# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### INTERVENTIONAL PROCEDURES PROGRAMME

# Interventional procedure overview of supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

Hip osteoarthritis is a condition in the hip joint that can cause pain, stiffness and difficulty walking. Sometimes the joint needs replacing surgically (total hip arthroplasty). In this procedure, smaller cuts are used to access the hip than in standard surgery. Also, tendons and muscles are moved apart rather than cut, and the hip does not need to be dislocated. Two small cuts are made in the skin on the outside of the hip, and surgical instruments are put through the cuts (percutaneous) to access the joint. The top of the thigh bone is removed, a dome-like structure is fitted into the socket of the joint, and a metal ball and stick are fitted into the bone (supercapsular). The procedure is done under a general or regional anaesthesia, and takes about 2 hours. The aim is to reduce symptoms and improve hip function, and reduce trauma during the operation compared with that during standard hip replacement surgery.

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#### **Abbreviations**

Word or phrase	Abbreviation
Congenital dislocation of the hip	CDH
Developmental dysplasia of the hip	DDH
Harris hip score	HHS
Hip disability and osteoarthritis outcome score	HOOS
Hip outcome score - activities of daily living subscale	HOS-AVD
12-item international hip outcome tool, short version	iHOT-12
National Joint Registry of England, Wales and Northern Ireland	NJR
Range of motion	ROM
Percutaneously assisted total hip	PATH
Standard deviation	SD
12-item short form health survey	SF-12
Supercapsular percutaneously assisted total hip	SuperPath
Total hip arthroplasty	THA
Timed stair climb	TUS
Timed up and go	TUG
Visual analogue scale	VAS
Western Ontario and McMaster Universities Osteoarthritis index	WOMAC

## Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

# Date prepared

This overview was prepared in June 2021.

#### Procedure name

Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

### **Professional societies**

- British Hip Society
- British Orthopaedic Association
- Royal College of Anaesthetists.

# **Description of the procedure**

#### Indications and current treatment

Osteoarthritis, also known as degenerative joint disease, is a disorder of synovial joints. It occurs when damage triggers repair processes leading to structural changes in a joint. There are 2 main types of osteoarthritis: primary (more generalised osteoarthritis with unknown aetiology) and secondary (osteoarthritis with a known cause, such as injury or inflammation in the joint). When it affects the hip, symptoms include joint stiffness, pain and reduced function, such as difficulty walking.

Care and management of osteoarthritis is described in <u>NICE's clinical guideline</u> on osteoarthritis. Current management of hip osteoarthritis includes lifestyle changes (such as weight loss), physical or occupational therapy, medications, and surgery (such as hip resurfacing, THA and osteotomy).

# What the procedure involves

Supercapsular percutaneously assisted THA is also described as the 'SuperPath' approach. It is a minimally invasive approach to THA. The aim, as with standard posterior or direct lateral approaches, is to reconstruct the hip to reduce symptoms and improve hip function, but with smaller cuts and less tissue damage.

The procedure is done under general or regional anaesthesia. The patient is usually put in the standard lateral decubitus position with the hip in 45 degrees of flexion and 10 to 15 degrees of internal rotation. A cut is made superior to the greater trochanter. The gluteal fascia is cut, the gluteus maximus muscle is split, the gluteus medius and minimus muscles are retracted anteriorly, and the piriformis tendon is retracted posteriorly. Once the joint capsule is exposed, it is cut from the base of the greater trochanter to 1 cm proximal to the acetabular rim. IP overview: Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

The femoral canal is then reamed and broached without dislocation. The femoral neck is osteotomised and the femoral head removed. The implant trial cup is placed into the acetabulum to allow access of instruments for its preparation. A second cut is made and using an external guide, a distal and posterior portal is then formed for acetabular reaming. Once the acetabulum is reamed, the definitive acetabular component and polyethylene liner are inserted and secured. Trial femoral components are reduced and tested for stability and tissue tension. Once the trial components are removed, the definitive femoral stem is inserted and the femoral head implanted. The hip joint capsule is preserved and closed with a suture. Then the gluteal fascia and skin are closed with sutures.

The procedure usually takes about 2 hours. Specific cementless implants and various specialised instruments are used. Postoperative rehabilitation is recommended for muscle strengthening and mobility.

#### **Outcome measures**

The Barthel Index consists of 10 items that measure a person's daily functioning, particularly the activities of daily living and mobility. The items include feeding, transfers from bed to wheelchair and to and from a toilet, grooming, walking on a level surface, going up and down stairs, dressing, and bowel and bladder continence. Scores range from 0 (totally dependent) to 100 (completely independent).

The HHS evaluates the results of hip arthroplasty. It covers pain (1 item, 0 to 44 points), function (7 items, 0 to 47 points), absence of deformity (1 item, 4 points), and ROM (2 items, 5 points). Scores range from 0 (maximum disability) to 100 (no disability).

The HOOS assesses the patient's opinion about their hip and associated problems, and evaluates symptoms and functional limitations related to the hip during a therapeutic process. It consists of 40 items assessing 5 subscales: pain, symptoms, activity limitations daily living, function in sport and recreation, and hip-related quality of life. Scores range from 0 (extreme symptoms) to 100 (no symptoms).

The HOS is a self-reported questionnaire, evaluating the outcomes of treatment for hip pathologies, divided into 2 subscales: activities of daily living (19 items) and sports (9 items). The activities of daily living and sports subscale scores are normalised to obtain a range between 0 and 100, with higher scores representing better function.

