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Multicentre study on capsular closure versus non-capsular closure during hip arthroscopy in Danish patients with femoroacetabular impingement (FAI): protocol for a randomised controlled trial

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The results of this study will be presented at national and international congresses and published in peer-reviewed journals.

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ABSTRACT

Introduction Hip arthroscopy has become a standard procedure in the treatment of hip joint pain not related to osteoarthritis or dysplasia in the young and active patient. There has been increasing focus on the contribution of the hip capsule to function and on stability following hip arthroscopy. It has been suggested that capsular closure after hip arthroscopy may prevent microinstability and macroinstability of the hip joint and reduce revision rate. However, it remains unknown whether capsular closure should be performed as a standard procedure when performing hip arthroscopies, especially in patients without additional risk factors for instability such as hypermobility or dysplasia of the hip. We hypothesised that capsular closure will lead to a superior outcome in hip arthroscopy for femoroacetabular impingement syndrome (FAIS) compared with non-capsular closure.

Methods and analysis In this randomised controlled, multicentre trial, 200 patients scheduled for hip arthroscopy for FAIS will be cluster randomised into one of two groups (group I: hip arthroscopy without capsular closure, group II: hip arthroscopy combined with capsular closure). Inclusion criteria are: age between 18 years and 50 years and FAIS according to the Warwick agreement. Exclusion criteria are: previous hip surgery in either hip, previous conditions of Legg-Calvé-Perthes or slipped capital femoral epiphysis, malignant disease, recent hip or pelvic fractures, arthritis, Ehlers-Danlos or Marfan disease, recent (within 6 weeks) application of intra-articular corticosteroids, language problems of any kind, and radiological signs of osteoarthritis, acetabular dysplasia or acetabular retroversion. Surgery will be performed in Denmark at four centres by four surgeons, all performing an interportal capsulotomy and closure with at least two absorbable sutures. Patients in both groups, who are blinded for the intervention, will receive the same standardised rehabilitation programme. As primary outcome scores, HAGOS (sport) will be used with HAGOS (symptoms, pain, function in daily living, participation in physical activities and hip and/or groin-related quality of life), Hip Sports Activity Scale, short validated version of the International Hip Outcome Tool, EQ-5D, Visual Analogue Scale for pain, complications and reoperation rate as secondary outcome tools. Using HAGOS (sport) as primary outcome parameter the power analysis required a minimum of 84 individuals per group. Together with a clinical examination performed by the patient's surgeon 1 year after surgery, patient reported outcome measures will be completed preoperatively, as well as at 3 months, 1 year, 2 years and 5 years postoperatively. In addition, adverse effects will be recorded.

Ethics and dissemination The study is approved by the Central Denmark Region Committee on Biomedical research ethics. The results of this study will be presented at national and international congresses and published in peer-reviewed journals.

Trial registration number NCT03158454; Pre-results.

Strengths and limitations of this study

- ► This is a randomised, blinded study with self-reported outcomes as end points.
- ► It is a nationwide study covering the vast majority of all patients undergoing hip arthroscopy for femoroacetabular impingement syndrome in Denmark; it includes consecutive patients.
- ► Due to the multicentre design, surgery and rehabilitation may be influenced by local tradition. This is compensated for by the randomised design and efforts to harmonise surgical technique and rehabilitation.
- ► Long-term complications such as degenerative cartilage changes due to microinstability caused by capsulotomy may not be possible to demonstrate within the 5-year follow-up.

