which is compliant with PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines.[115]

Figure 4.1: PRISMA flow diagram of search results (Source: Moher et al[115])



A detailed analysis of the 5 papers describing primary evidence and a synthesis of 48 review/discussion papers in order to identify non-operative treatment themes for FAI is presented.

4.7.1 Primary Experimental Evidence

Five papers were included which described primary studies involving the non-operative treatment of FAI – these included four case-series (three prospective and one retrospective) and one descriptive epidemiological study - outlined in Table 4.1 and Table 4.2. No randomised trials were identified.

Table 4.1: Details of papers that provide experimental evidence on non-operative treatment for FAI

Author	Type of Study	No. Patients	Diagnostic criteria for FAI	Age of patients	Type of FAI being managed and details of Non-operative care	Reported Outcome	Follow-up Period
Reynolds et al 1999	Retrospective case series	310 patients in study, 22 patients with FAI. 11 treated non-operatively, 11 treated with FAI surgery.	Acetabular retroversion confirmed by CT. Median roof edge angle -17deg retroversion (normal +5 deg)	Mean 28 years (15-50 SD 10)	FAI type = pincer Care not defined	No outcomes given	Not defined
Jager et al 2004	Prospective case Series	17 patients with FAI (9 treated non-operatively, 6 treated with surgery, 2 treated with THA)	Moderate clinical symptoms (Pain on VAS ≤5) Radiological femoral head-neck bump deformity (cam-type)	Average 34 years (14-60 SD 14)	FAI type = cam NSAIDs Physical therapy-led care No further details	All patients treated non-operatively were still complaining of pain and hip dysfunction. Patients who underwent surgical bumpectomy graded the result as excellent or good and had no clinical signs of FAI post operatively	Non-operative group - 16.2 months (SD 2.5) FAI surgery group 21.7 months (SD 7.7) THA group - 26.5 months (SD 12.5)
Feeley et al 2008	Descriptive epidemiological study	738 hip injuries in 678 NFL players, 13 with a labral tear and radiological FAI (8 treated non-operatively, 5 treated with FAI surgery)	Positive FADIR test MRI determined α angle in 7 out of 13 athletes. Average α = 63.2deg	Not defined	FAI type = not defined Physical therapy-led care No further details	All 8 treated non-operatively (with physical therapy) returned to playing NFL, 1 patient treated with surgery played 1 season of NFL then had to retire, 4 had returned to by 6 months.	Not defined
Emara et al 2011	Prospective case series	37 patients with FAI (37 treated non-operatively)	Unilateral hip pain Positive impingement test Radiologically determined alpha angle <60 deg. (cam-type) No lower limit for alpha angle.	Mean 33 years (23-47 SD 5)	FAI type = cam 4 stages of care 1. avoidance of excessive physical activity and NSAIDS for 2-4 weeks 2. physical therapy-led care for 2 to 3 weeks - stretching exercises (20 to 30 minutes daily) to improve hip external rotation and abduction in extension and flexion 3. Assessment of the normal range of hip internal rotation and flexion. 4. Modification of activities of daily living.	33 patients treated showed mean improvement in HHS + NAHS before and after treatment from 72 to 91 and 72 to 91 respectively. 4 "failed" non-operative treatment and were treated with surgery.	25 to 28 months
Hunt et al 2012	Prospective case series	52 patients presenting with pre-arthritic, intra-articular hip disorders including acetabular labral tears, developmental hip dysplasia and FAI. 18/52 had mild FAI. All underwent a trial of conservative management after which 6 were satisfied with outcomes, 11 progressed to surgery with 1 lost to follow up.	Head neck offset ratio <0.17, alpha angle ≥55deg (borderline alpha angle 50-54 deg). Lateral centre edge angle ≥ 36deg, acetabular index <0deg. Patients only needed to have one of these radiographic parameters to be labelled FAI. 94% had a positive impingement test.	32.9 years ± 10	FAI type = all types of mild FAI Initial 3 month trial of: patient education, activity modification, physical therapy, and NSAID's/narcotics as necessary. Physical therapy protocol well defined with key aims of decreasing anterior femoral glide and optimising the balance of muscle strength and length.	6 out of 17 patients were satisfied with treatment.11 progressed to surgery. Authors report outcomes of conservative management for a group of 23 patients (15 had no deformity, 2 had DDH, 6 had FAI). The results from baseline to 1 year were: NPS: 6 to 3.3 HHS: 69.4 to 78.9 WOMAC: 25.1 to 13.5 NAHS: 70.4 to 81.6	Baseline plus 3 months, 6 months, 12 months

Table 4.2: Sources of bias and quality assessment

Author	Level of Evidence	Sources of Bias	GRADE quality of evidence[113]	Evaluation of scientific quality score[114]
Reynolds et al 1999[116]	4	No outcomes defined No evidence of sample size calculation No evidence of group homogeneity testing	Very low	3 of 13
Jager et al 2004[117]	4	Primary outcome measure not defined No evidence of sample size calculation No clear eligibility criteria Selective outcome reporting with different outcome measures used for treatment groups Treatment groups had significant differences prior to treatment No evidence of group homogeneity testing No evidence of blinding for outcome assessment Marked differences in duration of follow up	Very low	5 of 13
Feeley et al 2008[118]	4	Primary outcome measure not defined No evidence of sample size calculation No clear eligibility criteria Descriptive differences between treatment groups No homogeneity testing	Very low	6 of 13
Emara et al 2011[82]	4	Primary outcome measure not defined No evidence of sample size calculation Selective outcome reporting - "failure" not defined	Low	11 of 13
Hunt et al 2012[119]	4	Outcomes reported for heterogeneous groups with mixed pathology (numbers too low to perform subgroup analysis) Primary outcome measure not defined	Low	11 of 13

The mean patient age amongst these five papers ranged from 28–34 years with a follow up between 3 – 28 months.[82,116-119] The pathology and pre-treatment patient characteristics varied considerably. Three studies report outcomes for cam-type FAI which has been diagnosed using plain radiographs/MR measure of either alpha-angle or other similar measures with differing 'cut-off' values.[82,117,118] One study reports outcomes from patients with FAI as a result of acetabular retroversion diagnosed by CT.[116] One study reports outcomes from patients with all mild types of FAI.[119] Patients were reported to have a positive anterior impingement test (flexion, adduction and internal rotation) in three of the five studies, of which one study assessed only professional athletes.[82,118,119] Non-operative treatments were: NSAIDS and physical therapy-led treatments in three of the five studies,[82,117,119]

physical therapy-led care alone in one study,[118] and no defined treatment in one study.[116] Where non-operative care was employed, two studies gave a detailed description of the regime used - see Table 4.1[82,119]

Analysis of the quality of evidence reviewed was very low for three of the studies and low for two studies according to the GRADE recommendations - see Table 4.2.[113] Outcomes were poorly defined and heterogeneous amongst the studies. Patient reported outcome measures were used in two studies where a mean improvement following non-operative treatment was shown.[82,119] The other studies either did not report an outcome or reported a return to normal sporting activity or continued pain. No study explicitly defined a primary outcome measure. There was no evidence of homogeneity testing in any study and there were substantial differences in the patient characteristics and the type/definition of FAI used across the five studies making a cross comparison of the results difficult. An assessment tool specifically designed for case series was used to assess the scientific quality of the studies reviewed.[114] The average score was 7.2 out of a maximum of 13. The low score was mainly attributed to the irreproducibility of the treatments employed due to a lack of detailed treatment protocols and a lack of clearly defined outcomes.

4.7.1.1 Assessment of homogeneity

There was no evidence that any of the five papers described were clinically homogenous or had any comparable measure of clinical outcome. It was therefore neither possible nor clinically meaningful to attempt a meta-analysis.

4.7.2 Review/Discussion Papers

Forty-eight (48) papers were either: full clinical reviews about FAI, clinical commentary about FAI and its treatment or primary experiments for another aspect of FAI with some discussion about non-operative care. No review / discussion papers focused solely on non-operative care. Similar non-operative treatment strategies emerged in all the review papers and they have been summarised in Table 4.3.

Table 4.3: Details of treatment themes and frequency of promotion amongst review / discussion papers

Theme	Number of papers promoting the theme with references (% out of total 48 papers)
A trial of conservative treatment	31 (65)[30,31,120-148]
Activity modification	39 (81)[30,31,109,120-123,125-133,135-140,142,144-159]
Avoid excessive hip movement and or rest	17 (35)[30,120,122,126,127,130,132,138-140,142,144,146,148,151,155,160]
Physical therapy	23 (48)[30,121-123,125-127,129,138,139,143,145,148-151,156,158,160-164]
Osteopathy and Chiropractic	1 (2)[163]
Non-steroidal anti-inflammatory medications	36 (75)[30,31,120-122,125-128,130-133,135-138,140,142-148,150-154,156,157,159,165]
Intra-articular corticosteroid injections	5 (10)[127,151,153,156,159]

The only treatment strategy reported with further detail was physical therapy, these details are summarised in Table 4.4. It is important to note that when details were provided for physical therapy amongst the review / discussion papers none provided references to sources of experimental evidence supporting the regimes proposed.

Table 4.4: Details of physical therapy when provided in review / discussion papers

Paper	Further details of physical therapy where available
Lavigne et al 2004[30]	Physical therapy may be beneficial but passive ROM and stretching is counterproductive.
Nicholls et al 2004[149]	Protected weight bearing, taping the thigh into abduction and external rotation, orthotics, and motor control strategies may be considered.
Bathala 2007[150]	Strengthening abdominal and gluteal muscles. Stretching paravertebral musculature to change posture or pelvic inclination.
Leunig et al 2007[145]	Improve core and hip flexor strength. Attempts to improve passive ROM may be counterproductive.
Maheshwari et al 2007[138]	Emphasis on muscle strengthening and avoidance of extremes of ROM.
Pierannunzii et al 2007[139]	Postural rehabilitation to reduce pelvic inclination. Achieved through strengthening abdominal muscles and gluteus maximus and stretching iliopsoas and the paravertebral muscles.
Kassarjian et al 2008[121]	3-6 months of rehabilitation / physical

	therapy. If no response then offer surgery
Keogh 2008[122]	Specific technique modification and muscle balance work for some athletes.
Sink et al 2008[123]	Pelvic muscle and core strengthening. Pilates, with abdomen and pelvic muscle strengthening.
Hart et al 2009[126]	Hip flexor stretches to deal with iliopsoas tightness and core stability strengthening
Kuhlmann 2009[161]	Improve hip muscle flexibility and strength, posture and other muscle or joint deficits.
Emary 2010[127]	Address hip flexor tightness. Stretching and manipulation of the FAI hip to improve passive. ROM may exacerbate the condition.
Kaplan et al 2010[156]	Muscle strengthening and education to avoid extremes of motion can alleviate symptoms. Avoid passive ROM or stretching which may exacerbate the symptoms.
Smith et al 2010[162]	Improve hip muscle flexibility and strength and posture. Sport technique modification
Pollard 2011[160]	Core muscle strengthening
Samora et al 2011[148]	Physical therapy can identify movements that exacerbate the pain and optimise the alignment and mobility of the joint. However, physical therapists should avoid passive ROM or stretch because these can exacerbate symptoms. Core strengthening is also recommended, which includes coordinative and proprioceptive training.
Jacoby et al 2011[164]	Physical therapy to improve hip muscle flexibility and strength may help with the painful symptoms of impingement.
Chakraverty et al 2012[163]	Attempt to identify the tissues causing the pain, and to attempt to offload these tissues by altering biomechanics through passive mobilization, joint distraction and stretching techniques, as well as active muscle strengthening approaches. Strong flexing mobilization (‘articulatory’) manoeuvres to the hip joint may only serve to exacerbate labral injury and are to be avoided.
Hackney 2012[158]	Core stability exercises and stretching.

4.8 Discussion

4.8.1 Available evidence

The experimental evidence examining non-operative treatment for FAI is limited to five papers. This may be because of an overwhelming focus on surgery for FAI. However, despite this amongst the two papers with a higher GRADE quality of evidence (Emara et al and Hunt et al) the suggestion is that physical therapy and activity modification for FAI can

benefit patients.[82,119] The physical therapy regimes that were tested in both these papers were based on a staged approach. Fundamental to both regimes was an exercise based programme focussing on the core hip musculature. These programmes were all augmented by education and advice to help reduce the frequency of impingement. In addition early use of simple analgesia and NSAID was promoted.

Three studies (Feeley et al[118], Jager et al[117] and Reynolds et al[116]) had a GRADE evidence of very low. This was based on the study design alone (i.e. case series and descriptive epidemiological study). We upgraded two studies (Emara at al[82] and Hunt et al[119]) for the following reasons; (1) both clearly define the methodology and interventions employed (i.e. details of the physical therapy regime), (2) both studies use quantitative outcome measures (e.g. NAHS, HHS) which provide a consistent and precise measure of the magnitude of the intervention. This increases our confidence in the results from these studies and is also reflected by their scientific quality scores in Table 4.2..

4.8.2 Emara et al[82]

The results from Emara et al[82] (a prospective case-series) suggest that a staged based regime of physical therapy and other treatment modalities including activity modification and NSAIDS can help patients' symptoms and function up to 28 months after treatment. The regime of non-operative care is clearly defined in this paper. However, the chosen population of patients with cam type FAI ("mild FAI") is questionable and includes only patients with a radiographic alpha angle of <60 degrees. Typically in order to establish a diagnosis of cam type FAI an alpha angle of at least 50 degrees or more is used.[75,166] The authors suggest that the outcome of their non-operative care regime is comparable to surgery, however as highlighted the criteria for study eligibility (i.e. the definition of FAI that is being used) is probably very different to the typical criteria used in studies measuring the outcome for surgery. The authors report that the mean alpha angle of the unaffected hip is 47 degrees versus 57 degrees for the affected hip ($p<0.01$) but do not provide the spread for this data. In part the authors acknowledge this by referring to the patients as "mild FAI". However, it is

possible that, given the eligibility criteria, some patients did not even have FAI. The authors refer to patients who “underwent surgical treatment after conservative management failed” (N=4). No indication is given for when this decision was made and the criteria used for failure of conservative management. In addition the authors do not comment on the compliance with the nonoperative care protocol.

4.8.3 Hunt et al[119]

The results from Hunt et al[119] (a prospective case-series) suggest that their regime of nonoperative care offers some therapeutic benefit to patients with “pre-arthritic” hip disease, of which FAI is one included subtype. However, the authors acknowledge that subgroup analysis would be inappropriate due to the small numbers involved. It is difficult to determine whether FAI patients alone benefit from their regime of non-operative care. The study used a cohort of patients who are defined as having “mild osseous” abnormalities. The criteria used (an alpha angle of 50-54 degrees for a diagnosis) seem more reasonable and in keeping with the published literature than those used by Emara et al for defining patients with “mild FAI”. The regime of nonoperative care is clearly defined which includes patient education, activity modification and a directed physical therapy protocol (including NSAIDS and narcotics as necessary), but the authors acknowledge the difficulty in standardising the delivery of this care. Importantly the authors report marked variability in the attendance at the physical therapy sessions which form part of the non-operative care protocol (range of therapy visits was 1 to 19, with an average of 6.4 visits), but they do not define what constituted a satisfactory delivery of care per protocol.

4.8.4 Conclusions

As a result of the substantial variability (heterogeneity) in the five experimental studies presented a meta-analysis was neither feasible nor clinically meaningful. This a further reflection of the lack of high quality research in this area.

Many of publications to date on the non-operative management of FAI are in the form of review/discussion papers. The consensus (>50%) of opinion amongst these papers promoted the following nonoperative treatment themes for FAI: a trial of conservative therapy, activity modification and NSAIDs. No further details about any of these themes were provided by the reviews' authors.

Forty eight percent of the review/discussion papers promote physical therapy led care for FAI. Interestingly all the experimental evidence, albeit limited, supporting nonoperative treatment of FAI uses physical therapy led care. However, the literature on nonoperative treatment does not appear to be supported by any randomised trials testing nonoperative care for FAI.

Theoretical arguments have been advanced that early FAI surgery may prevent the development of future OA, despite no formal evidence for this. An equally strong argument could be made that a well-constructed regime of activity modification and appropriate physical therapy led care for patients is likely to reduce the incidence of symptomatic impingement. This may prevent progression, allow established lesions to heal and prevent future recurrence of symptoms.

The strengths of the review include a registered review protocol, a reproducible search strategy, application of the PRISMA statement[115], and the use of quality assessment tools[114,167] to grade the quality of the evidence reviewed. The review is limited by the level of evidence available for analysis and as such the possible introduction of bias. An attempt to address this has been made by identifying potential sources of bias and applying the GRADE recommendations to assess the quality of evidence. The reason the review used such broad eligibility criteria was to capture all available literature. Preliminary searches revealed very few articles regarding the non-operative care for FAI and therefore wide eligibility criteria were used in our protocol to ensure all available data were included.

Presenting both the review based and experimental based literature in this systematic review has helped highlight that the published literature is saturated with messages promoting the use of nonoperative care for FAI despite the weak supporting clinical evidence. It seems likely that a considerable number of the review/discussion papers were expressing opinion rather than actual evidence based advice and should be viewed with some caution.

More high quality research, preferably RCTs to evaluate nonoperative treatment against surgery is required. The available evidence based literature seems to suggest that physical therapy led care and activity modification for FAI is a potential treatment strategy but its true clinical effectiveness is not yet known. Two publications provide some basic structure about how such care could be delivered.

Chapter 5 Nonoperative treatment for FAI: Design of a package of care

5.1 Declarations

This work has been presented at a national and international conference:

May 2012: Femoroacetabular Research Symposium, Chicago, USA. FASHIoN Study: Designing a non-operative comparator.

May 2013: Oswestry Research Day. Designing and testing a package of non-operative care for Femoroacetabular Impingement.

The parts in this chapter enititled “naming of the protocol” is research that was undertaken by Ms A. Realpe and Dr A Adams, qualitative researchers working at Warwick Medical School. The section has been included for completeness and to justify the name “Personalised Hip Therapy” being used.

This work was part of a larger project (UK FASHIoN study) funded by the NIHR Health Technology Assessment programme (project number 10/41/02) and the draft final report for the whole project has been submitted to HTA September 2013:

Griffin DR, Wall PDH, Realpe A, Adams A, Parsons N, Hobson R, Achten J, Fry J, Costa M, Petrou S, Foster NE, Donovan J. UK FASHIoN: Feasibility study of a randomised controlled trial of arthroscopic surgery for hip impingement compared with best conservative care.

5.2 Introduction

Many RCTs measuring the effectiveness of drug therapies use the so called “placebo controlled” design. Undertaking similar RCTs in surgery with a placebo controlled study

design is less straightforward and in some cases simply not feasible.[168] The typical logical placebo for surgical RCTs is a “sham” operation, and understandably many patients feel uncomfortable with this. Although many healthcare professional understand the rationale behind “placebo controlled” design, they remain strongly opposed to taking part on the grounds that it is unethical to subject their patients to such risks.[168] For this reason very few placebo controlled RCTs are ever conducted in surgery. A more acceptable, though still challenging, approach is to use a genuine nonoperative intervention for comparison. Examples of this include: knee arthroscopy versus physical therapy for patients with OA and carpal tunnel decompression versus hand therapy for carpal tunnel syndrome.[169,170] These types of operative versus nonoperative study designs tend to lead to more viable RCTs with acceptable levels of recruitment and adherence (see Chapter 8). Consequently if a RCT is to measure the effectiveness of FAI surgery a suitable nonoperative comparator will be required.

The systematic review reported in Chapter 4 suggested that nonoperative care is being used as a treatment for FAI. There is published primary research evidence that nonoperative care can improve patients’ symptoms.[171] Such nonoperative care is typically physical therapy led, with an exercise based regime, activity modification and appropriate analgesia.[171] Although there is literature supporting this type of physical therapy the only experimental evidence specific to FAI providing guidance on how such physical therapy led care should be delivered is work by Emara et al.[82] Unfortunately the nonoperative care outlined by Emara et al in Chapter 4 lacks sufficient detail to be implemented directly into a RCT.

As well as a substantial proportion of the published review literature promoting physical therapy led nonoperative care, a number of healthcare policy makers endorse it too. In 2011 the Cornwall and Isles of Scilly NHS Primary Care Trust in the UK published a policy statement that only patients who have failed to respond to all available conservative treatment options including activity modification, pharmacological intervention and specialist

physiotherapy should be considered for FAI surgery.[106] Similarly, the National Institute for Health and Clinical Excellence (NICE) published guidance on arthroscopic FAI surgery which suggested the management of FAI can include conservative measures, such as modification of activity and NSAID medication.[172] The inclusion of physical therapy led nonoperative care for FAI in NHS healthcare policy has important implications. It suggests that there are likely to be a number of physical therapists within the NHS who have experience in managing patients with FAI as part of normal healthcare.

5.2.1 Consensus gathering approaches

Where there is a lack of evidence to guide care it is not unreasonable to use a consensus gathering approach in order to develop and rationalise best practice.[173] Physical therapists are clearly an appropriate group with whom to develop a consensus for nonoperative care of FAI given that they are the professionals most frequently cited in literature and policy as providing this type of treatment.