The Merle d'Aubigné Hip Score is a hip function evaluation instrument and includes the parameters for pain, mobility and ability to walk, with each rated from 0 (worst condition) to 6 (best condition).

The TUG test is a simple test that assesses a person's mobility and needs both static and dynamic balance. It uses the time that a person takes to rise from a chair, walk 3 meters, turn around 180 degrees, walk back to the chair and sit down while turning 180 degrees.

The TSC test is a measure of ability to ascend and descend a flight of stairs. It uses the time needed to go up and down a flight of 12 stairs.

The WOMAC is a disease-specific measure for hip and knee osteoarthritis. It consists of 24 items: 5 items about pain (score range 0 to 20), 2 items about stiffness (score range 0 to 8) and 17 items about physical functioning (score range 0 to 68). Higher scores on the WOMAC indicate worse pain, stiffness and functional limitation.

The iHOT-12 is a self-reported outcome used to evaluate quality of life in people with hip osteoarthritis. The questionnaire captures pain, symptoms and activity impairments. Scores range from 0 to 100, with lower scores representing greater impact.

The SF-12 is a self-reported outcome measure that assesses the impact of health on an individual's everyday life. It covers physical health-related domains (general health, physical functioning, role physical and body pain) and mental health-related scales (vitality, social functioning, role emotional and mental health). Scores range from 0 to 100, with higher scores indicating better physical and mental health functioning.

Safe zones for acetabular cup position, based on radiographs:

- Anteversion: 15 degrees ±10 degrees (Biedemann 2005; Lewinnek 1978),
   15 degrees ±15 degrees (Dorr 1983) or 30 degrees ±10 degrees
   (McCollum 1990)
- Abduction: 40 degrees ±10 degrees (Lewinnek 1978; McCollum 1990)
- Inclination: 35 degrees ±15 degrees (Dorr 1983), 40 degrees ±10 degrees (McCollum 1990; Lewinnek 1978) or 45 degrees ±10 degrees (Biedemann 2005)

# **Efficacy summary**

## Improvement in symptoms and functioning

#### HHS

In a randomised controlled trial of 92 patients with unilateral primary hip osteoarthritis, the mean HHS scores were statistically significantly higher in the SuperPath group than the conventional posterior group at 1 week (73.8±3.89 compared with 69±4.81, p=0.009), 1 month (81.4±3.18 compared with 76.8±2.93, p=0.000) and 3 months (87.6±1.76 compared with 80.1±4.49, p=0.000) postoperation but not at 1 year (92.3±1.62 compared with 91.6±2.41, p=0.26; Xie 2017).

In a randomised controlled trial of 40 patients with unilateral end-stage primary hip osteoarthritis, the mean HHS scores were higher in the SuperPath group than the posterolateral group at days 1, 3 and 14, and months 3, 6 and 12 after operation. However, the differences were not statistically significant:

- postoperative day 1: 62.50±10.07 compared with 60.11±6.46, p=0.443
- postoperative day 3: 66.44±9.03 compared with 63.50±7.17, p=0.293
- postoperative day 14: 72.27±8.33 compared with 70.66±6.22, p=0.339
- postoperative 3 months: 82.44±3.51 compared with 82.38±2.68, p=0.815
- postoperative 6 months: 87.77±3.47 compared with 87.55±3.56, p=0.839
- postoperative 12 months: 92.16±2.76 compared with 92.66±2.80, p=0.988.

Improvement in hip function reached its maximum plateau between 3 and 12 months in both groups (Meng 2021).

In a randomised controlled trial of 44 patients with unilateral non-inflammatory degenerative joint disease, the mean HHS was statistically significantly higher in the SuperPath group than the mini posterior group at 6 weeks after operation (78.6±9.18 compared with 68.8±15.1, p=0.01). At baseline, both groups were comparable in HHS (45.6±11.3 compared with 46±11, p=0.79; Korytkin 2021).

In a non-randomised comparative study of 90 patients with hip arthrosis, the mean HHS scores were comparable between patients who had THA using the SuperPath approach and patients who had THA using the posterior approach at 3 months (91.6±8.8 compared with 93.7±5.4, p=0.51), 6 months (90.2±12.8 compared with 92.4±9.3, p=0.21) and 1 year (98.2±2.0 compared with 96.2±5.6,

p=0.24) after surgery. When comparing with preoperative values, the mean HHS scores statistically significantly increased at 1 year in both groups (SuperPath, 48.8±7.1 at baseline compared with 98.2±2.0 at 1 year postoperation, p<0.001; posterior, 50.0±14.5 at baseline compared with 96.2±5.6 at 1 year postoperation, p<0.001; Mas Martinez 2019).

#### HOOS

In the randomised controlled trial of 44 patients, the mean HOOS score was statistically significantly higher in the SuperPath group than the mini posterior group at 6 weeks after operation (81.3±10.9 compared with 72.47±13.5, p=0.01). There was no statistically significant difference in preoperative HOOS score between the 2 groups (40.1±10.3 compared with 41.3±15.7, p=0.75; Korytkin 2021).