INTRODUCTION

In recent years hip arthroscopy has become the method of choice in treating

intra-articular pathologies of the hip not related to osteoarthritis or developmental pathologies such as hip dysplasia or acetabular retroversion. Especially femoroacetabular impingement syndrome (FAIS) with intra-articular pathologies such as cam morphology, pincer type morphology articular cartilage and/or labral lesions are considered a primary indication for arthroscopic surgery. In contrast to (mini) open procedures or even open dislocation of the hip joint, hip arthroscopy allows direct visualisation and treatment of the pathology combined with minimal soft tissue trauma and fast postoperative mobilisation.[1 2] The arthroscopic technique of hip arthroscopy has evolved over recent years, as has the understanding of biomechanics of the hip joint. Apart from acetabular coverage, the acetabular labrum and the hip capsule have been identified as major contributors to hip joint stability.[3–7]

The hip joint has both dynamic and static stabilisers. The hip capsule consists of four major structures: the iliofemoral, pubofemoral and ischiofemoral ligaments and the zona orbicularis, where the iliofemoral ligament is of major importance due to its role in arthroscopic surgery. It is the strongest of the abovementioned structures and is crucial in resisting external rotation, anterior translation, extension and hip dislocation.[5 8] In hip arthroscopy an interportal capsulotomy is usually used to enter the hip joint, putting the hip capsule, and here especially, the iliofemoral ligament, at risk. In a cadaver study Bayne *et al* could show increased anterior translation and neutral rotation as well as increased posterior translation with the hip in flexion, when capsulotomy had been performed.[9]

Although gross instability or even traumatic hip dislocation after hip arthroscopy are rare complications,[10] postoperative microinstability due to insufficient capsular closure is believed to be a potential cause for an inferior functional outcome after hip arthroscopy.[11] Furthermore it has been stated that capsular closure may lead to a more predictable and reliable hip function with a lower rate of revision surgery.[8 11–13]

It has been postulated that capsular closure after hip arthroscopy leads to re-establishment of anatomical joint stability,[7] however, the positive effects on the clinical outcome following hip arthroscopy are yet to be proven. In clinical studies comparing the outcome of patients with borderline dysplasia with non-dysplastic patients with FAIS, there seems to be a favourable outcome when capsular closure is performed.[14 15] When comparing capsular closure with non-closure retrospectively, Domb *et al* reported no significant differences in clinical outcomes.[16] However, Domb *et al* concluded that capsule closure did not have any negative effect on the outcome either, keeping in mind that the conclusions drawn in their study were limited due to significant differences in age, body mass index, gender, preoperative patient reported outcome score (PROs) and degree of chondral damage in the groups compared. When comparing different types of capsular closures, complete closure seems to be superior to partial closure. In a prospective cohort study Frank *et al*[17] found superior outcome at 6 months, 1 year, 2 years and 5 years after hip arthroscopy for FAIS when comparing patients with full closure of a T-capsulotomy with a matched group of patients, where the interportal part of the T-capsulotomy was left unrepaired. In a biomechanical study analysing the strength of the capsule closure and the number of sutures needed Chahla *et al* reported no significant difference whether two or three No. 2 Vicryl sutures (Ethicon) were used, when closing an interportal capsulotomy.[18]

Gupta *et al*[19] reported preferences in surgical procedures by 27 high-volume orthopaedic surgeons specialising in hip arthroscopy (>50 hip arthroscopies per year). Although all performed capsulotomy routinely, the results showed a huge variability in how and when closure of the hip capsule was performed. Three surgeons closed the capsule every time. Ten and 11 surgeons, respectively, closed the capsule in more than 50% and less than 50% of the times. Three surgeons never closed the capsule.

According to the Danish Hip Arthroscopy Registry (DHAR), a national database with 14 participating centres, which was established in 2012 and with data from 3541 procedures (8 October 2016), capsular closure was performed in only 10% of all hip arthroscopies.[20] Further analysis of the data from DHAR showed that patients who underwent capsular closure had superior results in postoperative outcome scores (hip and groin outcome score (HAGOS), Hip Sports Activity Scale (HSAS), Visual Analogue Scale (VAS) and EQ-5D a standardised instrument of measuring generic health status) at 2-year follow-up when compared with a matched FAIS cohort (cohorts were matched according to age, gender, lateral centre edge and alpha angles).[21] Although capsule closure was only performed routinely by one single surgeon, these findings could indicate a positive effect on clinical outcome of capsule closure which needs further investigation in randomised controlled trials. In general, capsule closure is considered more technically challenging with an increased risk of iatrogenic injuries to, for example, femoral cartilage or a reduced external rotation due to an overtightening of the capsule;[22] however, there is no scientific evidence that capsule closure leads to inferior outcome or other adverse effects.[23]

AIM

The aim of this multicentre randomised controlled trial is to evaluate the effect of capsular closure in relation to postoperative outcomes and revision rates for patients undergoing hip arthroscopy for FAIS.