Murphy et al[173] summarised three formal consensus gathering techniques which have been used to guide healthcare in other subject areas:

i. **Delphi method** involves participants completing private questionnaires. The questionnaires invite participants to respond to “cues” i.e. statements that provoke decision making. Results are aggregated and reviewed for agreement. Successive rounds of questionnaires are undertaken until a set level of agreement is reached. The perceived advantage of this approach is that decisions are made in private, which some researchers regard as important to avoid contamination or influence decision making from others. In addition the technique can be applied over a large population and geographical area which might improve generalizability and applicability of findings.[173-175]

ii. **Nominal Group Technique (NGT)** involves a group process of generating ideas which are then either accepted or rejected by members. The process is structured with an aggregation of numbers of individual agreement. The process can continue

until a group judgment is reached. A modification of this technique is used most frequently for clinical guideline development.[173,176]

iii. **Consensus Development Conference (CDC)** requires a group of individuals to attend a conference in which evidence is presented to them by experts. The individuals then hold subgroup meetings in which they seek to establish group consensus based upon the information and evidence that has been presented to them.[173]

Figure 5.1 sourced from Murphy et al provides a summary comparison of these and other consensus gathering techniques.

Figure 5.1: Characteristics of consensus development as outlined by Murphy et al (Source: Murphy et al[173])

TABLE 1 Characteristics of informal and formal consensus development methods

Consensus development method	Mailed questionnaires	Private decisions elicited	Formal feedback of group choices	Face-to-face contact	Interaction structured	Aggregation method
Informal	No	No	No	Yes	No	Implicit
Delphi method	Yes	Yes	Yes	No	Yes	Explicit
NGT	No	Yes	Yes	Yes	Yes	Explicit
RAND version	Yes	Yes	Yes	Yes	Yes	Explicit
Consensus development conference	No	No	No	Yes	No	Implicit
Other methods						
Staticised group	No	Yes	No	No	–	Explicit
Social judgement analysis	No	Yes	Yes	Yes	No	Implicit
Structured discussion	No	No	No	Yes	Yes	Implicit

There is considerable overlap between these techniques and no one method can be regarded as superior to another. As a result researchers frequently modify/combine several techniques depending upon the particular problem with which they are faced.[173]

5.2.2 Developing complex interventions

The Medical Research Council (MRC) has published guidance for the development of complex interventions.[177] A complex intervention is defined as one which contains several

interacting components. In addition it is acknowledged that there are several dimensions to complexity such as the:

i. number of and interactions between components within the intervention;
ii. number and difficulty of behaviours required by those delivering or receiving the intervention;
iii. number of groups or organisational levels targeted by the intervention;
iv. number and variability of outcomes and the
v. degree of flexibility or tailoring of the intervention permitted

Physical therapy led care of any description would be regarded as a complex intervention based on these definitions and dimensions. Thus, if a physical therapy led nonoperative care protocol were to be developed it would be reasonable to use the MRC principles as guidance. The MRC suggest that in developing a complex intervention the following should be considered:

i. Identify the evidence preferably by carrying out a systematic review
ii. Identifying and develop relevant theory in order to improve the chances of an effective intervention being developed. The theory behind a complex intervention and how it might invoke change may not be clear at the start. It is therefore essential to develop a theoretical understanding of the likely process by which the intervention might invoke change; this can be achieved by using existing evidence and theory, supported if necessary by new primary research.
iii. Modelling process and outcomes. Before undertaking a full evaluation modelling the process and outcome may provide useful information to inform the design of the intervention.

5.3 Objectives

i. To develop a suitable nonoperative protocol of care for FAI that is feasible within the constraints of the NHS.

5.4 Methods

i. Identifying best methods of conservative care

A high quality, best conservative care treatment protocol for FAI was derived using an initial Delphi consensus technique supported by NGT methodology. Throughout, protocol development was guided by the available evidence and guidance from the MRC for developing a complex intervention.[177] A core study group was formed to oversee the development, evaluate information gathered and provide the layer of NGT consensus which supported the initial Delphi technique. The core study group comprised two senior musculoskeletal physical therapists with an interest in managing patients with FAI (DR and IH), an academic research physical therapist (NF) and PW.

The systematic review reported in Chapter 4 showed that only the work by Emara et al 2011[82] provided both an experimental evaluation and an explicit description of how treatment for FAI should be delivered. This programme was used as the starting point for a best conservative care treatment protocol for FAI (see Table 5.1). It was circulated to physical therapists involved in the management of patients with FAI in order to begin a process of Delphi consensus gathering.

Unfortunately at the time of this study, there was no way of knowing which therapists are directly involved in the management of patients with FAI, in order to construct a target sample. For this reason it was not possible to conduct simple random samples of the physical therapy profession in the UK. We therefore took a targeted approach to sampling, using networks of physical therapists most likely to be involved in the management of this patient group.

Adverts were posted nationally on the electronic network operated by Chartered Society of Physiotherapy (CSP) and in the CSP's "Frontline" magazine distributed to approximately 50,000 CSP members in the UK. UK physical therapists were invited to help develop a consensus for a best conservative care treatment protocol for FAI. Electronic invitations were also sent to physical therapists in the United States and Australia known to members of the core study group through previous collaborative work on FAI. To encourage a process of

“snowball sampling” within the international community, these therapists were encouraged to invite colleagues with experience and interest in managing FAI to join in the consensus development process.

Each physical therapist was sent an electronic copy of the first protocol in a questionnaire format (appendix B). The physical therapists were asked whether they agreed or disagreed with the proposed programme for the conservative treatment of FAI patients and where appropriate to provide comments and suggestions for improvement. Results were tabulated by the core study group and additional comments and treatment strategies suggested by the respondents were grouped into themes. An agreement level of ≥50% for this Delphi consensus technique was used. If no consensus was evident from the survey the core study group refined the protocol in light of the available feedback using a NGT type approach. The refined protocol was then recirculated to the physical therapists taking part in the Delphi consensus process and the cycle repeated until a consensus of ≥50% was achieved.

After a consensus was reached, the agreed best conservative care treatment protocol was implemented within a multicentre pilot RCT (see Chapters 8 and 9).

All physical therapists selected to provide best conservative care in the RCT were asked to detail exercises that would allow them to deliver the protocol. The exercises were then ranked and the most popular were included as a database resource (exercise template) to be used alongside the best conservative care protocol.

In the early phases of recruitment to the pilot RCT (Chapter 8) physical therapists involved in the pilot RCT and delivering the care were invited to a workshop (CDC technique) to share their experiences of delivering the protocol and make any suggestions for further amendments. All physical therapists delivering the best conservative care protocol were asked to complete case report forms for each patient, which included details about the number, nature and duration of the patient contact. In addition details of the exercises prescribed to each patient were recorded.

ii. Naming best conservative care

Prior to commencing recruitment to the RCT, a qualitative research study was undertaken to name the best conservative care treatment protocol for FAI. Previous qualitative research has highlighted the importance of naming treatments in order to improve uptake and compliance in particular when being used in RCTs.[178] Patients with FAI treated by one of the authors (DG) within the last 2 years and who also had up to date contact details were invited to take part in the qualitative study to help develop a name for the conservative treatment package. Patients who had been treated both operatively and conservatively were invited to take part. A maximum variation sample of about 16 of these patients who would have been eligible for the RCT (selected to include a range of age, sex, disease severity, activity and socioeconomic status) were to be included in the study group. Semi-structured qualitative interviews were undertaken with all the patients in order to derive a suitable name for the protocol.

5.5 Results

i. Identifying best conservative care

The initial conservative care treatment protocol proposed by Emara et al which was circulated to physical therapists for consensus development is shown in Table 5.1.

Table 5.1: Conservative care protocol proposed by Emara et al[82]

Initial assessment and treatment	**Stage 1**	Avoidance of excessive physical activity and anti-inflammatory drugs for 2 to 4 weeks
	Stage 2	Physical therapy for 2 to 3 weeks in the form of stretching exercises to improve hip external rotation and abduction in extension and flexion
Further assessment and treatment	**Stage 3**	Assessment of the normal range of hip internal rotation and flexion after the acute pain has subsided
	Stage 4	Modification of activities of daily living predisposing to FAI (e.g. hip internal rotation associated with flexion and adduction)

In total, 36 physical therapists responded and agreed to take part in the consensus process; 24 from the UK, 10 from the US and 2 from Australia. All 36 were senior musculoskeletal physical therapists who had previously managed patients with FAI. Details of the initial round

of consensus development received from 36 physical therapists are summarised in Table 5.2 and the further comments they provided are shown in Table 5.3.

Table 5.2: Level of agreement with the Emara protocol (initial protocol)

Agreement	Stage 1 and 2 of the Emara et al protocol (initial assessment and treatment) Level of agreement n (%)	Stage 2 and 3 of the Emara et al protocol (further assessment and treatment) Level of agreement n (%)
Yes	16 (44)	9 (25)
No	7 (19)	6 (17)
Unsure	13 (36)	21 (58)
Total	**36**	**36**

Table 5.3: Summary of additional comments made with respect to the Emara et al protocol (initial protocol)

	Additional themed comments made	Number of PTs suggesting theme	Origin of comments
Initial assessment and treatment (Stages 1 and 2)	Core stability exercise and movement control	21	UK x17, Australia x2, USA x2
	Muscle strengthening important	7	UK x6 USA x1
	See patients more frequently / over a longer period	5	UK x4 Australia x1
	Stretching exercise depending on what is limited.	4	UK x2 USAx2
	Soft tissue mobilisation to facilitate range of movement	3	UK x2 USA x1
	Address flexion contractures	2	UK x2
	Massage to relieve tightness in hip muscles	2	UK x1 Australia x1
	Avoid flexion stretching exercises during initial stages	1	UK x1
	Internal rotation stretching when pain free	1	USA x1
	Gentle exercise to mobilise the joint in all directions	1	UK x1
	Reduce overactive hamstrings muscles	1	UK x1
	Work on active abduction and external rotation	1	UK x1
	Avoid excessive hip flexion	1	UK x1
	See patients less frequently	1	UK x1
	Prolonged follow-up often needed	1	UK x1
Further assessment and treatment (Stages 3 and 4)	Advice that cycling is acceptable with activity modification	7	UK x 6 Australia x1
	Continue strengthening	6	UK x6
	Zigzag running no better than straight running	4	UK x3 Australia x1
	Reassessment important	2	UK x2
	Using orthotics may help	2	UK x2
	Encourage hip capsule stretches	2	UK x2
	Stretches can be harmful	2	UK x1 Australia x1
	Identify dysfunctional movement patterns to achieve long term change	2	UK x1 Australia x1
	More than twice monthly supervision required	2	UK x1 Australia x1
	Advice about lifestyle modification	2	UK x1 USA x1
	Advice about alternative forms of exercise	2	UK x1 Australia x1

	Advise to avoid deep squatting	1	UK x1
	Advice on return to sport specific training	1	Australia x1
	Strengthening of internal and external rotators of hip	1	UK x1
	Activity restriction on an individual basis	1	UK x1
	Modification of running on an individual basis	1	UK x1
	Ensure activities can be undertaken with minimal adduction/Internal rotation	1	UK x1

The level of agreement with the Emara et al protocol (initial protocol) amongst the 36 physical therapists was below the 50% threshold that had been set for the Delphi consensus method. However, using the additional comments made by the physical therapists, available evidence and established theory; two further protocols were developed independently by NF and PW (see appendix C and D) and presented at a core study group meeting. Using the two independent protocols presented, the core study group derived a second protocol based on a majority within the group (NGT type methodology). The second protocol which the core study group formulated had 4 core components and 4 optional components, which are described below along with a justification provided by the core study group for including each component:

Core component 1: Patient assessment

i. Both independently-developed protocols featured this component
ii. Although not formally a treatment and as such not specifically mentioned in the questionnaire feedback received, the core study felt that this component should be explicitly included in the protocol as it would underpin the remainder of the best conservative care treatment protocol.

Core component 2: Patient education and advice

i. Both independently-developed protocols featured this component
ii. 13 additional comments from questionnaire respondents suggested that physical therapists should provide patient specific education and advice about FAI with an indication that this should focus on lifestyle modification, advice on how to undertake different forms of exercise and how to undertake common activities such as walking, cycling, etc.

iii. Advice particularly with respect to activity modification was a feature of the published literature, including the Emara et al protocol.[82,119]

iv. In addition to points i, ii and iii, the core study group felt that education and advice would be regarded as a core component of best practice amongst physical therapists managing any painful musculoskeletal condition.

v. Both lifestyle and activity modification draws on relevant theory i.e. behavioural modifications that might lead to reduced functional impingement should result in reduced symptoms.[34]

Core component 3: Help with pain relief

i. Both independently-developed protocols featured this component

ii. This was a feature of the published literature, including the Emara et al protocol (stage 1), to which 44% of the physical therapists agreed.[82,119]

iii. Analgesia is an established treatment for musculoskeletal pain.[179,180] Controlling musculoskeletal pain associated with FAI with analgesia therefore follows MRC guidance that treatment draws on relevant theory.

Core component 4: Exercise based hip programme

i. Both independently-developed protocols featured this component

ii. 37 additional comments from questionnaire respondents endorsed both hip specific and more general exercises for managing patients with FAI. Of these, core or stability exercises were the most common (n=21 additional comments). The feedback suggested that the exercise programme should be individualised to the patient and progressed over time from core stability exercise and stretching to strengthening exercises.

iii. Exercise was a predominant feature of the Emara et al protocol and the other published literature for managing FAI nonoperatively.[82,118,119]

iv. Exercise is an effective treatment for many other musculoskeletal pain problems[181,182] and exercise-based programmes can produce similar improvements in symptoms to

surgery.[183] Therefore including an exercise based hip regime to help manage the symptoms of FAI follows MRC guidance that treatment draws on relevant theory.

Additional optional components

The core study group decided to include the following optional components which could be undertaken in addition to the core components in order to individualise treatment, at the discretion of the physical therapist delivering care:

Option 1: Additional symptoms that patients with FAI may present with can also be treated.
Option 2: Orthotics can be used to aid the treatment of biomechanical abnormalities
Option 3: Corticosteroid hip joint injection may be used for patients who cannot engage with 'core' treatment due to acute pain symptoms.
Option 4: Manual Therapy: hip joint mobilisations may be added if felt appropriate e.g. distraction and trigger point work.

The Emara et al protocol suggested that physical therapy should be offered over a period of between 2 to 3 weeks. The initial round of physical therapist responses suggested patients should be seen over a longer period and more frequently in order to provide best care. Currently within the NHS the average number of treatment sessions given by physical therapists to musculoskeletal pain patients is between 3 to 4 face to face contacts. There is evidence to suggest that better outcomes are achieved from exercise based regimes when they are supervised and the contact between the supervisor and patient is increased.[184,185] In order to allow more contact between therapists and their patients without increasing the burden of having to travel to clinic appointments non face to face contacts (e.g. telephone and email) were also allowed in order to progress the exercise programme and to support patients to adhere to the recommended exercise. The core study group decided that the agreed protocol could be delivered over a 12 week period. A minimum of 6 treatment sessions should be provided (of which at least 3 should be face to face). The duration of care

was both in keeping with established theory that suggests physiological changes in muscle occur after a 12 week programme of exercise.[186]

The core study group agreed on the following protocol exclusions:

i. Painful hard end stretches. Although only mentioned by two physical therapists in the initial questionnaire responses, there is some evidence in the literature to suggest that painful hard end stretches and forceful manual techniques in a restricted range of movement may be harmful. Therefore although stretching was permitted these hard end stretches were excluded.[30]

ii. Group based treatment. In order to ensure care was individualised.

iii. Care delivered by a technical or student instructor. In order to ensure the highest standard of care was delivered.

The second protocol is outlined in Figure 5.2.

Figure 5.2: Second protocol

Four core components. Each patient should receive all four core components over at least a twelve week programme with at least six patient contacts (at least three face to face contacts).

1. **Patient Education and advice**
   i. Education about FAI and available treatments
   ii. Advice about posture, gait and lifestyle behaviour modifications to try and avoid FAI. These may include: measures to encourage posterior pelvic tilt (reduce pelvic inclination); positioning when sitting, standing, sit to stand; positioning when sleeping; positioning when running / cycling were relevant
   iii. Advice about activities of daily living to try to avoid FAI (reducing/avoiding deep flexion, adduction and internal rotation of hip).
   iv. Advice about relative rest (for acute pain where patients cannot engage with their exercise-based personal hip programme) given that soft tissues take at least 8-10 weeks to heal. In particular, relative rest in a specific ROM where pain in that particular ROM is likely to represent on going inflammation and damage.
   v. Specific activity/sport technique advice and modification. Examples include running with a broader base to encourage abduction, cycling with less internal rotation on pedals, skiing with skis further apart and using knee flexion more than hip flexion to lower centre of gravity.

2. **Patient Assessment**
   i. History which should include (although not exclusively): history of presenting complaint; relieving and aggravating factors; past medical history; medications; previous treatments tried; social history including occupation; patients concerns/fears/beliefs, patients individual requirements and expectations.
   ii. Examination which should include (although not exclusively): the pain free and passive range of movement of the hip, strength of the hip and anterior impingement test

3. **Help with Pain Relief**
   i. Advice about anti-inflammatory medication for 2 to 4 weeks if not already tried and simple analgesics if they do not respond well to anti-inflammatory medication.

4. **Exercise-based hip programme**
   i. Engagement in and adherence to an exercise programme that has the key features of individualisation, progression and supervision.
   ii. A phased exercise programme that begins with muscle control work, and progresses to stretching and strengthening with increasing ROM and resistance.
   iii. Muscle control / stability exercise (targeting pelvic and hip stabilisation, gluteal and abdominal muscles)
   iv. Strengthening / resistance exercise firstly in available range (pain-free ROM)
   v. Stretching exercise to improve hip external rotation and abduction in extension and flexion (but not vigorous stretching – no painful hard end stretches). Other muscles to be targeted if relevant.
   vi. Exercise progression in terms of intensity and difficulty, gradually progressing to activity or sport-specific exercise where relevant.
   vii. A personalised and written exercise prescription that is progressed and revised over treatment sessions.
   viii. Encourage motivation and adherence through the use of a patient exercise diary to review progress.
   ix. Patients to have to access to resistance bands (e.g. therabands, exercise balls and exercise mats).

Additional optional components:

   i. Additional symptoms that patients with FAI may present with can also be treated as per the treating physiotherapists' preferred methods
   ii. Manual Therapy: hip joint mobilisations e.g. distraction and rigger point work.
   iii. Hip Joint Injection: for patients who cannot engage with 'core' treatment due to acute symptoms. Maximum of one steroid hip injection.
   iv. Orthotics: patients can be assessed for biomechanical abnormalities and either have these corrected e.g. referral to a podiatrist for custom made insoles.

Protocol exclusions:
   i. Forceful manual techniques in restricted range of movement. No painful hard end stretches.
   ii. Group based treatment
   iii. Care delivered by a student or technical instructor

At the second Delphi round 30 out of the original 36 participating (83%) physical therapists responded and agreed with the second protocol and provided no additional suggestions for change. One physical therapist did not respond and 5 disagreed with the second protocol and made suggestions for change. These points were discussed amongst the core study group and the following changes were made:

i. Two optional booster sessions that could be delivered between 12 weeks and 6 months were added to a revised protocol. This was in response to concerns that the initial 12 week programme could prove to be insufficient to correct what is likely to be a chronic biomechanical dysfunction. Booster sessions would also help with adherence to the programme.

ii. Taping techniques: to help with postural modification / reminding was added to the protocol. Although only mentioned by one physical therapist, it was noted that taping was a feature of the published literature and had been noted though not included in the NF protocol.[171]

Given the level of agreement (83%) achieved with the second protocol the core study group decided to use the second protocol with the modifications discussed above for implementation in the RCT.

Twelve physical therapists were initially part of the pilot RCT (Chapter 8) and delivering the best conservative care protocol. Examples of some of the most popular exercises that formed an exercise template to accompany the protocol are shown in appendix E. Eight physical therapists (out of 12 physical therapists participating in the RCT) from 8 recruiting centres attended the workshop to review the content and delivery of the protocol. Collectively the physical therapists were treating 18 patients within the pilot RCT. The therapists all felt that the protocol worked well but collectively they wanted to change the number of treatment sessions and the overall duration of the protocol, in order to ensure they were able to deliver best care. As a result one change was made to the protocol which allowed a minimum of 6 and a maximum of 10 contacts over a 6 month period. The physical therapists agreed that no further amendments would be needed to the protocol.

ii. Naming best conservative care

Sixteen patients with FAI took part in qualitative study to derive a name for the best conservative care protocol. They were asked to choose between 4 potential names which had been suggested by the core study group, with the option to suggest a different name if

they wished to do so. Eight patients opted for the name ‘Personalised Hip Therapy (PHT)’, 4 patients voted for ‘Personalised Hip Programme’, one patient preferred the name ‘Focused Hip Therapy’ and 3 offered their own suggestions (i.e. ‘Conservative Hip Rehabilitation Programme’ and the inclusion of the word ‘Non-Invasive’). ‘Conservative’ or ‘Non-invasive’ were disregarded because they appeared to have a value attached to them; for example the term conservative could be confused with terms used in politics. The word ‘personalised’ was preferred for most people, as exemplified in the quote below:

“I said the last two [personalised hip treatment and personalised hip therapy] because it makes it a personal issue for that person ....going down a non-operative route would require different treatment for every different patient” (Patient 3)

A patient explained the preference for the word ‘therapy’ as indicative that there was an effort to ‘solve’ or ‘cure’ the condition as opposed to ‘programme’:

“Therapy from a psychological point of view, people understand therapy (...) with regards to clinical treatment rather than a programme which can relate to anything in life” (Patient 13)

The results of this consultation showed that the ‘Personalised Hip Therapy’ appealed to and conveyed a positive message to patients. The purpose of the research to name the protocol was to convey a message that the treatment was active and different to more general regimes of physical therapy that patients may have previously tried.