#### ROM

In the randomised controlled trial of 40 patients, the mean ROMs for flexion of the affected hip were statistically significantly lower in the SuperPath group than the posterolateral group at postoperative days 1, 3 and 14 (SuperPath, 107.66°, 109.83°, 111.66°; posterolateral, 114.44°, 116.11°, 118.88°; all p<0.05). The differences between the 2 groups at 3, 6 and 12 months were not statistically significant (SuperPath, 119.72°, 121.44°, 124.72°; posterolateral, 121.22°, 123.05°, 124.16°). There were no statistically significant differences in mean ROMs for abduction, adduction and external rotation between the 2 groups at all time points (all p>0.05; Meng 2021).

#### WOMAC function

In the non-randomised comparative study of 90 patients, the mean WOMAC function scores were not statistically significantly different between the SuperPath group and the posterior group at 3 months (85.4±12.6 compared with 79.7±14.6, p=0.24), 6 months (92.9±12.9 compared with 89.6±14.6, p=0.28) and 1 year (93.0±13.6 compared with 91.6±13.4, p=0.44) after operation. When comparing with preoperative values, the mean WOMAC function scores statistically significant increased at 1-year follow up in both groups (SuperPath, 31.8±13.8 at baseline compared with 93.0±13.6 at 1-year follow up, p<0.001; posterior, 39.5±14.7 at baseline compared with 91.6±13.4 at 1-year follow up, p<0.001; Mas Martinez 2019).

#### Merle d'Aubigné Hip Score

In the non-randomised comparative study of 90 patients, the mean Merle d'Aubigné hip scores were not statistically significantly different between the SuperPath group and the posterior group at 3 months (10.7±1.4 compared with 11.0±1.3, p=0.55), 6 months (10.1±2.1 compared with 10.6±1.4, p=0.41) and IP overview: Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

1 year (11.8±0.4 compared with 11.3±0.8, p=0.14) after operation. When comparing with preoperative values, statistically significant improvements were reported at 1 year in both groups (SuperPath, 5.1±1.8 at baseline compared with 11.8±0.4 at 1 year postoperation, p<0.001; posterior, 5.7±1.9 at baseline compared with 11.3±0.8 at 1 year postoperation, p<0.001; Mas Martinez 2019).

## Improvement in activities of daily living

#### HOS

In the non-randomised comparative study of 90 patients, the mean HOS scores for activities of daily living were not statistically significantly different between the SuperPath and posterior groups at 3 months (84.2±14.7 compared with 75.1±18.8, p=0.15), 6 months (82.3±17.7 compared with 80.5±19.7, p=0.77) and 1 year (89.8±13.1 compared with 84.2±18.0, p=0.42) after surgery. When comparing with preoperative values, the mean HOS scores for activities of daily living statistically significantly increased at 1-year follow up in both groups (SuperPath, 38.6±13.5 compared with 89.8±13.1, p<0.001; posterior, 39.2±13.1 compared with 84.2±18.0, p<0.001; Mas Martinez 2019).

#### **Barthel index**

In the randomised controlled trial of 92 patients, the mean Barthel index scores for activities of daily living were statistically significantly higher in the SuperPath group than the conventional posterior group at 1-week (70.67±9.47 compared with 64.46±7.70, p=0.000), 1-month (79.6±10.01 compared with 74.26±5.76, p=0.017) and 3-month (90.26±7.12 compared with 83.07±8.62, p=0.01) follow ups but not at 1-year follow up (94.33±6.90 compared with 93.60±8.74, p=0.334; Xie 2017).

# Change in TUG, TSC and gait velocity

In the randomised controlled trial of 92 patients, the mean TUG and TSC were statistically significantly shorter in the SuperPath group than the conventional posterior group at 1 week, 1 month and 3 months after surgery:

- 1 week: TUG, 2.06±1.43 minutes compared with 3.2±1.47 minutes, p=0.002; TSC, 5.34±1.85 minutes compared with 7.2±2.04 minutes, p=0.000
- 1 month: TUG, 1.33±0.36 minutes compared with 2.57±0.59 minutes, p=0.016; TSC, 2.56±0.78 minutes compared with 3.47±0.83 minutes, p=0.022

 3 months: TUG, 0.92±0.10 minutes compared with 1.2±0.23 minutes, p=0.036; TSC, 1.96±0.69 minutes compared with 2.21±0.55 minutes, p=0.041.

The differences were not statistically significant at 1 year between the 2 groups (TUG, 0.52±0.12 minutes compared with 0.58±0.09 minutes, p=0.70; TSC, 1.06±0.13 minutes compared with 1.09±0.19 minutes, p=0.55; (Xie 2017).

In the randomised controlled trial of 44 patients, preoperative gain velocity was 3.02±0.72 km/h in the SuperPath group compared with 2.92±0.85 km/h in the mini posterior group (p=0.66). At 6 weeks after operation, gain velocity was 3.00±0.92 km/h compared with 2.69±1.00 km/h (p=0.28). Comparison of the mean differences between preoperation and 6 weeks postoperation did not found statistically significant difference between the 2 groups (p=0.06; Korytkin 2021).

## Improvement in quality of life

#### **SF-12**

In the non-randomised comparative study of 90 patients, the mean SF-12 physical and mental scores were statistically significantly higher in the SuperPath group than the posterior group at 1 year after surgery (SF-12 physical, 88.6±10.5 compared with 79.0±13.5, p=0.04; SF-12 mental, 85.6±12.0 compared with 76.1±15.3, p=0.02). The differences at 3 and 6 months were not statistically significantly different:

- SF-12 physical score at 3 months: 82.4±13.7 compared with 85.5±13.5, p=0.95
- SF-12 mental score at 3 months: 82.7±12.4 compared with 81.8±14.2, p=0.92
- SF-12 physical score at 6 months: 85.5±13.6 compared with 86.3±13.0, p=0.50
- SF-12 mental score at 6 months: 84.7±15.4 compared with 82.6±14.4, p=0.57.