HYPOTHESIS

We hypothesise that patients treated with hip arthroscopy for FAIS would have significantly improved subjective and clinical outcomes if capsular closure is performed.

DESIGN

A prospective, multicentre (n=4) study with a randomised controlled two-arm design is being conducted at four Danish hospitals. Two hundred participants scheduled for hip arthroscopy, due to FAIS, are randomly assigned in a 1:1 ratio to hip arthroscopy without (group I) or with (group II) capsular closure. The inclusion process started in June 2017 is expected to last approximately 2 years.

MATERIAL

Patients

All patients referred to the four participating orthopaedic departments in Denmark for hip arthroscopy and who meet the inclusion criteria, will be asked to participate in this study. In order to show a minimal clinically important difference (MCID) we estimated a 10-point increase in the HAGOS Sport subscale as a relevant MCID.[24] When the power is set at 0.9 and at an alpha value of 5%, the number of patients in each group should be 84 (SD=20). To allow for possible dropouts the total estimated sample size of patients included in each group is n=100.

Inclusion criteria

The participating patients have to be between 18 years and 50 years old and need to have radiological and clinical signs of FAIS as described by Griffin *et al*.[25] Symptoms of FAIS are: reported pain in the hip or groin area with painful active and/or passive range of motions as well as patient history of clicking, catching, locking, stiffness, restricted range of motion or giving way. Clinical findings of FAIS are defined by a positive reproduction of the patient's usual pain from the hip joint during hip impingement test such as the Flexion Adduction Internal Rotation (FADIR) test normally with limited range of motion, typically internal rotation in flexion.

Radiological findings of FAIS are defined here as an alpha angle >55° (cam-type morphology) in cross-table axial radiograph and a positive cross-over sign and/or a centre edge angle (CE angle) >39° (pincer-type morphology) on a standardised anteroposterior (AP) pelvic X-ray.[26] Since, so far, there is no scientific evidence of superiority in treating FAIS non-operatively, structured exercise prior to hip arthroscopy has not been a requirement for inclusion to this study. However, patients suspected for an accompanying extra-articular pain generator will be referred to structured physiotherapy for at least 3 months before being considered for surgical treatment.

Exclusion criteria

Patients are excluded from the study when one of the following features apply (table 1): previous hip surgery in either hip, previous conditions of Legg-Calvé-Perthes or slipped capital femoral epiphysis, malignant disease, recent hip or pelvic fractures, arthritis, Ehlers-Danlos or Marfan disease, recent (within 6 weeks) application of intra-articular corticosteroids, for example, methylprednisolone acetate (Depo-Medrol), language problems of any kind, and radiological signs of osteoarthritis, defined by a lateral joint space width <3 mm or grade >1 according to Tönnis classification; furthermore, radiological signs of acetabular dysplasia, defined by a CE angle <25 degrees (modified Wiberg,[27]), or acetabular retroversion, defined by a positive cross-over sign in combination with a positive posterior wall sign and a positive ischial spine sign when applying standardised AP pelvic X-rays.[24]

Patient involvement

Patients were not directly involved in the design of this study as the intervention in this study is not considered to change the postoperative regime or the patient's

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
► Age between 18 years and 50 years ► Femoroacetabular impingement syndrome according to the agreement paper from Warwick[25] ► Indication for surgery according to the examining surgeon	► Previous hip surgery in either hip ► Malignant disease ► Recent hip or pelvic fractures ► Ehlers-Danlos and Marfan syndromes ► Arthritic disease ► Hip joint dysplasia, defined by both centre edge (CE) angles $<25^0$ and Acetabular Index angle $>10^0$ ► Acetabular retroversion, defined by the combined presence of cross-over sign in the lower two-third of the joint, posterior wall sign and prominent ischial spine sign ► Osteoarthrosis grade ≥2 according to Tönnis classification ► Joint space width <3 mm at the lateral part of the sourcil on anteroposterior pelvis X-ray ► Legg-Calvé-Perthes ► Slipped capital femoral epiphysis ► Recent (within 6 weeks) medical treatment with corticosteroids ► Language problems of any kind

direct perception of the preoperative and postoperative processes. As the enrolment in a clinical trial may influence the patient's view of the clinical work or even feel like a burden, the patients will be interviewed randomly to identify adverse effects.