5.6 Discussion

The design of a structured protocol of physical therapy led nonoperative care for FAI has been outlined, including the approaches that were used to develop this protocol. The protocol has been designed with the support of available published evidence, expert consensus from physical therapists treating FAI patients including those that might be expected to provide the protocol of care as part of a pilot RCT. The systematic review of nonoperative care for FAI revealed a lack of both detail and quality of evidence but did suggest that nonoperative care might be effective. It is probably for this reason that the initial round of Delphi consensus gathering revealed low levels of agreement amongst physical therapists.

The Charted Society of Physiotherapy has approximately 50,000 members.[187] Only 36 physical therapists engaged with our research; the reasons for this are not clear but may reflect that a limited proportion will undertake regular musculoskeletal work and of these few may be sufficiently aware of FAI as a potential cause for young adult hip pain. As a result many may feel they were not appropriately qualified/experienced to make expert commentary about nonoperative care for patients with FAI. The approach used to gather experts for a Delphi method consensus does suffer from responder bias. As a result the subsequent protocol may not truly reflect the range of views and opinions of all physical therapists that routinely manage FAI. However, if the number of physical therapists that engaged in the initial survey had been much larger establishing a Delphi consensus with >50% agreement is likely to have been substantially more difficult even with subsequent iterations of the protocol.

A further criticism of the approach used to develop the protocol may be that it does not represent one true consensus gathering methodology in its purest form. However, previous literature suggests that consensus development in healthcare which purports to use an established methodology rarely does and in fact modifications are often more appropriate and entirely reasonable.[173]

It is already known that there is enthusiasm to undertake a RCT of surgery versus nonoperative care for FAI in the USA.[188] By including a small proportion of international physical therapists (USA and Australia) the PHT protocol should be more applicable to care outside the UK and may be an appropriate nonoperative comparator in its current format for such an RCT. If not, it would provide a starting point for a further level of Delphi method consensus in the local physical therapy population e.g. USA and Australia.

Where possible the protocol followed MRC guidance that an intervention is based upon some theory either proven or not. Research has already shown that exercise is an effective

treatment for many types of musculoskeletal pain[181,182], and has identified that exercise-based programmes can produce similar improvements in symptoms to surgery.[183] Personalised regimens of nonoperative care have been effective and sometimes superior to surgery in managing musculoskeletal problems, with the advantage of much less risk than that associated with surgery.

Some examples include:

i. Knee arthroscopy used to be a routine treatment for patients with knee osteoarthritis. We now recognise after performing similar large scale randomised controlled trials that regimes of pain medication and physiotherapy-led exercise are more effective at managing a patients symptoms without the risks of surgery.[189,190]
ii. Similar findings have been shown for the treatment of knee meniscal tears where exercise based physical therapy is equally effective as surgery without the same level of risk.[191]
iii. A large randomised trial of lumbar spine fusion versus intensive rehabilitation supervised by physical therapists found no difference in outcome between groups but considerably less risk in the non-surgical treatment group.[192]

Therefore it is not unreasonable to propose that PHT may have some treatment effect above and beyond placebo only effects. The PHT protocol has two goals:

i. Control and reduce symptoms
ii. Prevent recurrence of symptoms

It is proposed that the PHT programme will achieve these goals by teaching patients new techniques and ways of moving during everyday tasks and leisure activities to both reduce and avoid FAI. PHT will focus on improving the stability and fine control of movement around the hip, as well as improving the strength and flexibility of the joints and muscles close to the hip. Through this PHT, patients should be better equipped with the right knowledge and skills to modify and maintain ways of moving to reduce the effects of FAI. It is anticipated that these improved movement patterns will need to be consciously learnt to begin with but will

become routine with practice over time. The PHT programme aims to provide patients with a better understanding of FAI.

The PHT protocol provides some guidance to other clinicians and researchers in an area where evidence and guidance are very limited. The protocol is not truly a new treatment for FAI and it merely represents a collection of expert opinions about nonoperative treatment that is already being undertaken in the real world for patients with FAI. The PHT protocol will be tested for safety, compliance and deliverability in a pilot RCT – see Chapter 9. By road testing in a pilot RCT it is anticipated that the protocol may be further refined and evolve, which is line with MRC guidance that complex interventions should always undergo a process of modelling prior to a full evaluation.[177]

FAI affects a considerable proportion of young adults. It is important that FAI patients have access to and can decide between both operative and nonoperative care, until better evidence emerges in support of either treatment, particularly given the risks of surgery.

Chapter 6 Femoroacetabular Impingement: surgical workload

6.1 Declarations

This work has been presented at a national conference:

April 2013: Oswestry Research Day. Surgery undertaken for femoroacetabular impingement in the UK.

This work was part of a larger project (UK FASHIoN study) funded by the NIHR Health Technology Assessment programme (project number 10/41/02) and the draft final report for the whole project has been submitted to HTA September 2013:

Griffin DR, Wall PDH, Realpe A, Adams A, Parsons N, Hobson R, Achten J, Fry J, Costa M, Petrou S, Foster NE, Donovan J. UK FASHIoN: Feasibility study of a randomised controlled trial of arthroscopic surgery for hip impingement compared with best conservative care.

6.2 Introduction

The prevalence in the general population of symptomatic FAI is not known, nor is the proportion of these patients who subsequently undergo surgery. In order to plan and design a RCT to determine the effectiveness of surgery it is necessary to determine the quantity of FAI surgery (number of likely eligible patients) being undertaken. This information can be then used to predict the number of recruiting centres required for a RCT based on the required sample size. The National Institute for Health Research (NIHR) has suggested that a RCT comparing surgery and nonoperative care for FAI would be funded if such a study was deemed feasible within the NHS. In this context the workload of FAI surgery within the NHS was determined.[193] Unfortunately it is unlikely that any routinely collected procedural data such as Hospital Episode Statistics (HES) within the NHS will be homogenous or

accurate enough. FAI and its treatments are a comparatively new phenomenon within the NHS and no diagnostic or procedural codes have been agreed. Therefore a survey based approach was required in order to determine the workload of FAI surgery.

6.3 Objectives

To obtain an estimate for the quantity of surgery being undertaken for FAI within the NHS.

6.4 Methods

A list of all NHS Hospital Health Boards and Trusts within England, Northern Ireland, Scotland and Wales was compiled using the NHS online resource. All Hospital Trusts and Health Boards were then contacted by telephone to determine if they had an Orthopaedic service. Subsequently, each orthopaedic service was contacted to determine the number of Orthopaedic departments which made up the service and the identities of the Clinical Directors. A list of all Orthopaedic Clinical Directors in the UK was then compiled. Each orthopaedic Clinical Director was then contacted by letter requesting the names, and contact details of all surgeons in their unit performing surgery for FAI. A letter was then sent to each identified FAI surgeon requesting the following statistics for the financial year 2011/2012:

i. Number of NHS funded hip arthroscopies performed.

ii. Number of NHS funded hip arthroscopies performed for FAI.

iii. Number of NHS funded open surgical procedures performed for FAI.

Consultants who did not consider themselves as FAI speciality surgeons were removed from the database. Consultants who considered themselves to be FAI specialty surgeons but were not currently performing surgery were kept on the database. The reasons given were recorded e.g. no current primary care trust funding for the procedure. Those FAI surgeons who did not want to participate in the study were removed from the database. Data collection was undertaken over a 6 month period between May and October 2012. Where consultants gave results for a period of less than a year, the results were not re-scaled. Instead, conservative estimates were obtained by keeping case numbers the same, no matter the

period. Where consultants provided an estimation using a range, this was recorded and final calculations were made based on the lowest figure in that range.

In order to try and validate this workload data, NHS HES data was obtained for procedures undertaken in 2011/2012 using Office of Population Censuses and Surveys Classification of Interventions and Procedures (OPCS-4) codes within England. OPCS is a procedural classification for the coding of operations, procedures and interventions performed during in-patient stays, day case surgery and some out-patient attendances in the NHS. OPCS-4 is an alphanumeric nomenclature, with a 4 character code system. The first character is always a letter. The code system can also be combined to provide further detail. Combinations of codes are separated by a ".". Specific procedure codes for FAI surgery have not yet been established.

In the absence of any established OPCS-4 codes for FAI surgery the codes currently agreed and applied to FAI surgery within University Hospital Coventry and Warwickshire (UHCW) were used. These were:

i. Z843 which represents surgery on the hip joint was combined with the following categories
ii. w844 = endoscopic decompression of joint
iii. w802 = open debridement of joint

Validation of the HES data was undertaken using an independently locally collected database for FAI surgery at UHCW.

6.4.1 Statistics

IBM SPSS version 21 for Windows statistical software package was used for the statistical analysis.[86] Summary statistics including; mean (with standard deviations - SD) and median (with inter-quartile ranges) values were reported for the data.

6.5 Results

There were a total of 193 NHS Hospital Health Boards and Trusts in the UK. Of these 27 did not have an orthopaedic surgical service. The workload data for FAI surgeons that responded to our survey is shown in Table 6.1.

Table 6.1: Breakdown FAI surgeons and workload within the NHS

	No. of Hospital Health Boards and NHS Trusts with an FAI Surgeon	***No. of FAI Surgeons***	***No. of Hospital Health Board and NHS Trusts with no funding for FAI surgery***	***No. of open FAI surgery cases 2011/12***	***No. of arthroscopic FAI cases 2011/12***
England	**69**	110	6 (8 surgeons)	444	1791
Scotland	**2**	2	0	38	62
Wales	**2**	6	0	9	55
N. Ireland	**2**	2	2	0	0
Total	75	120	8	491	1908

Of the 120 FAI surgeons identified only 100 provided workload data. Four consultants gave results for a practise spanning less than a year. Of the 100 surgeons returning workload data 25 did not perform any arthroscopic surgery over the 2011/2012 financial year and 55 did not perform any open surgery over the same period. The mean and median workload of FAI surgeons for arthroscopy, open surgery and total FAI surgery is shown in Table 6.2.

Table 6.2: Workload for FAI surgeons

	Arthroscopic FAI workload per surgeon	**Open FAI per surgeon**	**Total FAI surgery workload per surgeon**
Mean (SD)	19 (23)	5 (12)	24 (34)
Median (IQR)	12 (0-30)	0 (0-4)	12 (0-34)

Figure 6.1 and Figure 6.2, show the spread of workload for arthroscopic and open surgery respectively.

Figure 6.1: Surgeon workload for arthroscopic surgery

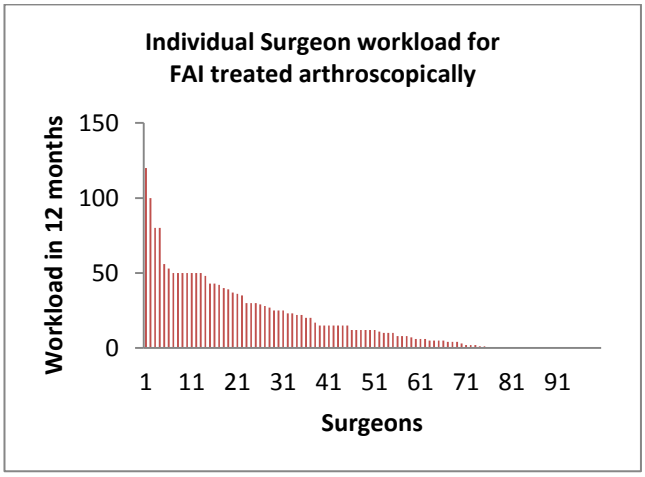
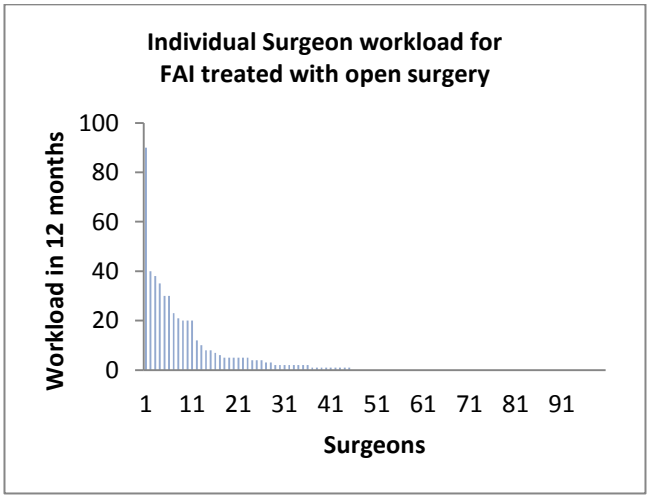


Figure 6.2: Surgeon workload for open surgery



Each surgeon returning data was assigned a postcode for their NHS practice and this was used to create a choropleth map of the workload data based upon regions within the UK. A choropleth map is a thematic map with areas shaded in proportion to the measurement of the variable being displayed on the map. Figure 6.3 and Figure 6.4 are UK choropleth maps for arthroscopic and open surgery respectively based on regions.

Figure 6.3: Choropleth map of arthroscopic surgery

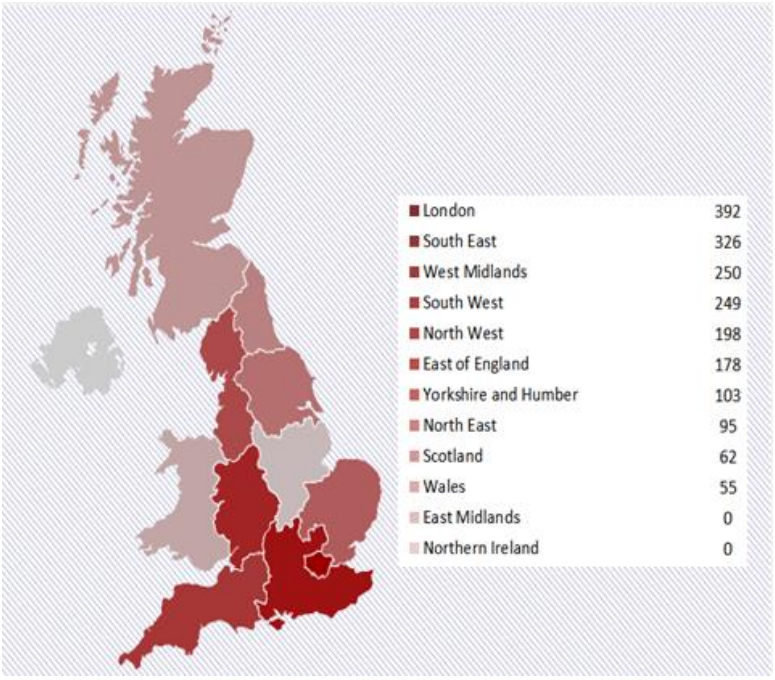
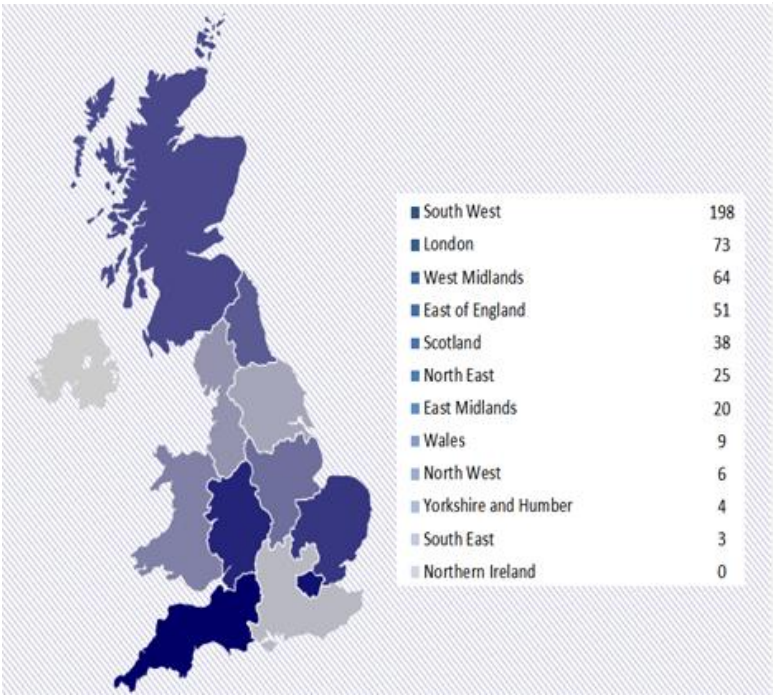


Figure 6.4: Choropleth map of open surgery



Prevalence rates were calculated for each region per 100,000 population using mid 2010 population estimates from the Office for National Statistics (ONS), the results are shown in Table 6.3: Prevalence of surgical workload based on regional populations.

Table 6.3: Prevalence of surgical workload based on regional populations

Region	Mid 2010 Population estimate[194]	Arthroscopic FAI surgery cases	Arthroscopic FAI surgery per 100,000 population	Open FAI surgery cases	Open FAI surgery per 100,000 population	Total FAI workload per 100,000 population
London	7,825,000	392	5.0	73	0.9	5.9
South East	8,523,000	326	3.8	3	0.0	3.9
West Midlands	5,455,000	250	4.6	64	1.2	5.8
South West	5,274,000	249	4.7	198	3.8	8.5
North West	6,936,000	198	2.9	6	0.1	2.9
East of England	5,832,000	178	3.1	51	0.9	3.9
Yorkshire & Humber	5,301,000	103	1.9	4	0.1	2.0
North East	2,607,000	95	3.6	25	1.0	4.6
Scotland	5,222,000	62	1.2	38	0.7	1.9
Wales	3,006,000	55	1.8	9	0.3	2.1
East Midlands	4,481,000	0	0.0	20	0.4	0.4
N. Ireland	1,799,000	0	0.0	0	0.0	0.0
Total	**62,261,000**	**1908**	**3.1**	**491**	**0.8**	**3.9**

The data was also sorted into individual hospital trusts undertaking FAI surgery. There were a total of 75 individual hospital trusts employing FAI surgeons. A summary of this data is shown in Table 6.4.

Table 6.4: Summary of workload for hospital trusts

Summary statistic	FAI surgeons per hospital trust	Arthroscopy per hospital trust in 2011/12	Arthroscopy for FAI per hospital trust in 2011/12	Open surgery for FAI per hospital trust in 2011/12
Mean	1.3	37.3	25.4	6.5
SD	0.6	52.7	34.0	17.2
Median	1	22	12	0
Interquartile range	1	45	41	5
Minimum and maximum	1-4	0-352	0-149	0-132

There were a total of 44 hospital trusts that undertook ≥10 hip arthroscopies for FAI in 2011/12 and 12 hospital trusts that undertook ≥10 open surgeries for FAI.

Table 6.5 provides details of the hospital trusts performing ≥10 hip arthroscopies for FAI in 2011/12.

Table 6.5: Hospital trusts performing ≥10 hip arthroscopies for FAI in 2011/12

Individual Hospital Trust	No. of surgeons	Hip arthroscopies in 2011/12	Hip arthroscopies for FAI in 2011/12	Open surgery for FAI in 2011/12
Frimley Park Hospital NHS Foundation Trust	2	159	149	1
Guy's and St Thomas' NHS Foundation Trust	2	333	144	9
Barts Health NHS Trust	3	50	140	30
Epsom and St Hellier University Hospitals NHS Trust	4	135	129	1
Royal Cornwall Hospital (Treliske)	3	157	100	132
Addenbrookes Hospital	2	143	91	0
The Royal Orthopaedic Hospital NHS Foundation Trust	2	135	90	15
Robert Jones and Agnes Hunt Hospital	2	90	80	1
South Tees Hospitals NHS Foundation Trust	2	73	73	0
Wrightington, Wigan and Leigh NHS Foundation Trust	2	76	71	2
Bangor Hospital	3	59	55	9
Buckinghamshire Healthcare NHS Trust	1	53	53	1
University College London Hospitals NHS Foundation Trust	2	50	50	0
Bolton NHS Foundation Trust	1	51	50	0
Harrogate and District NHS Foundation Trust	1	50	50	0
Royal National Orthopaedic Hospital NHS Trust	1	50	50	30
South London Healthcare NHS Trust	1	50	50	0
Oxford Radcliffe Hospitals NHS Trust	2	50	45	0
Great Western Hospitals NHS Foundation Trust	3	47	43	7
Sheffield Children's NHS Foundation Trust	1	102	43	0
Royal Infirmary of Edinburgh	1	48	42	0
King's College Hospital NHS Foundation Trust	2	40	39	6
Plymouth Hospitals NHS Trust	1	35	35	0
Yeovil District Hospital NHS Foundation Trust	2	40	33	7
Central Manchester University Hospitals	1	40	30	0
Northumbria Healthcare NHS Foundation Trust	1	30	25	0
The Princess Alexandra Hospital NHS Trust	1	25	25	5
Royal Devon & Exeter NHS Foundation Trust	1	28	23	0
Weston Area Health NHS Trust	1	352	23	4
Gateshead Health NHS Foundation Trust	2	22	22	5
Western Sussex Hospitals NHS Trust	1	22	22	0
Southern General Hospital –	1	38	20	38

Glasgow				
University Hospital of South Manchester Hospital	1	17	17	0
East Kent Hospitals University NHS Foundation Trust	1	15	15	0
Maidstone and Tunbridge Wells NHS Trust	1	40	15	1
University Hospital Coventry and Warwickshire NHS Trust	1	60	15	0
Wirral University Teaching Hospital	1	30	15	0
Blackpool, Fylde and Wyre Hospitals	1	31	12	0
Luton and Dunstable Hospitals NHS Trust	1	15	12	0
North Bristol NHS Trust	1	52	12	20
Royal Surrey County NHS Foundation Trust	1	12	12	0
South Warwickshire Hospital	1	18	12	0
Hull and East Yorkshire Hospitals	1	29	10	4
Poole Hospital	1	20	10	0

The workload data obtained from the surgeons relies heavily on the accuracy of their own recall. Only two surgeons volunteered that the data provided was from their own independent records.