When comparing with preoperative values, the mean SF-12 physical and mental scores statistically significantly improved at 1-year follow up in both groups (SF-12 physical: SuperPath, 39.8±12.3 compared with 88.6±10.5, p<0.001; posterior, 41.7±12.6 compared with 79.0±13.5, p<0.001; SF-12 mental: SuperPath, 46.1±13.7 compared with 85.6±12.0, p<0.001; posterior, 47.6±14.7 compared with 76.1±15.3, p<0.001; Mas Martinez 2019).

#### iHOT-12

In the non-randomised comparative study of 90 patients, the mean iHOT-12 score was statistically significantly higher in the SuperPath group than the posterior group at 3 months postoperation (78.2±15.6 compared with 63.5±22.8, p=0.04) but not at 6 months (76.0±24.8 compared with 70.6±22.5, p=0.74) and 1 year (78.5±18.3 compared with 76.8±14.9, p=0.53). When comparing with preoperative values, the mean iHOT-12 scores statistically significant increased at 1 year in both groups (SuperPath, 15.2±15.1 at baseline compared with 78.5±18.3 at 1 year, p<0.001; posterior, 22.2±18.7 at baseline compared with 76.8±14.9 at 1 year, p<0.001; Mas Martinez 2019).

#### Implant position

In the randomised controlled trial of 92 patients, radiographic evaluation revealed that the mean cup anteversion angle was 17.4±1.6 degrees in the SuperPath group compared with 18.5±1.8 degrees in the conventional posterior group (p=0.23), and that the mean cup abduction angle was 43.6±6.8 degrees compared with 44.5±6.5 degrees (p=0.41). Stem alignment was neutral in 43% of patients in the SuperPath group and 44% in the conventional posterior group (p=0.21; Xie 2017).

In the randomised controlled trial of 40 patients, postoperative radiographs showed that the mean cup abduction angle in the SuperPath group was significantly smaller than the posterolateral group (36.94±6.37 degrees compared with 42.66±3.58 degrees, p=0.004) and that the mean cup anteversion angles between the groups were comparable (13.94±4.73 degrees compared with 15.11 ±4.06 degrees, p=0.501; Meng 2021).

In the randomised controlled trial of 44 patients, postoperative radiographs showed that the mean cup anteversion and inclination were 18° and 43° in the SuperPath group, and 19 degrees and 44 degrees in the mini posterior group. Stem alignment was neutral in 100% of patients in the SuperPath group and 96% in the mini posterior group. No statistically significant differences were reported between the 2 groups (Korytkin 2021).

In the non-randomised comparative study of 90 patients, there was no statistically significant difference in the mean angle of acetabular inclination between the SuperPath group and the posterior group at 3 months after surgery (47.6° compared with 45.9°, p=0.41). All the femoral stems were implanted in neutral position (Mas Martinez 2019).

In the non-randomised comparative study of 99 patients, postoperative radiographic outcomes showed that cups in the SuperPath group were statistically significantly more anteverted (23.5±8.2 degrees) and less abducted IP overview: Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

(39.0±8.4 degrees) than cups in the PATH group (13.1±7.1 degrees and 42.9±7.6 degrees, respectively; all p<0.05; Rasuli 2015).

In a case series of 150 patients with osteoarthritis of the hip, the mean inclination angle was 39.3 degrees (range 28 to 50 degrees) and there was no leg length difference more than 5 mm. The mean anteversion angle was 17.1 degrees (range 6.2 to 31.9 degrees, SD=4 degrees) measured at a standard supine anteroposterior pelvis view, and the position of the stem was 0.17 degrees varus (range 2.7 degrees valgus to 3.3 degrees varus, SD=0.9 degrees) measured between the stem axis and the long axis of the femur. There was no radiological loosening of the components after a mean follow up of 16 months (Qultmann 2019).

## Length of hospital stay

In the randomised controlled trial of 92 patients, the mean length of hospital stay was statistically significantly shorter in the SuperPath group than the conventional posterior group (8.3±3.6 days compared with 11.4±2.4 days, p=0.000; Xie 2017).

In the randomised controlled trial of 40 patients, the mean length of hospital stay was 3.00±0.00 days in the SuperPath group compared with 2.72±0.57 days in the posterolateral group (p=0.161; Meng 2021).

In the randomised controlled trial of 44 patients, the mean length of hospital stay was 8.85±1.66 days in the SuperPath group compared with 8.66±1.63 days in the mini posterior group (p=0.35; Korytkin 2021).

In a non-randomised comparative study of 99 patients with degenerative hip arthritis, the mean length of hospital stay was statistically significantly shorter for patients who had THA using the SuperPath approach than patients who had THA using the PATH approach (2.2±0.9 days compared with 3.0±0.8 days, p<0.0001; Rasuli 2015).

In the case series of 150 patients, the length of stay at hospital was 9.9 days because of the regulations of the hospital and most of patients were able to go home earlier (Qultmann 2019).