Imaging

Prior to surgery, an AP pelvis radiograph and a cross-table axial radiograph of the index hip will be taken and evaluated according to the criteria defined by Tannast *et al*.[26] Patients with radiological signs of osteoarthritis, developmental dysplasia of the hip or acetabular retroversion will be excluded from the study.

Clinical examination

All patients will undergo a complete physical examination with passive and active range of motion of the hip, as well as testing for extra-articular and intra-articular pain generators such as psoas tendon pain, iliotibial band pain, adductor tendon pain or gluteal pain. Extra-articular pain generators will be reported. The patients will have the flexion, abduction and external rotation test and the anterior impingement test performed, as described by Ratzlaff *et al*.[28] The test is positive when the known pain is experienced in the upper/inner thigh or groin. To support the radiological and clinical findings an ultrasound-guided, diagnostic intra-articular injection with anaesthetics may be performed as this has been shown to be a sensitive tool in identifying intra-articular pain.[29 30]

Outcome parameters

The patient's outcome will be evaluated using patient-related outcome measurements preoperatively and at 3 months, 1 year, 2 years and 5 years after surgery. The primary outcome score is the HAGOS subscale Sport while HAGOS with its subscales Symptoms, Pain, Function in daily living, participation in physical activities and hip and/or groin-related quality of life (QOL), as well as the International Hip Outcome Tool (iHOT), HSAS, VAS and Numerical Rating Scale (NRS) will be secondary outcome scores. HAGOS consists of six subscales, which can be evaluated separately.[31 32] HAGOS is a questionnaire (37 questions in total) aimed at young to middle-aged adults undergoing hip arthroscopy or non-surgical treatment for patients presenting with groin pain. In this study the short validated version of iHOT (iHOT12) is also used for initial patient assessment and as postoperative follow-up. The iHOT12 is validated to measure health-related QOL and to identify changes after treatment in young and active patients with hip disorders. The total score is calculated as a simple mean of these 12-item responses ranging from 0 to 100, with a higher score representing a better overall QOL Score.[33] EQ-5D is a widely used generic health-related QOL measure.[34] HSAS is also used and recommended as a reliable and valid activity measurement useful for patients with FAIS.[35] Pain levels are measured using VAS and NRS pain scores at rest and after 15 min of walking on a flat surface. The timeline of the preoperative and postoperative follow-up examinations can be seen in table 2.

Information and patient approval

The patient will, after the initial clinical examination in the outpatient clinic when indications for surgical treatment of FAIS are confirmed and the patient is assigned for hip arthroscopy, be informed about the project and the possibility to participate. Written information will be given, and the patient—if he/she has possible interest in participating in the study—will be included or if he wishes, will be invited to a meeting in the outpatient clinic under undisturbed circumstances for further information. The patient may bring an assessor for this meeting. When the patient has had the time for considering participation and if he wishes to participate, informed consent is signed by the patient and the surgeon in accordance with the Declaration of Helsinki II.