From the initial survey there were 69 hospital trusts in England with at least one FAI surgeon. Of these 69 trusts, 53 trusts had evidence of coded procedural activity from the HES data search. However, the data for both arthroscopic and open surgery was different by > 5 procedures in 68 trusts when the two sources of data were compared. Local database results at UHCW showed that 12 arthroscopic and 0 open surgeries were undertaken for FAI. The corresponding HES data reported 15 arthroscopic and >1 but <5 open surgeries for FAI.

6.6 Discussion

There are a minimum of 120 practising NHS consultant FAI surgeons who collectively undertook a reported 2399 FAI surgical procedures in 2011/12 within the NHS. There is a considerable difference in the number of arthroscopic (mean 25.4 cases per hospital trust in 2011/12) and open FAI surgery (mean 6.5 cases per hospital trust in 2011/12) being undertaken.

Based upon a proposed sample size of 372 participants for a RCT (see Chapter 10) the workload data indicates that there is likely to be a large pool of eligible patients from which to undertake a RCT within the NHS. The data also suggests that a RCT could be conducted to measure the clinical effectiveness of arthroscopic FAI surgery alone. However, a RCT for open surgery alone would be much more challenging. A RCT measuring the clinical effectiveness of arthroscopic FAI surgery may be preferable to one combined with open surgery, given that the survey showed that the majority of FAI surgery was undertaken arthroscopically. The results of open and arthroscopic surgery are generally regarded as comparable but the risk of complications is greater for those undergoing open surgery (see Chapter 1). It is therefore likely that arthroscopic surgery will continue to be the preferred surgical option for patients with FAI.

The survey data relies heavily on surgeons' recall and memory which is likely to have some inaccuracies. However, the alternative using the coded procedural data suffers from two major problems:

i. Coding for surgical procedures is known to be inaccurate. The coding of one study has reported accuracy of 47%.[195] Coding is frequently undertaken retrospectively by staff with no medical training and there are multiple ways of coding the same procedure.[195]
ii. FAI surgery has no specific procedural codes and is therefore coded using alternative combinations of the OPCS–4 coding system across NHS trusts.

For this reason the HES data was used to triangulate/confirm locations of FAI surgery rather than provide any robust measure of the quantity of surgery.

Based on the ONS population data, the prevalence of surgery for FAI within the UK is 3.9 per 100,000 head of population. This figure represents a conservative estimate for prevalence of surgery for FAI within the UK because:

i. Twenty surgeons did not provide data.

ii. The survey does not include surgery without NHS funding. The extent of privately funded FAI surgery (of both types) is unclear. And no statistics appear to be readily available. Any future RCTs would clearly be better informed if privately funded FAI were included.

The prevalence data presented in this study has not previously been available because of the absence of any formal operative coding for FAI and because FAI surgical registries have only recently been introduced. Although all Health Boards and Trusts and their Clinical Directors responded to our enquiries it is possible that Clinical Directors are not always aware of the range of expertise within their department.

The results suggest the workload of FAI surgery is not spread evenly by surgeon or by region. For both arthroscopic and open surgery there was a positive skew with a small number of surgeons doing the majority of the surgery. Similarly, there is a suggestion that more surgery is taking place in the South West, London and the West Midlands per head of population, with marked variations in surgical workload across neighbouring regions e.g. West Midland and East Midlands (5.8 and 0.4 per 100,000 respectively). It seems unlikely that these differences are due to regional variations in the prevalence of FAI and are more likely to represent regional variation in both surgical expertise and funding for FAI surgery. Surgical treatment for FAI is a relatively new and technically demanding procedure[196,197] The availability of surgeons with sufficient experience and expertise is likely to be limited. This is corroborated by the high workload amongst a small number of surgeons nationally.

The survey results provide a conservative estimate for both the number of FAI surgeons currently practising with the NHS and the prevalence of FAI surgery being undertaken. The results also highlight marked regional variation in surgical workload and it is possible that some patients, for geographical reasons may not have easy access to appropriate care. The results are sufficient to enable planning for a multi-centre RCT based on the FAI surgical workload at each Hospital Trust.

Chapter 7 Femoroacetabular impingement: exploring equipoise amongst arthroscopic surgeons

7.1 Declarations

This work has been presented at an international conference:

May 2012: Femoroacetabular Research Symposium, Chicago, USA. FASHIoN Study: equipoise amongst arthroscopic FAI surgeons.

This work was part of a larger project (UK FASHIoN study) funded by the NIHR HTA programme (project number 10/41/02) and the draft final report for the whole project has been submitted to HTA September 2013:

Griffin DR, Wall PDH, Realpe A, Adams A, Parsons N, Hobson R, Achten J, Fry J, Costa M, Petrou S, Foster NE, Donovan J. UK FASHIoN: Feasibility study of a randomised controlled trial of arthroscopic surgery for hip impingement compared with best conservative care.

7.2 Introduction

Equipoise is a state of genuine uncertainty about the comparative therapeutic merits of each treatment arm in a trial.[198] In order to engage fully with and participate in RCTs, surgeons need to have a degree of uncertainty or equipoise between the relative merits of different treatments. Although the published literature suggests a degree of research equipoise about the optimal treatment for FAI, it does not necessarily follow that all those undertaking FAI surgery share this position. In fact, it is conceivable that many surgeons performing FAI surgery are not subjectively in a state of equipoise.

Quantitative research methodology has been used previously to help understand both community equipoise and manage equipoise amongst surgeons within a RCT.[199,200] However, qualitative research methodology can also be used to understand recruitment

difficulties and inform the development of strategies to improve recruitment in difficult RCTs such as those in surgery.[201-203] In a RCT, clinicians not only have to make diagnostic decisions but also consider recruiting their patients. By deconstructing the cognitive processes involved when a clinician considers recruiting a patient to a RCT, it is possible to elucidate the state of individual equipoise that may be influencing a recruitment decision.

7.3 Objectives

To identify through qualitative methods those arthroscopic FAI surgeons who are in equipoise about the optimal treatment for FAI and would therefore be most suitable to act as local investigators/recruiters for a pilot multi centre RCT (see Chapter 8 and 9).

7.4 Methods

Ethical approval was granted for this study by Research Ethics Committee - West Midlands (11/WM/0389). Following the FAI surgical workload survey (Chapter 6) a number of surgeons (n=14) expressed a provisional interest in taking part in a proposed multi centre pilot RCT (Chapter 8 and 9). These 14 hip arthroscopy surgeons were from 12 different hospital trusts within England. All of the surgeons performed more than 10 cases of arthroscopic FAI surgery in 2011/12 and on the basis of workload would be suitable candidates to act as local investigators / recruiters to a multicentre pilot RCT. A qualitative research study was undertaken amongst these surgeons using semi-structured interviews. The surgeons were interviewed and asked to articulate their thoughts out loud as they engaged in tasks involving diagnosis and recruitment to a theoretical RCT to determine the clinical effectiveness of arthroscopic FAI surgery.

In order to stimulate a process of decision making for the surgeons, three real life patient vignettes were prepared by PW. The written patient vignettes (which included a photograph) provided detail of:

i. Patient demographics (age, gender and occupation)

ii. Clinical history typical of FAI including details about the patient's previous treatments

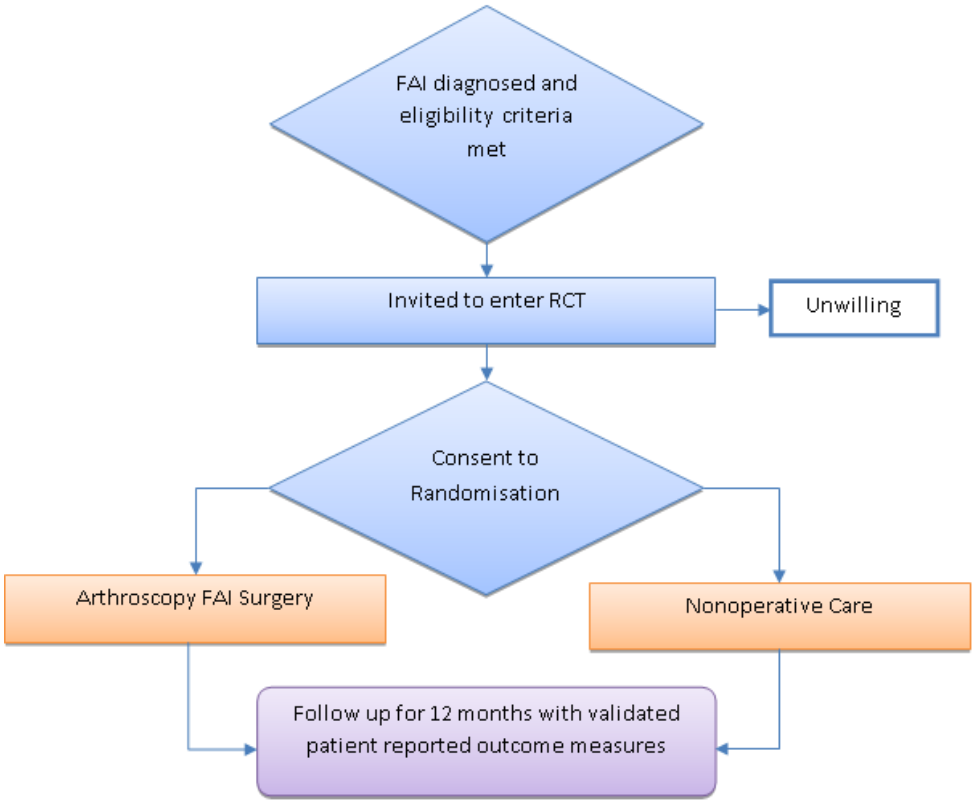
iii. Examination findings typical of FAI

iv. Imaging findings (Plain radiographs, CT and MRA) suggestive of FAI

v. Patient preference for treatment of FAI

In two of the vignettes, the patient had received extensive physical therapy prior to being eligible for the trial. The purpose of this was to test whether surgeons would still agree to randomise patients for potentially a further course of physical therapy as part of the RCT. In the third vignette the patient had not had prior physiotherapy. Surgeons were asked to pick two of the vignettes which were held faced down on a table. Therefore all surgeons received a vignette in which at least one patient had received extensive previous physical therapy. Only two vignettes where chosen because of time constraints with each surgeon. Typically each vignette took 20 minutes to fully review and discuss. Each vignette was presented to the surgeon along with an explanation of a theoretical model for a RCT comparing hip arthroscopy and nonoperative care for FAI. The vignettes were aided by a modified CONSORT flow chart for the RCT study design (see Figure 7.1).

Figure 7.1: Modified CONSORT flow chart for a RCT



All surgeons agreed to the interview being audio-recorded. The surgeons were then given the following instruction:

“These are the notes of a patient who may have FAI. I would like you to think aloud and tell me what is going through your mind as you read this case. I am particularly interested in thoughts you may have when considering an intervention, including referring the patient to the RCT.” Once the surgeons finished their description, further questions were asked to clarify their views:

i. Which patients would you try to recruit to a RCT such as this?

ii. Do you think the RCT is necessary?

iii. Are you in equipoise about the treatment for FAI?

The audio-recordings were transcribed and analysed thematically by PW and AR. For each surgeon interview a principle of theoretical saturation was applied when analysing the recordings (i.e. a point is reached when new data does not add materially to the current findings). Themes were analysed for frequency and tabulated.

7.5 Results

Surgeons did not dispute the diagnosis and relevance of the cases of FAI presented to them, with 12 surgeons explicitly revealing they felt the cases and scenarios were appropriate. When asked directly, 12 of the surgeons interviewed declared that they were in equipoise about the most effective treatment for FAI in the short and long term. The interviews revealed the factors that surgeons consider to be important when making a diagnosis of FAI and when considering treatment and possible trial randomisation. These are: activity level, age, gender, duration of symptoms, previous therapy and imaging findings - see Table 7.1.

Table 7.1: Patient factors surgeons consider when making diagnostic, treatment and eligibility decisions for a theoretical RCT

Patient factors considered	No. of surgeons citing factors (%)
Activity level	11 (79)
Age	9 (64)
Gender	7 (50)
Duration of symptoms	7 (50)
Previous therapy for FAI	7 (50)
Imaging findings	5 (36)
Expectations of patient	2 (14)
Patient preference	2 (14)
Severity of symptoms	1 (7)
Evidence of degenerative change in the hip	1 (7)

The surgeons were asked to consider inviting the presented ‘patients’ to take part in the theoretical RCT. During their deliberations they made inferences about FAI, its management and the RCT. The themes for the inferences made are presented in Table 7.2 and Table 7.3.

Surgeons' inferences were subdivided into themes expressing either certainty or uncertainty about FAI treatment and the proposed RCT.

Table 7.2: Certainty themes amongst surgeons about FAI treatment and RCT participation

Inferences expressing certainty	**No. of surgeons expressing theme (%)**	***Example quotes given when no. expressing theme ≥3***
About surgery		
Surgery is more effective than conservative care in the short term	5 (36)	*" I am reasonably convinced FAI surgery is superior in the short term in carefully selected patients"*
Some patients do not benefit from surgery	4 (29)	*"There are some patients who would be worse after this operation"*
Patients improve without surgery in the short term	2 (14)	
Surgery is effective in the long term	2 (14)	
No equipoise in the surgical community	2 (14)	
Surgeons have a vested interest in the success of surgery	1 (7)	
FAI with large cams benefit from surgery	1 (7)	
Surgery for cam type FAI has the best surgical outcome	1 (7)	
Surgery for pincer type FAI is not effective	1 (7)	
About alternative treatments		
Conservative care does not work	3 (21)	*"There is no evidence anywhere that conservative treatment will work"*
Conservative care works for some patients	2 (14)	
Treatments for FAI are comparable	2 (14)	
Conservative care works for patients with mixed type FAI	1 (7)	

Table 7.3: Uncertainty theme amongst surgeons about FAI treatment and RCT participation

Inferences and questions expressing uncertainty	**No. of surgeons expressing theme (%)**	***Example quotes given when no. expressing theme ≥3***
About surgery		
Uncertain long term outcome from surgery	8 (57)	When referring to the long term results of surgery “It is my personal opinion, I don't know”
About the RCT		
Is the trial duration adequate?	5 (36)	“You're going to follow up for only 12 months, I wonder if that gives enough time for recovery from surgery”
Mild cases of FAI may influence results	4 (29)	“The study may be weakened by a tendency for individuals with mild symptoms to accept randomisation”
Is the research question relevant?	3 (21)	“The question we really want to know is 'are we influencing the natural history of the condition.”
Do adequate outcome tools exist for the trial?	2 (14)	

7.6 Discussion

Twelve (86%) of the fourteen surgeons interviewed gave explicit indications that they were in equipoise about the efficacy of treatments for FAI in both the long and short term and suggested that a RCT to measure the clinical effectiveness of surgical treatment for FAI was desirable. These views are supported by current published literature which calls for such a trial.[48,204] However, the explicit statements of equipoise amongst the majority of surgeons were challenged by the interview data obtained when the surgeons discussed the patient vignettes. Five (36%) surgeons believe surgery is more effective in the short term than nonoperative care, which is not in keeping with a position of equipoise about the true efficacy of treatment for FAI. In addition, 3 (21%) surgeons suggested nonoperative care does not work which questions whether the majority of these surgeons are in total equipoise.

Of concern for future RCT research, is the fact that despite the majority believing they were in equipoise, only 3 (21%) surgeons believed that a RCT was the optimum solution to improve the evidence base. The current published literature describes FAI as a chronic painful hip condition in adults with evidence of hip shape abnormality on specialist imaging,

which can vary by gender.[37,42] This was reflected in the findings that the factors most frequently cited by the surgeons interviewed as influencing their diagnostic and treatment decisions were: patients' age, gender, activity level, duration of symptoms, imaging findings and previous therapy. All of these factors were mentioned by at least 5 of the surgeons interviewed emphasising not only their importance for validating a diagnosis of FAI, but also for making decisions about patients' treatment and suitability for a RCT.

The results suggest that explicit statements of equipoise used in isolation may be too simplistic in order to determine complete equipoise and while many surgeons may think they are in equipoise it is in theory only. Their actions and management decisions do not always support a position of "active equipoise". Such discrepancies may be fundamental to the success or failure of a RCT. Addressing these issues is important, but may not be straightforward. However, education, with reference to current literature, is likely to be helpful in establishing a more uniform state of equipoise amongst surgeons.

Current literature suggests that symptomatic FAI is a cause for subsequent OA.[23] In order to capture any effect surgery may have on progression to OA, it would be necessary to measure clinical outcome many years after a patient is randomised to treatment. Such a RCT may prove technically very challenging when surgeons, (also likely to be recruiters), are not whole-heartedly in equipoise, and are concerned that delaying surgery for any lengthy period may be detrimental. Although 8 (57%) of the surgeons interviewed in our sample highlighted that they were uncertain about the long term results of their surgery.

The survey reported in Chapter 6 suggests that there are approximately 75 active arthroscopic FAI surgeons practising within the NHS. The sample of 14 surgeons represents a small non-random sample (19%) of the population and therefore the conclusions drawn from this study may not be representative all the views of arthroscopic FAI surgeons.

Seven surgeons displayed both “theoretical” and “active” equipoise when assessing the case vignettes and these surgeons were invited to act as local investigators/recruiters in a multi-centre pilot RCT (see Chapter 8 and 9). Of these 7 there were 3 who clearly believed that a RCT was the optimum solution to improving evidence the evidence base. The qualitative approach described helped to identify areas of uncertainty amongst the surgical community, such as trial duration (5 surgeons), that would need to be addressed for a future full RCT.

The qualitative approach used does require an interview to be undertaken; in larger scale RCTs involving many more investigators/recruiters this approach may not be feasible. However, the qualitative principal of theoretical saturation (i.e. a point is reached when new data does not add materially to the current findings) may allow to be used in small samples in order to build up a picture of potential problems across the larger study group. Other techniques have been used to measure equipoise and uncertainty amongst clinical communities.[199] The qualitative method described provides a novel approach to determining a more complete assessment of clinical uncertainty and equipoise in a specialist area of orthopaedics (arthroscopic FAI surgery). As far as can be established this is the first examination using qualitative research methodology designed to better understand the presence or otherwise of equipoise amongst practising surgeons. Such an understanding is essential when planning a RCT, including selecting appropriate local investigators/recruiters and where subsequent recruitment of participants for a RCT will be equally challenging.

Chapter 8 Pilot RCT: recruitment

8.1 Declarations

The sample size calculation and randomisation sequence were completed by Dr N. Parsons at the University of Warwick.

This work was part of a larger project (UK FASHIoN study) funded by the NIHR HTA programme (project number 10/41/02) and the draft final report for the whole project has been submitted to HTA September 2013:

Griffin DR, Wall PDH, Realpe A, Adams A, Parsons N, Hobson R, Achten J, Fry J, Costa M, Petrou S, Foster NE, Donovan J. UK FASHIoN: Feasibility study of a randomised controlled trial of arthroscopic surgery for hip impingement compared with best conservative care.

8.2 Introduction

Several barriers to undertaking a RCT to measure the clinical effectiveness of surgery for FAI have already been explored in this thesis so far, such as:

i. Determining a nonoperative treatment comparator.

ii. Equipoise within the surgical community.

iii. The quantity of FAI surgery being undertaken within the NHS.

Of equal, if not more importance however is whether patients can be recruited to a RCT. An understanding of likely recruitment rates will help establish the viability and scale of a full trial. RCTs comparing orthopaedic surgical treatments with nonoperative treatment comparators historically show widely varying recruitment rates. For example:

i. **Jarvik et al** who undertook a RCT of surgery versus nonoperative treatment for carpal tunnel found that 408 patients refused to enter the RCT. A total of 116 patients were randomised and recruitment rate was 22%.[169] The loss to follow up at 1 year was 13%.

ii. **Klazen et al** who undertook a RCT of vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures recruited 202 of 479 eligible

patients; therefore the recruitment rate was 42%.[205] The loss to follow up at 1 year was 19%.

iii. **Kirkley et al** who undertook a RCT of arthroscopic surgery versus physiotherapy for osteoarthritis of the knee recruited 188 patients out of 219; therefore recruitment rate was 86%.[170] The loss to follow up at 1 year was 11%.