# Postoperative pain

In the randomised controlled trial of 92 patients, the mean VAS scores (a scale of 0 [no pain] to 10 [worst imaginable pain]) were statistically significantly lower for patients who had THA using the SuperPath approach than patients who had THA using the conventional posterior approach at 1 week  $(4.86\pm0.83$  compared with  $6.53\pm0.52$ , p=0.000) 1 month  $(2.6\pm0.82$  compared with  $3.4\pm0.63$ , p=0.009) and

3 months (1.4 $\pm$ 0.63 compared with 1.87 $\pm$ 0.74, p=0.048) postprocedure. The difference in pain was not statistically significant at 1 year between the 2 groups (0.87 $\pm$ 0.51 compared with 0.97 $\pm$ 0.35, p=0.16; Xie 2017).

In the randomised controlled trial of 40 patients, the mean VAS score was statistically significantly higher for patients who had THA using the SuperPath approach than patients who had THA using the posterolateral approach at postoperative day 3 (7.05±0.72 compared with 6.55±0.70, p=0.041). However, the differences between the 2 groups at postoperative day 1 (7.38±0.77 compared with 6.94±0.72, p=0.097), day 14 (5.00±1.02 compared with 4.44±0.92, p=0.097), month 3 (1.77±0.80 compared with 1.55±0.85, p=0.372), month 6 (0.66±0.68 compared with 0.72±0.57, p=0.743) and month 12 (0.05±0.23 compared with 0.11±0.32, p=0.791) were not statistically significant. In both groups, pain VAS reached its minimum plateau between 3 and 12 months postoperatively (Meng 2021).

In the randomised controlled trial of 44 patients, the mean VAS score was statistically significantly lower for patients who had THA using the SuperPath approach than patients who had THA using the posterolateral approach at 6 weeks postoperation (0.85±0.58 compared with 1.87±1.2, p=0.001). There was no statistically significant difference between the 2 group preoperatively (5.7±2.03 compared with 5.4±1.81, p=0.63; Korytkin 2021).

In the non-randomised comparative study of 90 patients, the mean WOMAC pain scores were not statistically significantly different between the SuperPath and posterior groups at 3-month (87.2±14.1 compared with 85.8±16.1, p=0.49), 6-month (96.2±12.5 compared with 92.7±12.9, p=0.57) and 1-year (97.0±11.6 compared with 91.2±12.8, p=0.42) follow ups. When comparing with preoperative values, pain was statistically significant worse at 1-year follow up in both groups (SuperPath, 38.2±14.6 at baseline compared with 97.0±11.6 at 1 year postoperation, p<0.001; posterior, 41.3±12.9 at baseline compared with 91.2±12.8 at 1 year postoperation, p<0.001; Mas Martinez 2019).

# Safety summary

#### Dislocation or subluxation

Dislocation was reported in 1 patient who had THA using the SuperPath approach at 1-week follow up and 2 patients who had THA using the conventional posterior approach at 2-week follow up in the randomised controlled trial of 92 patients (Xie 2017).

Subluxation was reported in 2 patients in the case series of 150 patients and for both patients, there was no complete dislocation because the head was captured IP overview: Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

by the closed capsule. For 1 patient, subluxation happened 3 weeks after the surgery during elevated sitting and this event related to the surgical technique. The patient had a closed reduction and was doing fine at 1 year after the surgery. For the other patient, subluxation happened in the operating room after turning the patient onto the back. This needed immediate exchange of the head to a longer one. The patient walked without crutches after a few days and had no complaints (Qultmann 2019).

#### **Fracture**

Intraoperative femoral calcar fracture was reported in 1 patient in each group in the non-randomised comparative study of 99 patients who had THA using either SuperPath or PATH technique. For the patient in the SuperPath group, the femoral calcar fracture was treated with extension of the skin incision, piriformis release and cerclage wiring. For the patient in the PATH group, the fracture of the femoral calcar was treated with extension of the skin incision and cerclage wiring. For both patients, postoperative weight bearing was permitted without incident (Rasuli 2015).

Intraoperative acetabular fracture was reported in 1 patient who had THA using the SuperPath approach in the non-randomised comparative study of 90 patients. The patient who had teriparatide for osteoporosis experienced this event while the cup component was being impacted. The external rotators were removed and the approach was converted to a conventional posterior approach. Given that osseous acetabular circumferential stability existed, a cemented stem was implanted. At 12-month follow up, evolution was satisfactory, with an HHS score of 82 and a Merle d'Aubigné hip score of 10 (Mas Martinez 2019).

Femoral diaphyseal fracture was reported in 1 patient at 4 weeks postoperation in the case series of 150 patients. The patient was retransferred from the rehabilitation clinic and needed cerclage wiring of the femur and exchange of the stem (Qultmann 2019).

# Implant revision

Profemur L Modular Stem: revision was reported in 5% (210/4,233) of primary THA procedures in which Profemur L Modular Stem was used in a NJR implant study of 433,020 patients with osteoarthritis, rheumatoid arthritis, avascular necrosis, fractured neck of femur, CDH/DDH or other indications. When comparing with the number of expected revisions for procedures in which all NJR cementless stems were used, adjusted for age, gender, indications and implantation year, the number of actual revisions for procedures using Profemur L Modular Stem (all bearing types) was statistically significantly higher (210 actual revision compared with 176.14 expected revisions, p=0.012).