Randomisation process

Assignment into groups will be performed using sequentially numbered opaque sealed envelopes. Each centre will be given 50 of these cluster-randomised envelopes,

Table 2 The timeline of the study and the preoperative and postoperative follow-up

Follow-up	Preoperative	Perioperative	3 months	1 year	2 years	5 years
Information/inclusion	X					
Clinical evaluation	x		x	x	x	X
Randomisation		X				
PROMS						
HAGOS	X		X	X	X	X
HSAS	X		X	X	X	X
iHot12	X		X	X	X	X
EQ-5D	X		X	X	X	X
VAS	X		X	X	X	X

HAGOS, Hip and Groin Outcome Score; HSAS, Hip Sports Activity Scale; iHOT12, short validated version of the International Hip Outcome Tool; PROMS, Patient Related Outcome Measures; VAS, Visual Analogue Scale.

randomised in blocks of 4–6 envelopes, at the beginning of inclusion. All envelopes and the sequence of the blocks is blinded to the surgeon. After completion of the regular hip arthroscopy procedure, the randomisation envelope indicating the subject's treatment will be opened. Subjects will be randomised into one of two groups (group I: hip arthroscopy without capsular closure, group II: hip arthroscopy combined with capsular closure). In order to ensure patient blinding the surgical report will only state whether the capsular treatment was in accordance with treatment I or treatment II.

Blinding

The patients are blinded to the allocation during the first 5 years. It will be recorded in the patient file that the capsule was treated according to randomisation but not whether the capsule was closed or not. As the patients have the right to know in which of the two groups he or she has been randomised into at any point of time, patients requesting this information before the end of the 5-year study period will be excluded.

Surgical procedure

The surgical techniques represented in this study may vary due to different portal placement, anchor types and bone resection instruments due to the fact that four surgeons in four surgical centres participate in this study. Hip arthroscopy is usually performed with the patient under general anaesthesia. The operative data reported are the amount and location of the portals, surgical procedure times including traction times, labral and cartilage injury assessment, and surgical technique characteristics such as anchor type, number of anchors used and depth of rim trimming in millimetres. The depth of the reported cam resection is measured in millimetres and the extent is measured in degrees using the omega angle as described by Rego *et al*.[36]

As a standard an anterolateral portal and an inferior mid-anterior portal are used. An interportal capsulotomy is performed approximately 5–10 mm distally from the labrum from the 11:00–14:00 o'clock position for the right hip and the 10:00–13:00 o'clock position for the left hip. For the capsulotomy an arthroscopic blade is used, making capsular closure more precise. Once the intra-articular pathologies have been addressed, the hip capsule will be closed or left open depending on what the patient has been randomised to. If the capsule is to be closed, the hip is flexed to approximately 30° while the capsule is closed with two to three No. 2 Vicryl sutures (Ethicon), using a 'Quebec City Slider' knot technique as described by MP.[37] As Chahla *et al*[18] could not show a significant difference in using two or three sutures when performing capsular closure, the decision if two or three sutures are used, will be made by the surgeon in order to achieve complete closure.

All participating surgeons have undergone supervised training by MP in the cadaver laboratory to standardise their capsular closure technique. In the period between cadaver training in September 2016 and the start of this study in June 2017 all surgeons have successfully performed capsular closure procedures. Video documentation of each surgeon was approved by the senior surgeon (MP). All deviations from the standard surgical procedure, such as the need for a T-shaped capsulotomy as well as perioperative complications will be reported. If a T-shaped capsulotomy was needed during surgery, that patient was excluded from the study.

Postoperative medications

The standard postoperative medication includes non-steroidal anti-inflammatory drugs (NSAID) and/or paracetamol for 2 weeks, and morphine as needed, but may vary between centres.

Postoperative rehabilitation

All patients will follow a standardised rehabilitation programme, which all participating centres prior to this study have agreed on. Apart from written training information, the patients will receive supervised instructions and/or training by experienced physiotherapists on a regular basis within the first 12 weeks after surgery. The rehabilitation programme is divided into four different phases with an estimated time frame for each phase. Progression from one phase to the other depends on the successful achievement of phase-specific goals. With regard to postoperative restrictions the rehabilitation focuses on gradual increase of the hip range of motion, core and hip stability, postural control, symmetry with functional tasks and gait, strength, endurance, agility and finally, the implementation of sport-specific tasks. As the patients are going to be discharged on the day of surgery, rehabilitation will take place in the outpatient clinic or local training facilities. Apart from simple exercises to avoid deep vein thrombosis, the patients receive the first of four rehabilitation manuals by a physiotherapist when discharged from the department. To avoid capsulolabral adhesions there is an emphasis on early range of motion , for example, by using a stationary bike. Caretakers will be involved in early passive range of motion exercises when possible. The standardised use of continuous passive motion devices is not planned.