In order to help estimate the recruitment for a full RCT comparing FAI surgery versus nonoperative care a pilot RCT was undertaken comparing hip arthroscopy (surgery) versus personalised hip therapy (nonoperative care).

8.3 Objectives

i. Estimate recruitment for a full RCT comparing hip arthroscopy versus PHT care for FAI.

ii. Road test the PHT protocol for deliverability, compliance and safety - see Chapter 9.

8.4 Methods

Ethical approval was granted for this study by Research Ethics Committee - West Midlands (11/WM/0389).

8.4.1 Sample size

The pilot RCT was not powered to measure any treatment effect. Instead the study was designed and the sample size calculated to estimate the recruitment rate. Table 8.1 shows the precision (95% CI) of 10, 20, 30, 40 and 50 recruitment percentage for sample sizes of; 15, 30, 60, 90 and 120 eligible patients. The pilot RCT was modelled around approaching 60 eligible patients to determine a recruitment rate with a reasonable degree of precision.

Table 8.1: 95% confidence intervals for recruitment based on sample sizes of 15, 30, 60, 90 and 120

		Number of eligible patients approached				
		n=15	**n=30**	**n=60**	**n=90**	**n=120**
Recruitment rate %	**10**	(0.0, 25.2)	(0.0, 20.7)	**(2.4, 17.6)**	(3.8, 16.2)	(4.6, 15.4)
	20	(0.0,40.2)	(5.7, 34.3)	**(9.9, 30.1)**	(11.7, 28.3)	(12.8, 27.2)
	30	(6.8, 53.2)	(13.6, 46.4)	**(18.4, 41.6)**	(20.5, 39.5)	(21.8, 38.2)
	40	(15.2, 64.8)	(22.5, 57.5)	**(27.6, 52.4)**	(29.9, 50.1)	(31.2, 48.8)
	50	(24.7, 75.3)	(32.1, 67.9)	**(37.3, 62.7)**	(39.7, 60.3)	(41.1, 58.9)

Eligibility criteria were initially drafted by PW and supervisor DG and then agreed in collaboration with the Multicenter Arthroscopy of the Hip Outcomes Research Network (MAHORN - number of FAI surgeons=12) and FAI surgeons who attended the American Academy of Orthopedic Surgeons (AAOS) Femoroacetabular Research Symposium in Chicago n=4 (see appendix F). Patients were eligible to participate in the study if:

i. Aged ≥16;

ii. They had symptoms of hip pain;

iii. They showed radiographic evidence of pincer- or cam-type FAI on plain radiographs confirmed with MR and/or CT;

iv. The treating surgeon believed that they would benefit from arthroscopic FAI surgery.

Patients were excluded from participation in the study if:

v. They had previous significant hip pathology such as Perthes' disease, slipped upper femoral epiphysis or avascular necrosis;

vi. They had a previous hip injury such as acetabular fracture, hip dislocation or femoral neck fracture;

vii. They already had osteoarthritis, defined as Tonnis grade >1[17], or more than 2mm loss of superior joint space width on AP pelvic radiograph;[75]

viii. There is evidence that the patient was be unable to adhere to trial procedures or to complete questionnaires, such as cognitive impairment or intravenous drug abuse.

A total of 10 hospital trusts agreed to take part in the multi-centre pilot RCT (see Table 8.2). Of these 10 hospital trusts, 5 (6 surgeons) had taken part in the preceding equipoise study having expressed both "theoretical" and "active" equipoise and a willingness to take part in the pilot RCT (see Chapter 7). One surgeon who had been identified as in "theoretical" and "active" equipoise did not want to take part in the pilot because of plans to begin their own similar trial which might clash with the pilot RCT outlined. A further 5 hospital trusts agreed to take part in the pilot RCT. These 5 trusts were identified during the FAI workload survey (see Chapter 6) having shown enthusiasm during correspondence. These surgeons were not formally interviewed in order to determine their level of equipoise but a level of implied equipoise was assumed amongst these pilot RCT enthusiasts.

Table 8.2: Recruitment sites

Site Number	Site Name
1	University Hospital Coventry and Warwickshire NHS Trust
2	Yeovil District Hospital NHS Foundation Trust
3	Royal Devon & Exeter NHS Foundation Trust
4	The Royal Orthopaedic Hospital NHS Foundation Trust
5	Frimley Park Hospital NHS Foundation Trust
6	Royal Cornwall Hospital (Treliske)
7	Epsom and St Hellier University Hospitals NHS Trust
8	Guy's and St Thomas' NHS Foundation Trust
9	Barts Health NHS Trust
10	University College London Hospitals NHS Foundation Trust

Patients attending dedicated hip clinics run by the local investigators were screened for eligibility. Those patients who were eligible were provided with a patient information sheet (see appendix G) and invited to take part in the pilot RCT. If patients agreed they provided written informed consent (see appendix H). Recruitment and consent was undertaken by either PW or a trained recruiter (TR). The TRs were research associates working in the local hospital sites who had been trained to recruit by PW. Randomisation was done by telephone. Randomisation sequences (1:1 allocation) were generated for each site. Patients were allocated to one of the two treatments:

i. Personalised Hip Therapy

ii. Arthroscopic FAI surgery

Although not the primary aim of this study, patients were followed up after the start of intervention. The purpose of the follow-up was to enable use of data from the pilot RCT in any future full RCT analysis (an internal pilot). The data collected as part of this follow up is shown in Table 8.3. Patients, surgeons, physical therapists and research associates were not blinded to treatment allocation.

Table 8.3: Follow up data collected

Time	**Data to be collected**
Baseline	NAHS, IHOT-33, SF-12, EQ5D
6 weeks	Complications questionnaire
3 months	NAHS, IHOT-33, SF-12, EQ5D; complications questionnaire
6 months	NAHS, IHOT-33, SF-12, EQ5D; complications questionnaire
12 months	NAHS, IHOT-33, SF-12, EQ5D; complications questionnaire
NAHS=Non Arthritic Hip Score; IHOT-33=International Hip Outcome Tool-33; SF-12=Short Form 12; EQ5D=EuroQol 5D	

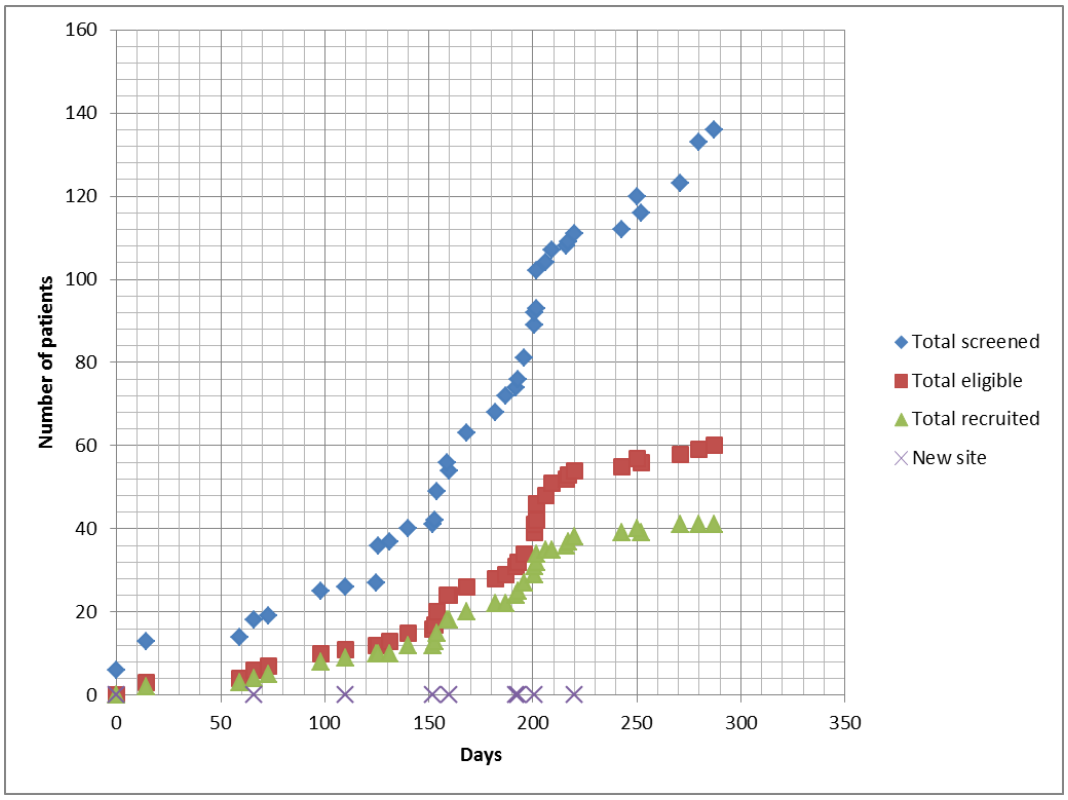
8.4.2 Statistics

Summary statistics and analysis were prepared using IBM SPSS version 21 for Windows.[86] Differences in mean recruitment activity between types of recruiter were analysed using an independent samples t-test.

8.5 Results

A total of 60 eligible patients were approached for recruitment to the pilot RCT across 9 centres. One centre (Site 10) was considerably delayed in being setup and did not attempt recruitment before 60 approaches had already been made. It took 9.3 months to approach 60 eligible patients for recruitment. Of these 42 patients consented to take part in the pilot RCT; therefore recruitment was 70% (95% CI 58-81). During this period a total of 134 patients were screened for eligibility. Due to time restrictions and other commitments of the TRs less than half of all suitable clinics at peripheral sites were screened and attended by a trained TR. Where possible potentially eligible patients were put into clinics that a TR would be able to attend and potentially recruit. Overall recruitment activity is shown in Figure 8.1.

Figure 8.1: Scatter plot of recruitment activity against time



Not all centres commenced the study at the same time due to delays in local Research and Development (R&D) departmental approval. Table 8.4 shows the duration each centre was open to recruitment.

Table 8.4: Site recruitment data

Site	Recruitment duration (months)	Eligible patients	Recruited patients	Eligible patients / month	Recruited patients / month	Recruitment %
1	9.3	24	19	2.6	2.1	79.2
2	7.1	7	3	1.0	0.4	42.9
3	4.4	3	2	0.7	0.5	66.7
4	5.0	6	3	1.2	0.6	50.0
5	4.1	4	4	1.0	1.0	100.0
6	3.1	4	4	1.3	1.3	100.0
7	3.0	1	1	0.3	0.3	100.0
8	2.8	10	5	3.6	1.8	50.0
9	2.2	1	1	0.5	0.5	100.0
10	n/a	n/a	n/a	n/a	n/a	n/a
Mean (all sites)	4.6	6.7	4.7	1.5	1.0	70.0 (95% CI 58-81)
Mean (excl.site1)	3.5	4.0	2.6	1.2	0.8	63.9 (95% CI

The data was broken down by recruiter in order to determine any difference in recruitment between PW and TRs (see Table 8.5). An independent samples t-test to determine if there was a significant difference in recruitment between PW and the TRs (see Table 8.6).

Table 8.5: Recruitment figures for PW and trained recruiters

	Site															
	1		2		3	4		5	6		7	8	9		All sites	
Recruiter	**PW**	**TR**	**PW**	**TR**	**TR**	**PW**	**TR**	**TR**	**PW**	**TR**	**PW**	**PW**	**PW**	**TR**	**PW**	**TR**
No. eligible	8	16	1	5	3	1	6	4	2	2	1	10	1	0	24	36
No. recruited	5	14	1	2	2	1	2	4	2	2	1	5	1	0	16	26
Recruitment %	63	88	100	40	67	100	33	100	100	100	100	50	100	0	67	72

Table 8.6: Independent samples test of recruitment % between recruiters

Mean recruitment % between PW and all TRs collectively	Sig (2-tailed)	Mean difference	95% CI	
			Lower	Upper
Recruitment %	0.65	-0.06	-0.3	0.19

8.6 Discussion

The pilot RCT suggests that recruitment of patients is possible across multiple sites. The recruitment rate of 70% was encouraging when compared to similar challenging RCTs (i.e. comparisons of surgical and nonsurgical intervention: see 8.2). As expected site 1 which was the lead site was recruiting for the longest period (9.3 months) and recruited the greatest

number of participants both in total and per month, which is in keeping with published research suggesting that lead sites/single centre RCTs achieve the highest recruitment in RCTs.[175] There was a marked difference in both the number of eligible patients and recruited patients per month between site 1 and sites 2-10 combined. Higher absolute recruitment at the lead site is probably a reflection of:

i. Local enthusiasm for the RCT amongst investigators.

ii. Delay at all peripheral sites in gaining R&D approval.

iii. Logistically it is much easier for the study team to identify and resolve problems with the lead site compared to peripheral sites.

To plan a full RCT it may be reasonable to exclude the lead site or make appropriate adjustments for its effect on the data in order to more accurately predict the effect of adding further study sites. Also when planning a full RCT a lengthy setup period for peripheral sites would need to be considered in order to negotiate the local R&D approval process prior to recruitment. In the pilot RCT only 2 out of 10 sites managed to recruit for greater than 5 months.

PW (a medically qualified doctor with a specialist interest in FAI) began recruitment at the lead site and then as additional sites became active he trained local recruiters (TRs) who were either research nurses or physiotherapists with no prior knowledge of FAI. At some sites this involved PW attempting recruitment of the first patient and the TR observing. As a result initially PW undertook a substantial amount of recruitment. The recruitment percentage by recruiter type, however, suggests that this model of training was effective and that recruitment by TRs was feasible. The collective mean recruitment percentage amongst the TRs was 72% compared to 67% for PW. There was no significant difference in recruitment percentage between TRs and PW. Although the pilot was not powered to undertake a statistical test of significance between recruiter types the results are nevertheless were promising and could be used to help inform and plan a full RCT. The results are in keeping with a study by Donovan et al that found similar recruitment rates between trained nurses

and surgeons in a trial of treatments for prostate cancer.[206] In this context TRs would be a more cost effective mechanism for recruiting patients within the NHS. Although unproven, the additional potential benefits of TRs recruiting patients are that they may be less likely to:

i. Systematically bias patients with their own views.

ii. Deviate from a position of pure equipoise.

iii. Have any vested interest in the research being proposed and therefore unlikely to demonstrate any conflict of interest to patients.

The number of patients screened (134) was over twice the number of eligible patients (60) in the pilot. This created a considerable amount of additional work for the TRs in order to recruit patients. As a result not all potential patients were screened i.e. not all available clinics were screened for patients, due to constraints on the availability of TRs (as already mentioned less than half of all available clinics at peripheral sites were screened). This information has implications for a full RCT when substantially more recruitment of patients will be required and therefore screening of patients will need to increase proportionately along with corresponding increases in funds for and availability of TRs. In the pilot RCT, a conscious effort was made across all sites to ensure patients likely to be eligible were in clinics that were scheduled to be screened by recruiters.

The pilot study suggests that patients can be recruited to a full RCT comparing hip arthroscopy versus PHT and that the recruitment percentage may be favourable (70%). The pilot data also suggests that recruitment by trained non specialist recruiters is feasible. Although the lead site shows better recruitment activity, it is also clear that peripheral sites can also achieve good recruitment activity. Whether the recruitment achieved could sustain a full RCT when scaled up will be explored further in Chapters 10 and 11.

Chapter 9 Pilot RCT: testing the nonoperative comparator

9.1 Declarations

This work was part of a larger project (UK FASHIoN study) funded by the NIHR HTA programme (project number 10/41/02) and the draft final report for the whole project has been submitted to HTA September 2013:

Griffin DR, Wall PDH, Realpe A, Adams A, Parsons N, Hobson R, Achten J, Fry J, Costa M, Petrou S, Foster NE, Donovan J. UK FASHIoN: Feasibility study of a randomised controlled trial of arthroscopic surgery for hip impingement compared with best conservative care.

9.2 Introduction

The protocol of PHT was designed with support and input from physical therapists and was subsequently delivered by physical therapists at all the recruiting centres. However, PHT is a new protocol and a period of testing to determine safety, deliverability and acceptability amongst both patients and physical therapists is needed.

9.3 Objectives

i. To determine the lead time to commencing intervention.

ii. To determine the number and frequency of any adverse events up to 3 months.

iii. To determine the frequency of per protocol PHT delivery.

iv. To determine patient and physical therapist compliance with PHT including frequency of withdrawal and/or crossovers.

9.4 Methods

Physical therapists completed a case report form (CRF) for all patients recruited to the pilot RCT (chapter 8) and allocated to PHT (see appendix I). Patients were assessed to determine

the number and type of any reported adverse events (AE) using a questionnaire completed at 6 weeks and 3 months (see appendix J and K). All serious adverse events (SAE) were reported to the lead site within 24 hours of the local site investigator becoming aware of them. AEs were defined as any untoward medical occurrence in the pilot RCT which do not necessarily have a causal relationship with the treatment.

SAEs were defined as any untoward and unexpected medical occurrence that:

i. Results in death
ii. Is life-threatening
iii. Requires hospitalisation or prolongation of an existing inpatient's hospitalisation
iv. Results in persistent or significant disability or incapacity
v. Is a congenital anomaly or birth defect
vi. Any other important medical condition which, although not included in the above, may require medical or surgical intervention to prevent one of the outcomes listed

At 3 months all patients were checked to see if they had withdrawn from the study or had received the intervention to which they were not allocated (crossover).
All the completed PHT CRFs were reviewed by the core study group (see Chapter 4) in order to determine by consensus whether each patient had received per protocol care. When reviewing the CRFs the core study group looked for evidence of an individualised supervised exercise programme which was progressed over at least 12 weeks and had involved a minimum of 6 patient contacts.

9.5 Results

Forty-two (42) patients were recruited to the pilot RCT. Of these 21 patients were allocated to PHT. Twenty patients provided follow up data at 6 weeks and 3 months. shows the outcome for all 21 patients.

Table 9.1: Outcome of those allocated to PHT

Patient ID	Site ID	Time to commence PHT (days)	Reported AE / SAE at 6 weeks	Reported AE / SAE at 3 months	Per Protocol Care Y / N. If N reason given	Outcome at 3 months E / W
1	1	32	Muscle soreness	X	Y	E
3	1	32	Muscle soreness	X	N	E
6	1	43	Muscle soreness	X	N	E
8	1	70	Muscle soreness	X	Y	E
11	2	25	Muscle soreness	X	Y	E
14	3	61	X	X	Y	E
15	1	33	Muscle soreness	X	Y	E
16	5	22	Muscle soreness	X	Y	E
19	1	40	Muscle soreness	X	Y	E
21	1	46	Muscle soreness	X	Y	E
22	5	12	Muscle soreness	X	Y	E
26	1	39	Muscle soreness	X	Y	E
28	8	61	L	L	N	L
30	8	27	X	X	Y	E
31	6	76	Muscle soreness	X	Y	E
32	6	DNSI*	X	X	N - CO	E
35	1	25	X	X	Y	E
36	7	56	Muscle soreness	X	Y	E
38	2	19	Muscle soreness	X	Y	E
39	1	32	X	X	Y	E
43	4	53	X	X	Y	E
Total 21 patients		Mean = 40 SD = 17 Median = 36 Mode = 32	14 cases of muscle soreness	X	17 (81%) per protocol	20 (95%) still engaged with study

DNSI = Did Not Start Intervention
*Patient decided that they were unable to travel for treatment and therefore did not receive any intervention.
Y = Yes, N = No, X = nil reported, CO = Cross Over, E = Engaged with the study, L = Lost to follow up W = Withdrawn from the study

A breakdown of all the physical therapists providing PHT at each study site is shown in Table 9.2.

Table 9.2: Expertise and Experience of Physical Therapists Delivering PHT

Physio. ID	Site ID	Manage Patients with Musculoskeletal Diease	Previously managed patients with FAI			Job Tite	NHS Banding
				Post Surgery Physiotherapy	Primary Physiotherapy		
1	1	Yes	Yes	5	5	Senior Physiotherapist	Band 6
2	1	Yes	Yes	30	20	Extended Scope Physiotherapist	Band 8a
3	2	Yes	Yes	6	1	Clinical Specialist Physiotherapist	Band 7
4	2	Yes	Yes	6	6	NIHR Research Physiotherapist	Band 7
5	3	Yes	Yes	10	75	Extended Scope Physiotherapist	Band 8a
6	4	Yes	Yes	8	15	Specialist Research Physiotherapist	Band 7
7	5	Yes	Yes	10	2	Physiotherapy Gym Team Leader	Band 7
8	6	Yes	Yes	18	35	Clinical Lead Physiotherapist	Band 7
9	6	Yes	Yes	30	60	Specialist Physiotherapist	Band 6
10	7	Yes	Yes	0	3	Clinical Specialist Physiotherapy	Band 8a
11	8	Yes	Yes	2	3	Highly Specialist Physiotherapist	Band 7
12	8	Yes	Yes	0	4	Clinical Specialist Physiotherapist	Band 8a

9.6 Discussion

The results from the 21 patients allocated to PHT suggest that 81% received treatment as per protocol. This is in keeping with similar exercise based intervention regimes used in RCTs for musculoskeletal disease such as:

i. Van de Baar et al 2001.[207] Effectiveness of exercise in patients with OA of the hip or knee: 9 months' follow up. In this RCT, one group received exercise treatment (12 week duration) from a primary care physical therapist of these 92% received per protocol treatment.

ii. Foley et al 2003.[208] Does hydrotherapy improve strength and physical function in patients with osteoarthritis—a RCT comparing a gym based (6 week programme) and a hydrotherapy based strengthening programme. Although no definition / description of per protocol treatment is given, in this RCT there was a compliance rate of 75% for the prescribed gym sessions.

iii. Fransen et al 2007.[209] Physical Activity for Osteoarthritis Management: A RCT evaluating Hydrotherapy or Tai Chi Classes (12 week programme). Although no definition / description of per protocol treatment is given, in this RCT there was 61% attendance at half the Tai Chi classes.