Analysis of the reasons for revision showed statistically significant differences in implant fracture stem (13 actual revisions compared with 2.58 expected revisions, p<0.001), dislocation or subluxation (38 actual revisions compared with 23.99 expected revisions, p=0.007), infection (37 actual revisions compared with 21.60 expected revisions, p=0.002) and malalignment stem (11 actual revisions compared with 5.05 expected revisions, p=0.02; NJR 2020b).

**Procotyl L Cup**: revision was described in 3% (187/6,568) of primary THA procedures in which Procotyl L Cup was used in a NJR implant study of 683,939 patients with osteoarthritis, rheumatoid arthritis, avascular necrosis, fractured neck of femur, CDH/DDH or other indications. There was no statistically significant difference between the number of actual revisions for procedures using Procotyl L cup (all bearing types) and the number of expected revisions for procedures using all NJR cementless cups, adjusted for age, gender, indications and implantation year (187 actual revisions compared with 179.45 expected revisions, p=0.574). When considering the reasons for revision, statistically significant differences were reported in adverse soft tissue reaction (11 actual revisions compared with 25.05 expected revisions, p=0.003), infection (38 actual revisions compared with 27.02 expected revisions, p=0.042) and implant fracture stem (19 actual revisions compared with 3.27 expected revisions, p<0.001; NJR 2020c).

**Profemur L Classic Stem**: revision was reported in more than 1% (11/829) of primary THA procedure in which Profemur L Classic Stem was used in a NJR implant study of 432,625 patients with osteoarthritis, rheumatoid arthritis, avascular necrosis, fractured neck of femur, CDH/DDH or other indications. The difference was not statistically significant between the number of actual revisions for procedures using Profemur L Classic Stem and the number of expected revisions for procedures using all NJR cementless stems, adjusted for age, gender, indications and implantation year (11 actual revisions compared with 8.56 expected revisions, p=0.388; NJR 2020a).

# Other complications

#### Wound dehiscence

Wound dehiscence was described in 1 patient at postoperative day 8 in the case series of 150 patients and the patient had a new skin closure. This event related to a new skin suture technique but not to the SuperPath technique (Qultmann 2019).

#### Progressive pain

Progressive pain in the buttock on the affected side was reported in 1 patient who had THA using the SuperPath approach at 6 months postoperation in the non-randomised comparative study of 90 patients. Complete radiolucency of the stem without implant mobilisation was detected in the radiological control, and the patient was pending surgical revision (Mas Martinez 2019).

#### Anaemia

Anaemia (haemoglobin 74 g/litre) was found in 1 patient who had THA using the SuperPath approach after returning to hospital following discharge complaining of fatigue in the non-randomised comparative study of 99 patients. The patient had a blood transfusion and subsequently developed an acute haemolytic transfusion reaction. However, the patient recovered with supportive care (Rasuli 2015).

#### Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened).

For this procedure, professional experts listed the following anecdotal adverse events: acetabular reamer breakage and calcar fracture. They considered that the following were theoretical adverse events: intraoperative fracture, postoperative subsidence of implants and other adverse events that are similar to standard hip replacement.

### The evidence assessed

# Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis. The following databases were searched, covering the period from their start to 28 June 2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the <a href="literature search strategy">literature search strategy</a>). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The <u>inclusion criteria</u> were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

#### Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies.
	Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.
	Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with osteoarthritis of the hip.
Intervention/test	Supercapsular percutaneously assisted THA (SuperPath).
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

#### List of studies included in the IP overview

This IP overview is based on 525 patients from 3 randomised controlled trials (Korytkin 2021; Meng 2021; Xie 2017), 2 non-randomised comparative studies (Rasuli 2015; Mas Martinez 2019) and 1 case series (Qultmann 2019). This overview also includes 3 implant summary reports for the Profemur L Modular Stem, Profemur L Classic Stem and Procotyl L Cup from the NJR (NJR 2020a, 2020b, 2020c).

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

# Summary of key evidence on supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

# **Study 1 Xie J (2017)**

#### Study details

Study type	Randomised controlled trial
Country	China (single centre)
Recruitment period	2015 to 2016
Study population	n=92 (SuperPath, n=46; conventional posterior, n=46)
and number	Patients with unilateral primary hip osteoarthritis
Age and sex	SuperPath group: mean 66.6 years; 74% (34/46) male; BMI, mean 23.62±1.63 kg/m²
	Conventional posterior group: mean 64.5 years; 59% (27/46) male; BMI, mean 24.06±2.72 kg/m²
Patient selection	Inclusion criteria: patients with unilateral primary hip osteoarthritis.
criteria	Exclusion criteria: femoral neck fracture, severe acetabular defect, metastatic disease, and overweight patients with a body mass index over 40.
Technique	The SuperPath approach (MicroPort Orthopedics Inc., Arlington, TN, USA) was done in 1 group and the conventional posterior approach (Moore approach) in another group. All patients were implanted with the same cementless THA implants (such as acetabular component, acetabular liner, femoral component and femoral head).
Follow-up	1 year
Conflict of	Conflict of interest: none
interest/source of funding	Funding: This study was supported by the Health Science and Technology Special Projects Foundation of Zhenjiang, Jiangsu Province (SHW2016005).

#### **Analysis**

Follow-up issues: Patients were followed up in the same rehabilitation unit at 1 week, 1 month, 3 months and 1 year after operation.