The following postoperative restrictions apply for the first 2–3 weeks: partial weight bearing the first 2 weeks, no external rotation >30° and hyperextension for the first 3 weeks. Deviations will be recorded (online supplementary appendix 1).

Data security

The main part of the data will be collected from DHAR which is approved by the Danish Health Agency. The questionnaires 3 months postoperatively will be collected by and stored at the research facility at the Division of Sports Traumatology, Department of Orthopedics, Aarhus University Hospital THG, Denmark. These data will be stored under lock and destroyed by the end of this study. Follow-up data at 1 year, 2 years and 5 years will be

registered in DHAR. Data including standardised X-ray measurements will be stored in a database system with a password. In general data will be handled according to the regulations of the Act on Processing of Personal Data. Relevant anonymised patient -level data are available on reasonable request from the authors.

Statistics

We have estimated a 10-point increase in the HAGOS Sport subscale as a minimal clinically relevant difference between groups. When the power is set at 0.9 and at an alpha value of 5%, the number of patients in each group should be 84 (SD=20). To allow for possible dropouts the total estimated sample size of patients included in each group is n=100.

Risks and adverse effects

The only change in this process compared with other hip arthroscopy procedures is the closure of the hip capsule. This procedure has, to our knowledge, no additional adverse effects compared with the complications described after hip arthroscopy, such as nerve injury, infections, deep vein thrombosis, avascular femoral head necrosis or hip fracture.[38]

Limitations and strengths of the study

There are some limitations due to the multicentre design of the study. Although all four participating surgeons routinely perform hip arthroscopy and have trained together in a wet lab performing capsular closure on cadaver hip specimens, the techniques of treating the underlying hip pathology as well as performing the capsular closure may differ. Furthermore, postoperative rehabilitation will be organised and executed in the local communities around the four participating hospitals. Although a study group including physicians and physiotherapists has implemented a standard postoperative regime, there might be individual, logistical and regional differences in how postoperative rehabilitation will be carried out. However, these differences in surgical technique and postoperative rehabilitation reflect the general challenges when comparing clinical results after hip arthroscopy, and they are principally eliminated by the randomised design. The major strength of this study is that the data provided in this randomised controlled trial represent the majority of all patients undergoing hip arthroscopy for FAIS in Denmark, due to its multicentre design and the high volume of patients at the participating centres.

DISCUSSION

During the past years the number of hip arthroscopies has increased rapidly and is now a standard procedure in treating intra-articular hip pathologies not related to osteoarthritis or developmental abnormalities such as hip dysplasia or acetabular retroversion. Due to a more precise decision making and a better understanding of the biomechanics of the hip joint, outcome of hip arthroscopy shows promising results. However, the influence of (micro)instability on the outcome following hip arthroscopy has been a topic of interest in recent years. The question of whether the hip capsule should be closed in every hip arthroscopy or if this decision should be made depending on the patient's biomechanical preconditions, has not been answered yet. The results of this multicentre, randomised trial will hopefully lead to a better understanding of the role of capsular closure after hip arthroscopy for the short-term and long-term outcomes.

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Contributors BM-K and CD took the initiative for the study and worked on the protocol and ethical approval. Apart from the four main investigators (BM-K, CD, OK, BL), the heads of the respective departments ML, MK and PH helped design the study. MP and KB provided surgical expertise and scientific sparring in the planning phase of the study. CD wrote the initial draft for the manuscript of the protocol article, while all authors helped to revise it and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent Obtained.

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Data sharing statement Data are pseudonymised and all analyses are conducted with fully anonymised data sets. On request relevant anonymised patient level data are available on reasonable request from the authors. Researchers will be provided the data and questionnaire for a specified time period after signing a data usage contract when the proposal is positively evaluated.

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