There had been some concern at the start of the pilot RCT (raised in the surgeon interviews (Chapter 7) that a substantial number of patients might wish to cross over from PHT to surgery after randomisation. This might be because they saw no perceived benefit from PHT or because many of them would have tried some sort of physical therapy previously without benefit. It was encouraging that only one patient crossed over from PHT to surgery in the pilot RCT. This was at the 3 months stage and was because the patient was unable to attend the PHT sessions and therefore surgery was more convenient. Any evidence of a large number of "crossovers" in the pilot RCT would have raised concerns about the viability of a full RCT. A large number of patient crossovers would make an intention to treat analysis difficult to interpret as any observed differences in treatment effect could not necessarily be attributed to one defined intervention. A per protocol analysis would also be likely to have an inadequate sample size to draw any meaningful conclusions.

There were no reported SAEs in by the 20 patients who provided follow up data. The only AEs reported were muscle soreness in 14 patients' up to 6 weeks, but none were reported at 3 months. Early muscle soreness was expected as part of an exercise based physical therapy regime as the muscles adapt to the increased demand. Reassuringly this had resolved in all cases at 3 month. The results suggest that PHT is safe which is in keeping with other RCTs measuring exercise based physical therapy regimes.[207,208] Although AEs are possible after the intervention has completed, these are less likely to be a result of the intervention itself. However, a longer period of follow up and a larger sample size in a full RCT would be required in order to capture both late and rarer AEs / SAEs.

Evidence gathered from pilot testing of PHT revealed that patients typically start treatment within 2 months (mean 40 days SD 17 days) of randomisation. When planning a full RCT a long lead time before intervention commences would make comparisons of treatment effect more difficult particularly if the time to primary outcome measurement is short.

The starting band for a physical therapist in the NHS is Band 5. All patients in the pilot RCT received their PHT treatment from a physical therapist at Band 6 level or above, confirming that delivery of PHT by non-trainee physical therapists was achievable and that a reasonable level of seniority could be expected.

The evidence gathered from the pilot testing suggests that PHT is deliverable within the context of NHS services, and patient compliance with the treatment is good. While there is evidence of some early AEs these are typical of similar exercise based regimes and are to be reasonably expected. There is no evidence of them unduly affecting the delivery of care or patient compliance. There no SAEs although a larger sample size and longer period of sampling / surveillance is needed to provide a more robust safety profile of PHT.

Chapter 10 Design of a full RCT

10.1 Declarations

The sample size calculation for a full RCT was performed by Dr N Parsons at the University of Warwick.

A full grant proposal has been submitted to the HTA for a full randomised controlled trial of athroscopic surgery for hip impingement versus personalised hip therapy. The proposal draws on many of the findings from this thesis. The following people are study collaborators for this grant proposal:
Damian Griffin (Chief Investigator), Peter Wall, Nadine Foster, Juul Achten, Nicholas Parsons, Stavros Petrou, Ann Adams, Jeremy Fry (lay representative), David Ralph (lay representative), Simon Gates, Jenny Donovan and Matt Costa.

10.2 Introduction

The pilot RCT (Chapter 8) used a pragmatic type design; in order to keep the environment in which the RCT is conducted as close to standard NHS practice as possible. Historically RCTs have been criticised, for not generating results/answers that are generalizable enough for application in day to day practice.[210] For example a purely experimental RCT might seek to establish which of the two treatments is superior under ideal conditions, such as hip arthroscopy being conducted on a good surgical candidate, performed by the most experienced surgical team with a very structured post-surgical rehabilitation programme. Such a scenario is unrealistic in clinical practice. Establishing the effectiveness of hip arthroscopy under ideal conditions is useful information at an experimental level but is not as helpful for most patients or clinicians. A more pragmatic approach involves knowing the effectiveness of hip arthroscopy for a typical patient, done by a typical surgeon with routine post-surgical rehabilitation. A pragmatic design is made to be much more representative of

usual practice within the NHS and the subsequent results are much more helpful in guiding actual NHS practice.

However, a pragmatic RCT design may dilute any potential treatment effects of the interventions under scrutiny because of the many variables introduced. Larger sample sizes are therefore typically required in order to better test the null hypothesis and maintain power.

10.3 Outcome measures for a full RCT

There are many potential ways of measuring the outcome after treatment for FAI. For example:

i. Symptomatology such as pain, function and quality of life.

Although the purpose of the pilot RCT was not to determine clinical effectiveness, patient reported outcome measures (PROMs) were collected. These are standardised questionnaires completed by the patient before and after the intervention. PROMs focus on symptomatology, and allow a patient to report their own view on matters as such as: pain, functional ability and quality of life.[211] PROMs can be disease specific or generic; the pilot RCT used both types. Disease specific PROMs have greater face validity and credibility, but generic PROMS facilitate comparisons across conditions.[211] PROMs are now widely used in hip surgery in an attempt to objectively quantify levels of hip disease and measure the results of an intervention. Using a PROM in a RCT avoids observer bias and reflects the importance of a patient being the most appropriate person to report their own levels of pain, disability and quality of life.

A variety of PROMs have been used for FAI. Some, such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Modified Harris Hip Score (MHH) were originally designed for patients with more severe hip symptoms typically undergoing THA. As a result these PROMs tend to exhibit ceiling effects when applied to pre-arthritic conditions such as FAI where patient function is at a higher level. Newer instruments such as IHOT-33 and the NAHS have been designed in an attempt to capture a clinically relevant outcome, but have only recently been validated and not had the same scrutiny as the older outcome measures. For an outcome measure to be formally recognised

and accepted a process of validation is required.[212] Content validity, criterion validity and construct validity are all aspects that are typically considered.[212] The outcome measure must also be reliable, sensitive and have internal consistency and reproducibility.[212] The NAHS and IHOT-33 were used in the pilot RCT and could be used as the primary outcome for a full RCT. NAHS is valid compared to other measures of hip performance, internally consistent and reproducible.[213] However, the IHOT-33 has the advantage that it was developed with patients undergoing hip arthroscopy. There was no evidence of a ceiling / edge effect when used in this setting. In addtionathe minimum clinically important difference (MCID) has been determined (6.1 points) for IHOT-33.[85]

ii. Examination findings such as hip ROM and presence of a positive anterior impingement test.

iii. Imaging findings such as evidence of a change in hip shape and a normalisation of radiographic hip parameters (alpha and CE angle).

Examination and imaging findings could be used to determine the outcome from the interventions. However, the relationship between these outcomes and patient benefit is less clear. In particular there remains controversy about what constitutes an abnormality of hip shape or hip ROM (see Chapter 1) and so interpreting the clinical significance of any measured differences in hip shape or hip ROM between interventions would be difficult.

10.4 Timing of outcome measures for a full RCT

A primary outcome measurement at one year was proposed for the pilot RCT. Observational evidence suggests that patients have fully recovered from either surgery or nonoperative care by 12 months.[75,82,214] This is in keeping with other hip surgery such as hip arthroplasty whereby optimal/plateaued patient reported outcome scores are reported at 12 months.[215] Other outcome time points were undertaken in the pilot RCT at 3 and 6 months. Similar patterns of outcome scores at 3, 6 and 12 months in a full RCT would help to support any observed treatment effect at 12 months. In the pilot trial, participants allocated to hip arthroscopy usually had surgery within 10 weeks, and those allocated to PHT usually

commenced treatment within 4 weeks, therefore outcome assessments earlier than 3 months would not have been helpful.

Longer term assessments are important such as an effect of surgery on progression of FAI to OA .[23,37] However, such a trial would require a much long term follow-up to answer this question. It was therefore agreed the first and most important question to answer was whether surgery in the short to medium term was effective (improves hip related quality of life and is safe, therefore a 12 month primary outcome assessment remains appropriate

10.5 Sample size for a full RCT

Although the published evidence suggests that arthroscopic hip surgery can have a standardized effect of up to 2, there is also likely to be an effect with PHT.[216] Cochrane reviews have shown that good exercise based regimes treating musculoskeletal conditions typically have a standardised effect in the order of 0.3.[217,218] Pragmatic RCTs tend to yield small to moderate differences in standardised effect size between treatments when measuring clinical effectiveness, for the reasons discussed earlier in section 10.2. The published development work for IHOT-33 which shows that the MCID and SD is 6.1 and 19.3 respectively is helpful. In this context IHOT-33 would be capable of detecting a standardised effect size between treatments of 0.32. The published data (MCID = 6.1 and SD = 19.3) provide an upper bound for the required sample size for a full RCT, as outcome data for a full RCT is likely to be less variable (more homogeneous). Assuming an approximate normal distribution for the IHOT-33 score, the expected total sample size (sum of both groups) is shown for scenarios with 80% and 90% power to detect an effect, if it exists, at the 5% significance level in Table 10.1. The scenarios tabulated span a range of standardized effect sizes from small to moderate (0.32) to moderate (0.47).

Table 10.1: Total sample size for MCID = 6.1

Standard Deviation	Power		Standardized Effect Size
	80%	90%	
13	144	192	0.47
16	218	292	0.38
19.3	316	422	0.32

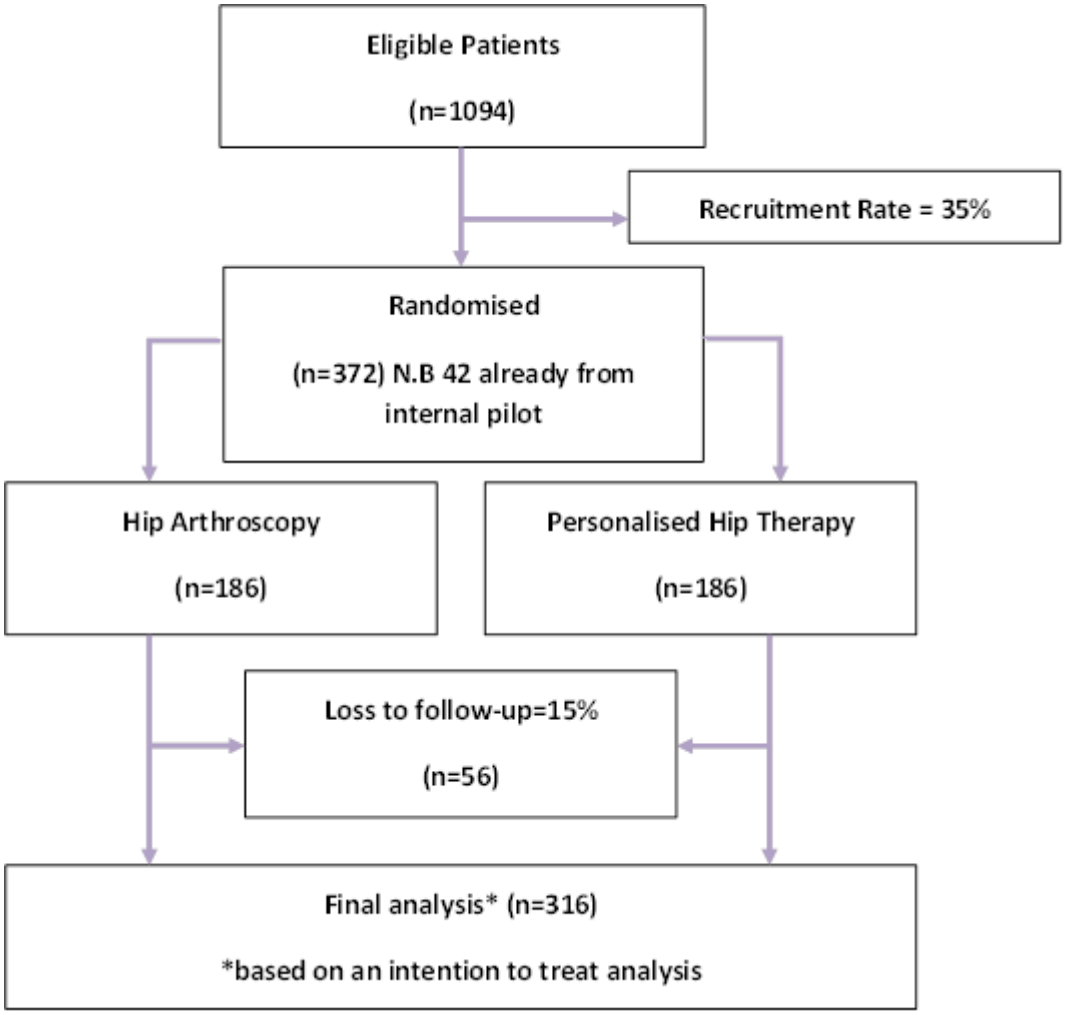
A conservative strategy for a full RCT would be to base the sample size calculation on an SD of 19.3, which requires 316 (158 in each group) patients to be recruited for a final 12 month primary outcome analysis.

Loss to follow up in similar multicentre orthopaedic RCTs using a PROM at 12 months varies between 10 and 20% (see Chapter 8). Assuming an average loss to follow-up of 15%, 372 (186 in each group) patients would be needed in total for a full RCT. This would provide 80% power to detect a difference of 6.1 IHOT-33 units, if any. It is possible that the population SD for IHOT-33 scores might be lower in a full RCT. A recent publication and the original IHOT-33 paper suggest a baseline SD of 20.1 and 19.3 respectively.[85,219] However, both papers used patient cohorts undergoing hip arthroscopy in contrast to a full RCT which would potentially reflect a more homogenous population with a single diagnosis of FAI. The potential for a lower SD in a full trial is however, merely an observation that may allow improved power in a full RCT and is far from certain.

The preferred method for analysing pragmatic RCTs is on an intention to treat (ITT) basis.[217] An ITT analysis includes every participant who is randomised according to the treatment to which they were allocated. ITT ignores noncompliance, protocol deviations, withdrawal, and any other patient related changes after randomisation. As a result the ITT analysis tends to lead to more conservative results.[217] ITT provides an estimate of the effect of a change in treatment policy rather than of any potential effect in patients who receive treatment exactly as planned.[217] The ITT analysis therefore follows a more pragmatic approach and takes account of events that would tend to happen in day to day practice. By virtue of the ITT approach loss to follow-up is the only additional factor that needs to be considered when planning the sample size for a full RCT, as all the patients who deviate from the study protocol (crossover etc.), will all be counted in the final analysis.

If the key features of the pilot RCT (see Chapter 8) are retained (e.g. blinding, outcomes and follow-up) then the data from the pilot could be pooled with a full RCT making the pilot a so called “internal pilot study”.[220] As 42 eligible patients have already been recruited in the pilot RCT, an additional 330 patients would be required for a full RCT. Using the figures discussed, and a conservative recruitment rate (half the pilot RCT recruitment rate) and an assumed loss to follow up of 15% it is possible to build a CONSORT diagram for a full RCT (see Figure 10.1).

Figure 10.1: CONSORT for a full RCT



10.6 Duration and size

The duration and size of a full RCT has been informed by results from the pilot RCT (Chapter 8) and workload survey (Chapter 6). The pilot RCT achieved a recruitment of 70% with 1 patient recruited per centre per month. The recruitment achieved in the pilot RCT may drop

during a full RCT as the initial enthusiasm to recruit tapers off. For RCTs in orthopaedics comparing operative and nonoperative treatments, on-going recruitment of 70% is rare.[169,170,205] Therefore, it may be reasonable to plan a full RCT based on a more conservative halving of the pilot recruitment rate.

Table 10.2 shows the potential variation in recruitment duration for 10, 15, 20, 25 and 30 recruiting centres and a recruitment rate of 1 patient per centre per month (rate achieved in pilot - 70% recruitment) or 0.5 patients per centre per month (half the rate achieved in the pilot – 35% recruitment).

Table 10.2: Recruitment duration in months for a full RCT based on 10, 15, 20, 25 and 30 centres and a recruitment rate of 0.5 or 1 patient per centre per month

Number of centres	Recruitment per centre per month	
	0.5 (35% recruitment)	1 (70% recruitment)
10	66 months	33 months
15	44 months	22 months
20	33 months	17 months
25	27 months	14 months
30	22 months	11 months

Each centre in a full RCT would require at least 18 eligible patients per year in order to be able achieve the recruitment figures achieved in the pilot RCT and quoted in Table 10.2. The workload survey (Chapter 6) suggests that there are a further 22 hospital trusts within the UK that might have ≥18 eligible patients per year

It may be appropriate to consider a larger sample size based around 90% power and reduce the chance of type II statistical error. However the implications of having to recruit a further 106 patients (a longer recruitment period of between 6 and 22 months-see Table 10.3) would have to be weighed against the improved power. One of the major risks with lengthy recruitment periods is that the interventions under assessment change so markedly between the start and finish of a trial that any subsequent results are difficult to meaningfully interpret; a particular risk with hip arthroscopy were new more sophisticated instruments are released regularly.

Table 10.3: Additional months recruitment required to achieve 90% power based on 10, 15, 25 and 30 centres and a recruitment rate of 0.5 or 1 patient per centre per month.

Number of centres	Recruitment per centre per month	
	0.5 (35% recruitment)	1 (70% recruitment)
10	22	16
15	15	11
20	11	8
25	9	7
30	8	6

A full RCT would potentially continue to recruit from the original 10 centres included in the pilot RCT therefore requiring up to an additional 20 centres depending upon the chosen recruitment duration.

The pilot RCT showed that the actual identification rate of eligible patients per centre per month was low (mean 1.5). As a result any drop in recruitment rates of patients could make a full RCT difficult. Therefore, efforts to increase the pool of eligible patients at each centre are likely to help expedite a full RCT. Measures that could be used include:

i. Providing education to primary care about FAI and its diagnosis, in order to optimise referral of patients for specialist opinion.

ii. Ensuring all outpatient clinics with potentially eligible patients are covered with a trained recruiter.

iii. Lobbying policy makers to facilitate patients with FAI being treated in centres that have been identified as undertaking high volumes of arthroscopic FAI surgery and have surgeons with adequate levels of equipoise.

10.7 Recruitment strategies

Recruitment in surgical RCTs is often very challenging and as already discussed previous RCTs in surgery have shown quite varied recruitment rates (Jarvik et al[169] 22%, Klazen et al[205] 19% and Kirkley et al[170] 86%). Kirkley et al was a single centre RCT as opposed to Klazen et al and Jarvik et al which were both multi-centre RCTs. Therefore the large discrepancy in recruitment rates between these RCTS is likely to be largely structural. A full

RCT outlined for FAI would need to be multicentre and therefore measures to optimise recruitment may need to be utilised in order to successfully complete it. As already discussed one such strategy would be to use trained researchers to recruit patients and thus minimise biasing patients to one particular treatment. Other methods not reported in this thesis but tested within the pilot RCT are qualitative measures. Qualitative research methodology can be used to understand recruitment difficulties and inform the development of strategies to improve recruitment in difficult RCTs such as those in surgery.[201-203] Particular aspects of this may include:

i. Develop with public and patient involvement patient information material that is user friendly and with no treatment biases.
ii. Interviewing all investigators and TRs to ensure that the RCT is being described, and recruitment procedures followed, according to the study protocol, and to identify where they are not.
iii. Develop training packages to correct common problems.
iv. Identify structural features associated with successful recruitment, such as running targeted clinics and ensuring referred patients arrive with expectations of receiving treatment for FAI rather than being told they had been referred for surgery.

It is possible that recruitment to a full RCT will be less easy over time. The overwhelming focus in the published orthopaedic literature is the favourable outcome from surgical intervention. As evidence, albeit weak, grows in favour of surgery the number of high volume arthroscopic surgeons that are in equipoise and prepared to randomise their patients will fall. At present the pool of surgeons and centres keen to engage and recruit patients to a RCT is sufficient to achieve the required sample size, but a shift in the levels of surgeon equipoise would quickly change this, lending considerable urgency to the initiation of a full RCT.

Chapter 11 Conclusions

11.1 Summary of new findings

Since early descriptions of subtle hip shape abnormalities and their relationship to hip pain and OA in the 1960s and 1970s, the concept of bony hip impingement has developed under scrutiny. Over the last 15 years the term FAI as a condition which can cause hip pain and subsequent OA in adults has become established in the medical literature.

The cause of FAI hip shape abnormalities and the impact they have remains less clear. New information presented in Chapter 2 of this thesis reports on SCFE and its relationship with longer term hip symptoms. SCFE including subtle cases is one mechanism thought to cause cam type FAI. However, this thesis found no evidence of a strong or even moderate correlation between changes in hip shape secondary to SCFE (including FAI like morphology) and long term hip specific quality of life. This finding is in keeping with epidemiological research on FAI (Chapter 1) which has found that although the prevalence of hip shape abnormalities in the general population is high the reported symptomatology is much less. These findings along with established epidemiological research discussed in Chapter 1 suggest that the relationship between abnormalities of hip shape and hip pain is weak and that other factors in addition to hip shape morphology have a role in the development of symptoms associated with FAI.