Study design issues: This prospective, randomised controlled trial compared the SuperPath approach with the conventional posterior approach, in terms of the early outcomes and radiological results. This study was carried out according to the 'CONSORT statement' guidelines for randomised controlled trials. All surgeries were done by one senior orthopaedic chief surgeon.

Functional outcomes were evaluated using the following measures: HHS, Barthel index, VAS for pain level, TUG and TSC. Other results included incision length, blood loss, skin-to-skin operative time, length of stay, and complication rates. All analyses were based on the intention-to-treat group and per-protocol group. And

the result of the intention-to-treat analysis would be compared with that of the per-protocol analysis to check whether the results were consistent.

Study population issues: At baseline, there was no statistically significant difference in terms of age, sex, BMI, VAS, HHS and Barthel index.

Other issues: There were several limitations, including small sample size, short-term follow up, patients not being blinded for the approach chose. There was no information relating to the comparison of the results based on intention-to-treat analysis with that of the per-protocol analysis for consistency as planned.

# **Key efficacy findings**

Number of patients analysed: 92

#### **Perioperative outcomes**

	SuperPath (n=46)	Conventional posterior (n=46)	P value
Operation time, minutes	103.6±11.8	106.5±16.5	0.53
Incision length, cm	7.4±1.06	14.5±2.38	0.000
Blood loss, ml	303.6±106.3	326.4±127.2	0.11
Transfusion rate	4.3% (n=2)	11% (n=5)	0.24
Length of stay, days	8.3±3.6	11.4±2.4	0.000

All patients were assessed according to their ability to walk weight bearing as tolerated on the first postoperative day. All the patients in the SuperPath group mobilised without restriction while the conventional posterior group mobilised with hip precautions for 4 weeks.

## **Pre- and Post-operative outcomes**

	Follow-up time	SuperPath	Conventional posterior	P value
VAS	Baseline	7.62±1.63	7.06±1.72	0.53
	1 week	4.86±0.83	6.53±0.52	0.000
	1 month	2.6±0.82	3.4±0.63	0.009
	3 months	1.4±0.63	1.87±0.74	0.048
	1 year	0.87±0.51	0.97±0.35	0.16
TUG, minutes	1 week	2.06±1.43	3.2±1.47	0.002
	1 month	1.33±0.36	2.57±0.59	0.016
	3 months	0.92±0.10	1.2±0.23	0.036
	1 year	0.52±0.12	0.58±0.09	0.70
TSC, minutes	1 week	5.34±1.85	7.2±2.04	0.000
	1 month	2.56±0.78	3.47±0.83	0.022
	3 months	1.96±0.69	2.21±0.55	0.041
	1 year	1.06±0.13	1.09±0.19	0.55
HHS	Baseline	28.9±11.32	29.3±17.40	0.40
	1 week	73.8±3.89	69±4.81	0.009
	1 month	81.4±3.18	76.8±2.93	0.000
	3 months	87.6±1.76	80.1±4.49	0.000
	1 year	92.3±1.62	91.6±2.41	0.26
Barthel index	Baseline	68.9±8.35	65.3±7.64	0.13
	1 week	70.67±9.47	64.46±7.70	0.000
	1 month	79.6±10.01	74.26±5.76	0.017
	3 months	90.26±7.12	83.07±8.62	0.01
	1 year	94.33±6.90	93.60±8.74	0.334

# Radiological evaluation of the position of the implants

	SuperPath	Conventional posterior	P value
Cup abduction angle, °	43.6±6.8	44.5±6.5	0.41
Cup anteversion angle, °	17.4±1.6	18.5±1.8	0.23
Stem alignment neutral, °	43	44	0.21
Varus, °	2	1	0.62
Valgus, °	1	1	-

If the angle was under 1° valgus or varus, it was considered as good.

# **Key safety findings**

None of the patients had fractures, postoperative infection, nerve damage or heterotopic ossification. No significant postoperative complications were reported in either group.

#### SuperPath group:

Dislocation after 1 week: n=1

#### Conventional posterior group:

Deep venous thrombosis: n=1

Dislocation after 2 weeks: n=2

At the 1-year follow-up, no prosthesis was loosened or subsided.

# Study 2 Meng WK (2021)

#### Study details

Study type	Randomised controlled trial			
Country	China			
Recruitment period	2017 to 2018			
Study population	n=40 (SuperPath, n=20; posterolateral THA, n=20)			
and number	Patients with unilateral end-stage primary hip osteoarthritis			
Age and sex	SuperPath group: mean 64.55 years; 40% (8/20) male; BMI, mean 23.26±2.55 kg/m <sup>2</sup>			
	Posterolateral group: mean 65.25 years; 45% (9/20) male; BMI, mean 22.82±2.61 kg/m²			
Patient selection criteria	Inclusion criteria: patients had unilateral end-stage primary hip osteoarthritis, provided signed consent for implanting and agreed to complete the scheduled postoperative 12-month follow-up.			
	Exclusion criteria: patients had non-inflammatory degenerative joint diseases (e.g., osteonecrosis, bilateral osteoarthritis, and post-traumatic arthritis), inflammatory joint diseases (e.g., reactive arthritis, ankylosing spondylitis, rheumatoid arthritis, and gout), inadequate neuromuscular status (e.g., previous paralysis and inadequate abductor strength), and overt infections or distant foci of infections.			
Technique	SuperPath and mini-incision posterolateral THA were done with specific prostheses (SuperPath group: Microport Orthopaedics, Arlington, TN, USA; posterolateral group: DePuy Synthes, Warsaw, IN, USA).			
	Standardised postoperative care was provided, including infection prophylaxis, venous thromboembolism prevention, nausea and vomiting management, wound care and functional rehabilitation.			
Follow-up	12 months			
Conflict of interest/source of funding	Funding: Research funding and support was provided by the National Health and Family Planning Commission of the People's Republic of China (No. 201302007) and the Sichuan Science and Technology Support Project (No. 2018SZ0145 and No. 2018SZYZF000). WKM received financial support from the China Scholarship Council.			
	Conflict of interest:  • LG: a section editor of Annals of Translational Medicine.  • Other authors: no conflicts of interest.			