The thesis has demonstrated that a large amount of surgery is being undertaken for FAI within the NHS and that the majority of this is done arthroscopically despite limited evidence to suggest it is clinically effective. Much of the workload is undertaken in centres in London, the South West of England and the West Midlands. In addition this thesis has demonstrated that FAI can be treated nonoperatively but there is even less evidence to guide care.

So why in a modern world, is a syndrome such as FAI not fully understood, yet treated in such an enthusiastic but unproven way, with surgery taking place across multiple centres, and by an even greater number of surgeons? Similarly why is nonoperative care for FAI so haphazard and without any robust research? It is likely the answer in part is because FAI as a concept was developed amongst surgeons. Therefore the solutions are predominantly surgical, and the livelihood of many surgeons relies on a FAI workload. As a result the majority of information and research publications concern surgery for FAI. Without access to a systematic analytical review of the literature the typical patient and or clinician could be forgiven for being misguided into thinking that the only and best solution is surgery. There is a marked "publication bias" in favour of surgery which now permeates through into the so called "grey literature and popular press". In addition scepticism amongst the research community about the true effects of surgery are not formally voiced and publicised in the literature. It is likely that these factors have slowed a more evidence based understanding and treatment of FAI and made constructing a RCT more difficult. This thesis sought to untangle the problem and begin the process of constructing a RCT.

The lack of a clear non-operative comparator to FAI surgery was one major obstacle to undertaking a RCT. Other areas of musculoskeletal research determining the feasibility of surgical RCTs have found so called "sham" procedures or simple observation to be unworkable because of both low recruitment and lack of surgical equipoise. The findings in Chapter 4 and developed in Chapter 5 which reports for the first time a consensus amongst physical therapists about how best to manage patients with FAI nonoperatively. The regime developed (PHT) has shown that it can be delivered successfully and within the budgetary constraints of a state run health care system (Chapter 8 and 9). This thesis has highlighted that factors other than hip shape may play a role in the development of symptoms of FAI. There is existing research which demonstrates a degree of muscle dysfunction associated with FAI.[81] It is therefore possible that muscle dysfunction is one important additional primary

factor (rather than a secondary consequence) in the development of FAI symptoms. This could be effectively addressed with the exercise based treatment approach (PHT) described.

A pilot RCT comparing arthroscopic surgery and nonoperative care was undertaken and reported in Chapter 8. The purpose was to test recruitment to such a trial. The results showed that 42 out of 60 (70%) patients agreed to participate. These results are encouraging and suggest that there is sufficient enthusiasm and equipoise amongst patients and healthcare professionals for a full RCT to be viable. However, the pilot did not measure long term follow up rates, withdrawals or protocol violations all of which could have a marked effect on such a study.

Although the qualitative research presented in Chapter 7 suggested that there is support for a RCT and many surgeons believe they are in equipoise, it would be important to monitor additional recruitment centres in a full RCT to ensure that they too were in “active” equipoise. A lack of suitable additional centres with clinicians in equipoise could potentially be addressed by channelling patients to centres where recruitment is not impeded by a lack of equipoise; however it is likely that such a strategy would encounter numerous bureaucratic obstacles.

The protocol for nonoperative care (so called “personalised hip therapy”) is likely to have been an important part of the success of the pilot RCT. Many patients with FAI have experienced some form of physical therapy for their symptoms prior to being considered for surgery. In some regions a trial of physical therapy is a pre-requisite before surgery can be considered. It follows that at the time of recruitment to a RCT a patient’s previous experience of physical therapy may not be positive. The regime of physical therapy on offer in the pilot RCT was likely to be different to previous therapy because it was customised to the patient, specifically designed for FAI and delivered by a senior physical therapist.

The sample size for a full RCT with 80% power was estimated to be 372 patients (Chapter 10). Based upon the workload survey results (Chapter 7) and pilot RCT recruitment (Chapter 9) this number of patients could be recruited across 20 centres (the original 10 pilot centres and a further 10 new centres) over 17 months. Even if recruitment was half that achieved in the pilot RCT then 20 centres could recruit sufficient numbers over 33 months. A trial with 90% power would require an additional 106 participants. Across 20 centres this would lengthen recruitment by a further 16 months at 70% recruitment and 22 months at 35% recruitment.

We have evidence of only 22 additional new centres that may have ≥18 eligible patients per year and may be suitable to act as a new recruitment centres. Therefore the feasibility of a full trial may in part depend upon surgeons with adequate levels of equipoise in at least 10 of these 22 new centres.

The research presented in this thesis has outlined the design of a RCT capable of measuring the clinical effectiveness of surgery. However, the feasibility may be very finely balanced. Critical areas are likely to be:

i. The flow of patients.

   Both the number of eligible and recruitment rate of patients will need to be closely monitored. Strategies to optimise both of these aspects have been outlined in Chapter 9 but implementing many of them will considerably increase the cost of running a trial.

ii. The chosen design strategy.

   Both 80% power and a primary outcome assessment at 12 months have been chosen in the potential design outline in order to allow a workable trial that recruits patients and answers an important research question in a timely manner. A change to 90% power although more robust would lengthen recruitment (and cost) considerably. Similarly striving to determine the long term effects of FAI treatment such as its

effects on OA although desirable may divert attention from the first step which is to establish if treatments have any effect in the short to medium term.

iii. Setup times

The pilot trial was only able to recruit in two out of the ten sites for greater than five months. Each site encountered delays in obtaining local R&D approval with one site failing to obtain approval within nine months. Similar delays in a full RCT could lengthen the recruitment period considerably and would need to be avoided in a RCT to prevent:

i. Apathy and loss of interest amongst other recruiting centres as the trial duration lengthens.

ii. Changes in the intervention technology that mean the research question is no longer pertinent.

11.2 Implications and future directions

The aetiology and epidemiology of FAI is not fully understood. Although the prevalence of FAI hip shape abnormalities within the general population has been explored by researchers the reasons why only a small proportion of patients report pain is not known. There are likely to be several other variables which contribute to this and these need to be clarified. One solution would be to undertake a cohort study of asymptomatic patients with hip shape abnormalities and record which patients develop symptoms and when. Such a cohort study would ideally be continued to monitor patients who develop symptomatic FAI without any subsequent intervention to document the true natural history of FAI. This thesis has highlighted that such a study would be technically challenging because patients with symptoms typically undergo some form of treatment which in many cases may involve shape corrective surgery.

At present, patients with symptomatic FAI are in the unenviable position of either undergoing surgery for their symptoms without good evidence of effectiveness, or considering nonoperative treatment for which there is less risk of complications but also very limited

evidence to support effectiveness. This thesis outlines some of the challenges and solutions for achieving higher quality evidence to guide best practice in treating FAI. The solutions presented have been tested within a pilot RCT and developed into the design for a full RCT which could commence as soon as appropriate funding and support is secured.

A further important natural development to this research could deal with the question whether surgery or other interventions for FAI influences a patient's risk of developing future OA. The first step to answering such a research question would first be to establish the effectiveness of FAI treatments in the short to medium term using a RCT. Thereafter long term monitoring of these patients for symptoms and signs of OA would provide valuable evidence of any link.

Appendices

Appendix A – Example search strategy (Chapter 3)

Example search strategy
Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

1 exp Femoracetabular Impingement/
2 femoroacetabular.tw.
3 fai.tw.
4 femoro-acetabular.tw.
5 pincer.mp.
6 (cam adj3 impingement).tw.
7 or/1-6
8 exp Surgical Procedures, Operative/
9 su.fs.
10 (surger$ or surgical$ or operat$).tw.
11 exp osteotomy/
12 exp osteoplasty/
13 osteochondroplasty.tw.
14 mini-open.tw.
15 (arthroscopic adj2 assisted).tw.
16 ganz.tw.
17 Arthroscopy/
18 arthroscop$.tw.
19 hueter.tw.
20 (trochanteric adj3 flip).tw.
21 cheilectomy.tw.
22 or/8-21
23 randomised controlled trial.pt.
24 controlled clinical trial.pt.
25 randomized.ab.
26 placebo.ab.
27 drug therapy.fs.
28 randomly.ab.
29 trial.ab.
30 groups.ab.
31 or/23-30
32 (animals not (humans and animals)).sh.
33 31 not 32
34 7 and 22
35 33 and 34

Appendix B - initial survey used

Instructions
Please read through the following text. You will be asked to indicate your response after each section. The space below each response is an opportunity to add further reasoning, comments and suggestions for change. We accept that non-operative care for femoroacetabular impingement is controversial. We are aware of only one formal non-operative care package that is outlined in the literature.[1] We would like your feedback on the protocol of non-operative care outlined below and any suggestions for change.

1. Initial assessment and treatment:

Stage 1: Avoidance of excessive physical activity and anti-inflammatory drugs for 2-4 weeks.

Stage 2: Physical therapy for 2 to 3 weeks in the form of stretching exercises to improve hip external rotation and abduction in extension and flexion.

Please indicate circle your response here: Yes No Unsure
Please add additional comments below if you have answered no or unsure.

2. Further assessment and treatment

Stage 3: Assessment of the normal range of hip internal rotation and flexion after the acute pain has subsided. Patients are instructed to adapt to their safe range of movement (between maximum internal and external rotation) and perform activities of daily living with minimal friction.

Stage 4: Modification of activities of daily living predisposing to FAI (e.g. hip internal rotation associated with flexion and adduction). Patients are taught to avoid running on a treadmill or narrow straight trails to prevent internal rotation of the lower limbs. Such activities are to be replaced by running in a zigzag and wide courses (requiring some abduction and external rotation during turns). Cycling is to be avoided if possible, as this involves hip flexion and internal rotation at the same time. When cycling is unavoidable, the patients are advised to externally rotate the legs to give some rest to their hip and also elevate the bicycle seat to avoid deep hip flexion. Patient avoid sitting continuously for a long time with the spine fully straight and the hip in flexion; when sitting, lean back every 5 or 7 minutes (to decrease hip flexion) is encouraged.

Please indicate circle your response here: Yes No Unsure
Please add additional comments below if you have answered no or unsure.

References

1. Emara K, Samir W, Motasem EL, Ghafar KA. Conservative treatment for mild femoroacetabular impingement. *J Orthop Surg (Hong Kong) 2011;19-1:41-5.*

Appendix C– Independent protocol prepared and presented by NF

Patient education and advice

i. Education about FAI aetiology and treatments
ii. Advice about posture, gait and lifestyle behaviour modifications to avoid FAI and reduce pelvic inclination (including sitting, standing, sit to stand, sleeping, running / cycling were relevant)
iii. Advice about activities of daily living to avoid FAI (reducing / avoiding internal rotation of hip)
iv. Advice about relative rest (for acute pain where patients cannot engage with exercise-based programme)
v. Specific activity/sport technique modification

Help with pain relief

i. Advice about anti-inflammatory medication for 2 to 4 weeks.
ii. Advice about simple analgesics if don't respond well to NASIDS
iii. Hip joint corticosteroid injection
iv. Exercise-based rehabilitation
    a. Individualised, progressed and supervised over at least 12 weeks with option for 'booster' follow-ups between 3 months and 6 months
    b. Consider notion of a phased exercise programme – starting with muscle control work, progressing to stretching and strengthening with increasing range and resistance
    c. Muscle control / stability exercise (targeting pelvic and hip stabilisation, gluteals and abdominals)
    d. Strengthening / resistance exercise in available range (targeting gluteal, internal and external rotator, abdominal and lower limb muscles) when initial irritability reduced
    e. Stretching exercise to improve hip external rotation and abduction in extension and flexion (but not vigorous stretching) (targeting iliopsoas, hip flexors tightness, rotators)
    f. Progress to activity or sport-specific exercise
    g. Will need a personalised written exercise prescription – exercise leaflet – that is progressed and revised over treatment sessions
    h. Consider use of an exercise diary to help motivate participants and to review progress
    i. Equipment might be needed e.g. theraband, exercise balls, exercise mats

Proposed 'additional' optional components

There seems justification for adding optional manual therapy techniques and perhaps referral for orthotics where available. Acupuncture or taping need not be part of the protocol.

i. Manual therapy
    a. Hip joint mobilisations, e.g. distraction, distraction with flexion, AP glides
    b. Trigger point work.
ii. Hip joint injection. Potentially useful for patients who do not improve with treatment
iii. Orthotics. May need assessment for orthotics to help hip stability

Suggested protocol exclusions

i. Forceful manual techniques in restricted range of movement (Grade V mobilisations, or forceful stretching)
ii. Group-based treatments
iii. Hydrotherapy
iv. Care from a student or technical instructor
v. Acupuncture
vi. Electrotherapy
vii. Taping

Appendix D– Independent protocol prepared and presented by PW

Patient Education and advice

i. Soft tissues at least 8-10 weeks to heal
ii. Pain likely to represent on going damage / inflammation
iii. Keep to pain free ROM
iv. Pain free ROM will allow soft tissues to heal
v. After 8-10 weeks begin to experiment with ROM to re test painful ROM

Assessment

i. Determine pain free ROM in hip.
ii. Determine whether acute inflammation / injury at present.
iii. Determine individual requirements to guide progression.

Acute Inflammation

i. One steroid hip injection if desired
ii. NSAIDs for up to 4 weeks
iii. Allow soft tissues 8-10 weeks to heal and only do pain free ROM exercises at this stage

Primary Hip Therapy

i. Hip – both movement and muscle strengthening
ii. Movement progression should be passive to active assisted and then active
iii. Strengthening progression – use principle of overload using ten repetition maximum
iv. Hip stretches
v. Improve the external rotation and abduction in both extension and flexion

Secondary Hip Therapy

i. Local Joints / Musculature – movement and strengthening
ii. Core stability aim to encourage pelvic control to adapt to pain free positions.
iii. Pelvis and Lower Back aim to encourage posterior pelvic tilt to reduce apparent anterior
iv. Knee – aim to improve strength to manage ground reaction forces
v. Activity Modification
    a. Gait - aim for pain free gait based on pain free ROM
    b. Other activity encouraged provided it is not painful.
    c. Determine the painful movements involved in the activity
    d. Aim to modify the movements based on pain free ROM
    e. If this is unsuccessful manage for acute inflammation / soft tissue injury and attempt again after 8-10 weeks.

Manual Therapy

i. Sacroiliac Joint Mobilisations
ii. Capsule stretches - Anterior and Posterior hip capsule
iii. Massage - Hip, lower back, pelvic, and lower limb muscle massage can be used.

Indirect Hip Therapy

i. Acupuncture can be used as treatment for chronic pain.
ii. Simple analgesics can be used as a treatment for chronic pain.

Appendix E – Examples of exercises for Personalised Hip Therapy

1. Gym Ball Exercise

Description

- Practise sitting on the ball and gently moving your pelvis forwards and backwards, side to side and in circles.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

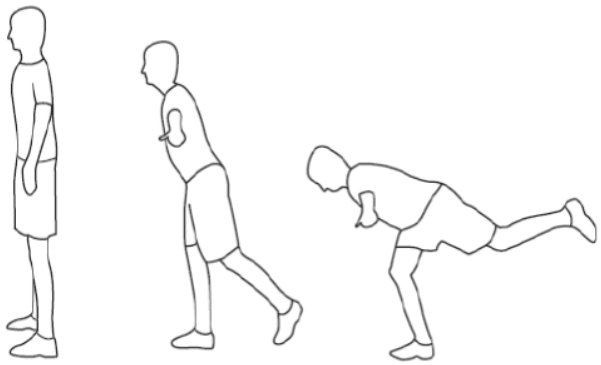
Frequency _____

Additional information _____

Extra option 1

- Lift one foot from the floor whilst maintaining your balance and keeping good symmetrical posture on the ball.
- Relax and repeat on alternate legs.

15. Inverted Hamstring Strength Exercise



Description

- Straight arms.
- Maintain core.
- Fully extend hip and knee.
- Hold for ___ seconds.
- Aim to do ___ repeats.

Prescription

To be customised for the patient and progressed. E.g. duration, frequency, repeats, addition of theraband etc.

Duration _____

Frequency _____

Additional information _____

Appendix F - Designing the Eligibility Criteria and Operative Protocol for a Pilot RCT

Introduction

To date no RCTs have been undertaken for FAI surgery. As a result no previous eligibility criteria exist as guide for the pilot RCT. In addition as a relatively new procedure, there are a variety of surgical techniques for arthroscopic FAI surgery and therefore it is necessary to develop and define a protocol of operative care in order to ensure that patients received the same standard intervention and that a process of quality control could be systematically implemented.

Methods

Researchers PW and DG discussed and produced two provisional documents:

Document 1 - Initial Eligibility Criteria Survey

Please read through the following text and bullet points. You will be asked to indicate your response after each point / section. Please delete the words so that your response remains. The space below each response is an opportunity to add further reasoning, comments and suggestions for change.

Patients will be eligible to participate in this study if:

9. Aged 18-50;

   Please indicate circle your response here: YES No UNSURE
   Please add additional comments below if you have answered no or unsure.

10. They have symptoms of hip pain - they may also have symptoms of clicking, catching or giving way;

    Please indicate circle your response here: YES No UNSURE
    Please add additional comments below if you have answered no or unsure.

11. They show radiographic evidence of pincer- or cam-type FAI on plain radiographs and cross-sectional imaging;[66]

    Please indicate circle your response here: YES No UNSURE
    Please add additional comments below if you have answered no or unsure.

12. The treating surgeon believes that they would benefit from arthroscopic FAI surgery.

    Please indicate circle your response here: YES No UNSURE
    Please add additional comments below if you have answered no or unsure.

13. Able to give written informed consent

    Please indicate circle your response here: YES No UNSURE
    Please add additional comments below if you have answered no or unsure.

14. Able to participate fully in the interventions

    Please indicate circle your response here: YES No UNSURE
    Please add additional comments below if you have answered no or unsure.

Patients will be excluded from participation in this study if:

15. They have previous significant hip pathology such as Perthes' disease, slipped upper femoral epiphysis or avascular necrosis;

    Please indicate circle your response here: YES No UNSURE
    Please add additional comments below if you have answered no or unsure.

16. They have had a previous hip injury such as acetabular fracture, hip dislocation or femoral neck fracture;

    Please indicate circle your response here: YES No UNSURE
    Please add additional comments below if you have answered no or unsure.

17. They already have osteoarthritis, defined as Tonnis grade >1[17], or more than 2mm loss of superior joint space width on AP pelvic radiograph;[75]

    Please indicate circle your response here: YES No UNSURE

Please add additional comments below if you have answered no or unsure.

18. There is evidence that the patient would be unable to participate fully in the interventions, adhere to trial procedures or to complete questionnaires, such as cognitive impairment or intravenous drug abuse.

Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

Documents 2 - Initial Operative Protocol Survey

Please read through the following text and bullet points. You will be asked to indicate your response after each point / section. Please delete the words so that your response remains. The space below each response is an opportunity to add further reasoning, comments and suggestions for change.

7. General anaesthetic with muscle relaxation.
Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

8. Supine or lateral patient positioning.
Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

9. Operating table with facility for traction and allows range of movement testing.
Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

10. Arthroscopy of central compartment.
Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

11. Arthroscopy of peripheral compartment working with one of the following; intact capsule, capsulotomy or capsulectomy.
Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

12. Ability to undertake bony surgery to correct abnormalities on both the femoral head neck junction and acetabular side of the hip joint.
Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

13. Ability to undertake soft tissue repair and or debridement to the labrum and or articular cartilage.
Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

14. Ability to record with either video or photos the intraoperative findings and solutions.
Please indicate circle your response here: YES No UNSURE
Please add additional comments below if you have answered no or unsure.

These documents were based on their own experience as surgeons and the available published literature. Hip arthroscopy surgeons, recognised as international experts in the field were then invited to comment upon these provisional documents. These expert surgeons were from the Multicenter Arthroscopy of the Hip Outcomes Research Network (MAHORN) n=12 and surgeons who attended the American Academy of Orthopedic Surgeons Research Symposium on Femoroacetabular Impingement in Chicago n=4. All surgeons approached agreed to participate (16 out of 16). Each surgeon was asked to provide feedback on the two provisional documents. The feedback they provided was then used by PW and DG to modify the two documents. A final version of both

documents was agreed and is being used in the pilot RCT. The two documents continue to be evaluated in light of feedback from the recruiting sites.

Results

The feedback received from the initial consultation about the eligibility criteria and operative protocol with expert hip arthroscopy surgeons is summarised in Table 0.1, Table 0.2 and Table 0.3.

Table 0.1: Feedback on the eligibility criteria – first part

	Eligibility Criteria (1-3)					
Surgeons	1	Additional Comments	2	Additional Comments	3	Additional Comments
1	Y		U	Pain felt to be from the hip joint region	N	Need to define pincer morphology. LCE >40degrees or consistent with profunda with LCE >35degrees.
2	U	Many < 18 suffer from FAI. Also, it is likely that many patients over the age of 50 could benefit from FAI surgery.	Y		N	Define radiographic measures. Many patients with pincer impingement have a LCE angle > 40degrees.
3	Y	Range is quite reasonable. May be worth considering a larger range such as 18-55.	Y	May need to define hip pain more precisely. We know that the symptoms and signs are somewhat nebulous.	U	This needs to be very clear and reproducible.
4	Y	Some patients <18, and rarely some >55.	Y		Y	
5	Y		Y		Y	
6	Y		Y		Y	
7	Y		U	Not just mechanical symptoms	Y	Consider defining alpha angle
8	Y		U	May need to be clearer	U	Maybe too open
9	Y		Y		Y	
10	Y		Y		Y	
11	Y	Applicability of results, given the age range.	Y		Y	
12	Y		Y		Y	
13	Y		Y		Y	
14	Y		N	Need to define location of hip pain – groin/inguinal. Mechanical symptoms not mandatory.	Y	
15	Y		Y		Y	
16	Y		Y		Y	Chingford cohort, paitents had alpha angle >60 degrees
Total	Y=15 (94%) U=1(6%)		Y=13(81%) U=3(19%) N=1(6%)		Y=12(%) U=2(%) N=2(%)	

Table 0.2: Feedback on the eligibility criteria – second part

	Eligibility Criteria (4-9)									
Surgeons	4	Additional Comments	5	6	Additional Comments	7	Additional Comments	8	9	Additional Comments
1	Y		Y	Y		Y		Y	U	Difficult to define
2	Y		Y	Y		Y	Many patients with Perthes or previous SCFE can benefit from FAI surgery.	Y	N	Some patients with Tonnis 2 can benefit from surgery.
3	U	A consensus agreement may be required. I would use the IHOT33 score as one of the criteria.	Y	U	May need to exclude professional athletes.	Y		Y	U	Are these gradings and measurements reliable between observers?
4	Y	Maybe subjective	Y	Y		Y		Y	Y	What about cotyloid fossa osteophytes?
5	Y		Y	Y		U	Exclude SCFE that had prior surgery only	Y	Y	
6	Y		Y	Y		Y		Y	Y	
7	Y		Y	Y		Y		Y	Y	
8	Y		Y	Y		Y		Y	Y	
9	Y		Y	Y		Y		Y	N	Not easy to define OA.
10	Y		Y	Y		Y		Y	U	Will this exclude too much?
11	Y		Y	Y		Y		Y	Y	
12	Y		Y	Y		Y		Y	Y	
13	Y		Y	Y		Y		Y	Y	
14	Y		Y	Y	Also those unable to comply with postop protocol	Y		Y	Y	
15	Y		Y	Y		Y		Y	Y	
16	Y		Y	Y		Y		Y	Y	Seems reasonable
Total	Y=15(94%) U=1(6%)		Y=16(100%)	Y=15(94%) U=1(6%)		Y=15(94%) U=1(6%)		Y=16(100%)	Y=11(69%) U=3(19%) N=2(12%)	

Table 0.3: Feedback on surgical the protocol

	Surgical Protocol										
Surgeons	1	2	3	4	Add	5	6	7	Add	8	Add
1	Y	Y	Y	Y		Y	Y	Y		Y	
2	Y	Y	Y	U	Document articular cartilage damage	Y	Y	Y		Y	
3	Y	Y	Y	Y		Y	Y	Y		U	May need inclusion in the consent form for the photos/video.
4	Y	Y	Y	Y		Y	Y	U	Define "ability to treat"	Y	
5	Y	Y	Y	Y		Y	Y	Y		Y	
6	Y	Y	Y	U	Need to examine labrum	Y	Y	Y		U	Consider ROM testing instead
7	Y	Y	Y	Y		Y	Y	Y		Y	
8	Y	Y	Y	Y		Y	Y	Y		Y	
9	Y	Y	Y	Y		Y	Y	Y		Y	
10	Y	Y	Y	Y		Y	Y	Y		Y	
11	Y	Y	Y	Y		Y	Y	Y		Y	
12	Y	Y	Y	Y		Y	Y	Y		N	Image intensifier to show shape corrected
13	Y	Y	Y	Y		Y	Y	Y		Y	
14	Y	Y	Y	Y		Y	Y	Y		Y	
15	Y	Y	Y	Y		Y	Y	Y		Y	
16	Y	Y	Y	Y	Cartilage assessment	Y	Y	Y		Y	
Total	Y=16(100%)	Y=16(100%)	Y=16(100%)	Y=14(88%) U=2(12%)		Y=16(100%)	Y=16(100%)	Y=15(94%) U=1(6%)		Y=13(81%) U=2(13%) N=1(6%)	

In light of the relatively high level of agreement 69% and 81% for both documents only a small number of minor changes were made as described below.

Modifications made to eligibility criteria in light of feedback

v. Age range should be changed to accommodate feedback. Considered appropriate to include all patients' ≥16 years.
vii. Radiographic evidence of FAI should be further defined to include:
iv. Femur – an alpha angle of >55 degrees or
v. Acetabulum - a lateral centre edge angle Wiberg of >40 degrees

Modifications made to operative protocol in light of feedback

It would be appropriate to stipulate that:

vii. The entire acetabular labrum should be examined
viii. The entire articular surface should be examined
ix. Confirm that FAI has been relieved using either range of movement testing or an image intensifier.
x. No need to record with video of photos as the results will be difficult to interpret / validate. Not a reliable measure of surgical quality. Exclude from final protocol
xi. Need to document intra-operative complication and their solutions

The final agreed eligibility criteria and operative protocol are outlined below:

Final Eligibility Criteria

Patients will be eligible to participate in this study if:

ii. Aged ≥16;
iii. They have symptoms of hip pain - they may also have symptoms of clicking, catching or giving way;
iv. They show radiographic evidence of pincer- or cam-type FAI on plain radiographs and cross-sectional imaging;[66]
    a. Femur – an alpha angle of >55 degrees or
    b. Acetabulum - a lateral centre edge angle Wiberg of >40 degrees
v. The treating surgeon believes that they would benefit from arthroscopic FAI surgery.
vi. Able to give written informed consent
vii. Able to participate fully in the interventions

Patients will be excluded from participation in this study if:

viii. They have previous significant hip pathology such as Perthes' disease, slipped upper femoral epiphysis or avascular necrosis;
ix. They have had a previous hip injury such as acetabular fracture, hip dislocation or femoral neck fracture;
x. They already have osteoarthritis, defined as Tonnis grade >1[17], or more than 2mm loss of superior joint space width on AP pelvic radiograph;[75]
xi. There is evidence that the patient would be unable to participate fully in the interventions, adhere to trial procedures or to complete questionnaires, such as cognitive impairment or intravenous drug abuse.

Final Operative Protocol

3. General anaesthetic with muscle relaxation.
4. Supine or lateral patient positioning.
5. Operating table with facility for traction and allows range of movement testing.
6. Arthroscopy of central compartment.
7. Examine entire acetabular labrum
8. Examine entire articular surface
9. Arthroscopy of peripheral compartment working with one of the following; intact capsule, capsulotomy or capsulectomy.
10. Ability to undertake bony surgery to correct abnormalities on both the femoral head neck junction and acetabular side of the hip joint.
11. Ability to undertake soft tissue repair and or debridement to the labrum and or articular cartilage.
12. Confirm impingement has been relieved using either range of movement testing or an image intensifier.
13. Document intra-operative complications and their solutions e.g. fracture, iatrogenic cartilage damage, anaesthetic problems etc.

Appendix G – pilot RCT patient information sheet

Version 3 PIS 6th June 2012

Patient Information Sheet

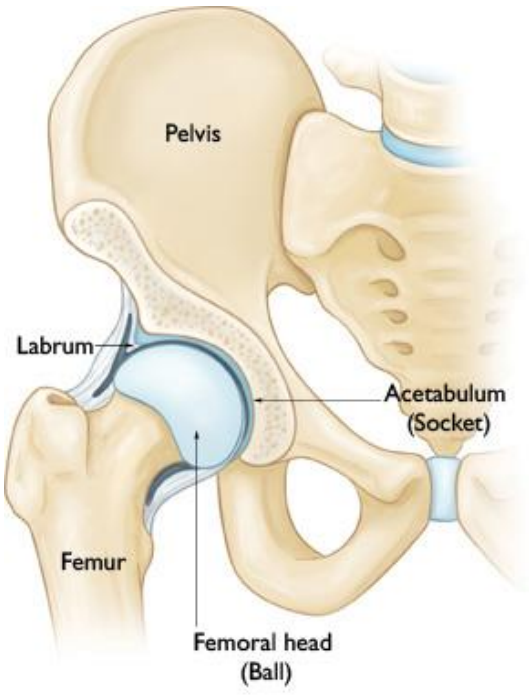
UK FASHIoN Study

Chief Investigator: Professor Damian Griffin

You are invited to take part in our research study. Before you decide whether to take part we would like you to understand why the research is being done and what it would involve for you. Once you have had a chance to read and absorb this information sheet a member of our team will personally go through the information with you and answer any questions you may have.

Background Information

Your hip joint has two bones that fit together like a ball in a socket, see diagram.



Normal Hip Joint

In some people like you these bones have abnormal shapes. Therefore as your hip moves these abnormally shaped bones press against each other and damage the local soft tissues such as the labrum (a soft cushioning around the hip joint- see figure 1) which can cause pain.

This is called Hip Impingement and the medical term for this is femoroacetabular impingement (FAI for short). Hip impingement has only been discovered in the last 10 years and we do not understand everything about the condition. Most importantly it is not clear what the best treatment for hip impingement is. Good results have been shown for both physiotherapy and hip arthroscopy (explained below) as treatments for hip impingement, but we do not yet know if one is better than the other. There is thought to be a long-term risk of osteoarthritis in patients with hip impingement. It is not known either of these two treatments (physiotherapy or hip arthroscopy) has any effect on this risk. In order to decide which treatment is best for you and future patients we need a study to compare these two treatments.

What is the purpose of this study?

This study aims to compare two different treatments for your condition - hip impingement:

iv. ***Personalised Hip Therapy*** – this is a new individualised and structured programme of exercise therapy designed for you by a physiotherapist. A more detailed description is provided later.

v. ***Hip Arthroscopy*** – this is keyhole surgery and is designed to reshape the bone around your hip joint. A more detailed description is provided later

Why have I been chosen to take part in the study?

We need 60 volunteer patients like you with hip impingement to take part in the study.

Do I have to do to take part?

It is up to you to decide whether or not to take part. If you do take part you can withdraw at any time and this will not affect the care you receive.

What will happen to me if I take part?

If you decide to take part you will be asked to sign a consent form. You will then be invited to one of the two treatments. In order to make our study work it is crucial that we have equal numbers of volunteers in each treatment group and that the one you (are invited to) join is determined by a sophisticated machine designed for this purpose, and not influenced by us. More information about the two possible treatments is given below. Whichever treatment you have, please be assured that your care will be based on meeting your individual needs, and you will continue with the same team of physiotherapists and surgeons throughout. Both

these teams work closely together and they will be able to monitor your progress and share information with one another about your individual case continually. During the study we will ask you to complete 4 short questionnaires by post /email (whichever is easier for you). You will do one questionnaire before you begin treatment and then one at 3, 6 and 12 months after your treatment. If you need help completing a questionnaire, a researcher can contact you by phone soon after you receive it to help you complete it.

Which treatments are you comparing?

The two treatments that are being compared are:

iii. ***Personalised Hip Therapy*** - this is a personalised programme of hip therapy that is supervised by a senior physiotherapist and designed to meet your individual needs. You may already have had a course of physiotherapy for your hip, however this programme of care is different and has been designed specifically to relieve pain in your hip and improve how it works. You will meet a senior physiotherapist with a specialist interest in hip impingement who will undertake a thorough assessment of your condition including the effect it has on your life. They will then customise a specific programme of hip exercises designed to help your hip. They will teach you these exercises in clinic and you will then be able to practise these exercises at home. This programme of exercises will gradually increase in intensity and difficulty so that by the end of the programme (12 weeks) we hope you will have developed improved control and strength around your hip with less pain. In addition to the hip exercise programme, a range of additional treatments will be offered to you. These include:

   a. Techniques to improve the control and strength of your posture and walking
   b. Personalised advice on techniques to modify the way you undertake daily activities
   - Specific advice about pain medications to help control your pain in the initial stages of the therapy.

   The programme lasts 12 weeks and you will need to be able to attend the physiotherapy clinic at least 3 times to be assessed, and to have your treatment progressed by your physiotherapist. In addition to this, your physiotherapist will keep a close eye on your progress over the telephone and will contact you at least 3 times in order to ensure you progress well with the programme. The exercises you will be taught will focus on muscle control and balance in the first few weeks. You will then progress to resistance and stretching exercises, and activity/sport-specific exercises in later stages of the programme. You and your physiotherapist will be able to arrange an additional 2 “booster” sessions of assessment / treatment if either of you feel that more time is required to undergo the therapy after the 12 week plan is over.

- ***Hip arthroscopy*** – The procedure is done under a general anaesthetic (you will be put to sleep). The surgeon opens up a small passage through to your hip joint using special instruments introduced through incisions on the surface of your skin. A telescope is passed through these small passages, to look inside the hip, and further instruments are inserted that allow the surgeon to reshape the hip joint and repair locally damaged tissues, such as the labrum. You will normally need to stay in hospital for between 1-3 days after the procedure. Depending on the extent of surgery, some patients have to use crutches to walk for between 6-8 weeks after the procedure. There is a period of rehabilitation after the procedure, which will be supervised by a physiotherapist in clinic, and practised at home. It will take between 2-3 months to complete the rehabilitation programme.

What are the possible risks of taking part?

The treatments are designed to help you, however, this cannot be guaranteed. The individual risks of each treatment are outlined below:

- **Personalised Hip Therapy -** There are some small risks with pain medications and joint injections. However, the main risk is muscle soreness and short-term increases in pain from the exercises that you will undertake. Generally the risks of this treatment are much lower than hip arthroscopy (surgery)

- **Hip Arthroscopy –** about 1 in 50 people have specific complications from hip arthroscopy. One very rare but serious risk is a break (fracture) of the hip during the surgery. If this happened you would need an additional operation to fix the break. Other risks of hip arthroscopy include:

  - Infection within the joint or around the wounds. This can sometimes be treated with antibiotics alone. In more serious cases it requires a further procedure to washout the hip.
  - Bleeding from the wounds, but this is usually a very small amount and quickly settles.
  - Numbness in groin, leg or foot. To undertake hip arthroscopy we need to apply a pulling force on your leg in order to access the hip joint. This can cause some numbness in your groin, leg or foot as a result. This usually resolves within a few hours or days after the procedure.

How do these treatments work?

Personalised Hip Therapy – this therapy works by allowing soft tissues which are damaged and painful as a result of hip impingement, such as the labrum, a period of relative rest, so that they can heal naturally. This can take up to several weeks or months. During this period you will have learnt and practised many exercises that improve the movement and control of the hip and local joints (such as your lower back and pelvis), which should ensure that your hip impingement can no longer occur, and that damaged soft tissues, such as the labrum, can continue to heal.

Hip Arthroscopy – this procedure relies on surgically removing bits of bone from around the hip so that they no longer rub together and damage the soft tissues such as the labrum. Once the bits of bone have been removed, a period of rehabilitation is required so that the soft tissues can continue to heal.

One of the long-term concerns with hip impingement is that you have an increased risk of developing arthritis of the hip. It is really important that you know that at the moment we have no evidence that any treatment (including personalised hip therapy or hip arthroscopy) will have any effect on whether you subsequently develop arthritis of your hip. However by taking part in this study it will help us in the long term to determine if either of these two treatments can help prevent arthritis.

What if new information becomes available?

Sometimes during the course of a study, new information becomes available about the treatments that are being studied. If this happens, someone from our research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, you can discuss your continued care with your doctor. If you decide to continue in the study you might be asked to sign an updated consent form. Also, on receiving new information, we might consider it to be in your best interests to withdraw you from the study. If this happens we will explain the reasons to you and arrange for your care to continue.

What happens when the research study stops?

You will be in the study for one year. If you are still having problems after this time, we will arrange for you to see your hip specialist to continue your care.

What if something goes wrong?

In the event that something goes wrong and you are harmed during the research due to

someone's negligence, then you may have grounds for legal action for compensation against the University of Warwick (contact Miss Nicola Owen, Deputy Registrar, 02476 522713) and /or UHCW NHS Trust (contact Mrs Ceri Jones, Research & Development Services Manager, 02476966196), but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Research data including your name and address will be sent to the University of Warwick so that research staff can stay in touch with you over the course of the year, and send you follow-up questionnaires at 3, 6 and 12 months by post or email. These details will be sent from the hospital by secure means, and kept in locked filing cabinets or in password-protected computer databases accessible only to essential research personnel at the University of Warwick. All other information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. If you agree, your GP and other doctors who may treat you, but are not part of this study, will be notified that you are taking part in this study.

What will happen to the results of the research study?

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. If you would like to obtain a copy of the published results, please contact the study coordinator Rachel Hobson on 02476-968629 or email: fashion@warwick.ac.uk

Who has reviewed this project?

This study has been reviewed and approved by West Midlands Edgbaston Research Ethics Committee. Approval was granted on 15th February 2012.

Appendix H: pilot RCT consent form

Version 2: 8th February 2012

<<<TO BE PRINTED ON LOCAL HEADED PAPER>>>

CONSENT FORM – Randomisation

UK FASHIoN

Chief Investigator: Professor Damian Griffin

1. I confirm that I have read and understand the information sheet dated 8th February, 2012 – version 2 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University of Warwick, from regulatory authorities, or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature
_____		
Role of person taking consent		

Copies

1 for Patient, 1 for Hospital Notes

Original document retained in site file

Appendix I: Personalised Hip Therapy Case Report Form

Personalised Hip Therapy: Case Report Form

Patient Initials ☐☐☐ Patient DOB (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐ Site ID: ☐☐ Participant ID: F A S ☐☐

Treating Physiotherapist: .....

Date of visit and treating physiotherapist's initials (e.g. 27/3/10, JY)	..../..../.... Initials:	..../..../.... Initials:	..../..../.... Initials:	..../..../.... Initials:	..../..../.... Initials:	..../..../.... Initials:
If patient UTA'd or DNA'd visit (please tick ✓)						
Length and the type of consultation (e.g. 20 mins face to face/via telephone)						
Discharged (please tick ✓)						
Core Modalities used (please tick ✓)						
1. Assessment / Reassessment						
2. Education and advice						
3. Help with pain relief						
4.a. Supervised exercises in clinic						
4.b. Exercise prescription given						
4.c. Exercise diary given / reviewed						
4.d Exercise progressed (please state e.g. ↑ reps, harder exercises)						
Type of exercises provided (please state)						
Ex Number from Core:						
Ex Number from Core:						
Ex Number from Core:						
Ex Number from Core:						
Ex Number from Core:						
Ex Number from Core:						
Other none- core Exercise : (please state)						
Other none- core Exercise : (please state)						
Other treatment used: (please state e.g. manual therapy, hip steroid injection, orthotics)						
Adverse Events: (e.g. muscle soreness, injury whilst exercising)						
General Comments:						

If you have any questions regarding the study please contact | Clinical Research Fellow: Peter Wall 07803 042920 / p.d.h.wall@warwick.ac.uk

V 1.2 | 03102012

Appendix J: Six week telephone complications questions

In the past 6 weeks has the patient experienced or been treated for any of the following events?

i) Please complete for patients who have undergone <u>hip arthroscopy ONLY.</u>

1. Numbness in the groin leg or foot? Yes ☐ No ☐
If yes, please give details: .....

.....

2. Wound infection? Yes ☐ No ☐

Was the wound i) Deep ☐ ii) Superficial ☐

Was a course of antibiotics prescribed? Yes ☐ No ☐

Was further surgery required? Yes ☐ No ☐

3. Hip fracture (break) Yes ☐ No ☐
If yes, please give details: .....

.....

4. Further surgery because of your hip impingement? Yes ☐ No ☐
If yes, please give details: .....

ii) Please complete for <u>ALL patients</u>

1. Problems with pain medications for your hip impingement? Yes ☐ No ☐
If yes, please give details: .....

.....

2. Problems with hip joint injections Yes ☐ No ☐
If yes, please give details: .....

.....

3. Muscle soreness from exercises that you have been undertaking? Yes ☐ No ☐
If yes, please give details: .....

.....

4. A regional pain syndrome? Yes ☐ No ☐
If yes, please give details: .....

.....

5. Deep Vein Thrombosis (DVT)? Yes ☐ No ☐

If yes, were you prescribed medication? Yes ☐ No ☐

6. Any other complications? Yes ☐ No ☐

If yes, please give details: .....

.....

7. Have you had any other unscheduled appointment at hospital because of your hip impingement? Yes ☐ No ☐
If yes, please give details: .....

.....

Appendix K: Three month complications questions

Q01 In the past 3 months have you been treated for any of the following events?

Wound complication (if you have had surgery)	☐ Yes	☐ No	☐ N/A
Unplanned surgery because of your femoroacetabular impingement	☐ Yes	☐ No	
A regional pain syndrome	☐ Yes	☐ No	
Deep Vein Thrombosis (DVT)	☐ Yes	☐ No	
If yes, did you see the DVT nurse	☐ Yes	☐ No	
If yes, were you prescribed medication?	☐ Yes	☐ No	

Q02 Any other complications? ☐ Yes ☐ No

If yes, please specify:

Q03 Have you had any other unscheduled appointment at hospital because of you femoroacetabular impingement. ☐ Yes ☐ No

If you are unsure about any of these questions please cross here ☐ and someone from the research team will get in contact with you to help you answer these questions.

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