### **Analysis**

Follow-up issues: Patients were followed up at postoperative days 1, 3 and 14, and then at 3, 6, and 12 months after surgery. No patients were lost to follow up or stopped the intervention.

Study design issues: This prospective, double-blind, randomised controlled trial compared the short-term outcomes between SuperPath and mini-incision posterolateral THA for patients with unilateral end-stage primary osteoarthritis. The hypothesis was that SuperPath would yield superior outcomes for osteoarthritis IP overview: Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

patients compared to posterolateral THA, with better perioperative status and improved postoperative function. This study was conducted according to the principles of the Declaration of Helsinki and presented in accordance with the CONSORT reporting checklist.

All surgical procedures were completed by the same team, led by a senior surgeon specialising in lower limb reconstruction, with over 15 years' experience doing primary and revision THA (over 250 cases annually). To minimise the influence of a learning curve, the senior surgeon had done more than 50 SuperPath cases prior to the present trial. Patients were randomised to each group, using a shuffled deck of cards (even: SuperPath, odd: posterolateral).

Postoperative rehabilitation: Both groups had an identical rehabilitation program, which was delivered by an experienced physical therapist who received extensive training in managing postoperative hip conditions before this study. The physical therapist was blinded to the patient allocation. Briefly, immediate hip flexion, pneumatic compression with foot pumps, and deep breathing exercises were emphasized to minimise thromboembolic and pulmonary complications. After obtaining written approval from the physical therapist, patients began indoor walking independently with a tolerated weight bearing. Patients were educated in self-care and home-based rehabilitation before discharge. They were instructed to walk daily and to gradually increase their walking distance toward a goal of 2 km/day.

Study population issues: At baseline, there was no statistically significantly difference between the 2 groups in terms of age, sex, BMI, comorbidities and American Society of Anaesthesiologist grade.

Other issues: The sample size was relatively limited without a power analysis done in the research planning phase, and the postoperative follow-up was short. The extent of muscle damage was only assessed with serum markers within 2 weeks postoperatively, while no radiographic analyses were done to confirm perioperative alterations of these serum markers.

# **Key efficacy findings**

Number of patients analysed: 40

All patients were discharged at postoperative day 3 and allowed to walk with a cane.

## Perioperative data, mean (SD)

	SuperPath (n=20)	Posterolateral (n=20)	P value
Incision length, cm	7.83 (1.12)	12.45 (1.71)	<0.001
Operative time, minutes	102.72 (13.55)	66.22 (11.59)	<0.001
Blood loss, mL	1,007.38 (174.22)	844.55 (161.16)	0.005
Length of stay, days	3.00 (0.00)	2.72 (0.57)	0.161
Transfusion rate	0	0	n/a
Readmission within 12 months postoperatively, n (%)	0	0	n/a
Reoperation with 12 months postoperatively, n (%)	0	0	n/a

# Radiological evaluation of acetabular cup positioning on postoperative day 1, mean (SD)

Variable	SuperPath (n=20)	Posterolateral (n=20)	P value
Abduction angle, °	36.94 (6.37)	42.66 (3.58)	0.004
Anteversion angle, °	13.94 (4.73)	15.11 (4.06)	0.501

# Preoperative and postoperative ROM (°), pain VAS and HHS within 12 months postoperatively, mean (SD)

Variable	Time point	SuperPath (n=20)	Posterolateral (n=20)	P value
Flexion	Preoperative	90.33 (14.11)	89.61 (11.81)	0.815
	Postoperative day 1	107.66 (7.87)	114.44 (4.81)	0.004
	Postoperative day 3	109.83 (6.54)	116.11 (4.39)	0.002
	Postoperative day 14	111.66 (6.18)	118.88 (3.23)	<0.001
	Postoperative 3 months	119.72 (5.80)	121.22 (3.65)	0.501
	Postoperative 6 months	121.44 (4.52)	123.05 (5.97)	0.628
	Postoperative 12 months	124.72 (5.27)	124.16 (7.12)	0.481
Abduction	Preoperative	21.94 (10.86)	23.05 (9.09)	0.521
	Postoperative day 1	28.61 (5.89)	29.44 (5.65)	0.584
	Postoperative day 3	28.88 (5.82)	30.55 (5.65)	0.323
	Postoperative day 14	31.38 (4.79)	32.77 (4.27)	0.339
	Postoperative 3 months	34.44 (4.16)	35.27 (3.19)	0.521
	Postoperative 6 months	36.11 (4.39)	36.66 (3.42)	0.767
	Postoperative 12 months	38.61 (4.13)	38.33 (2.97)	0.815

Adduction	Preoperative	16.75 (3.95)	14.75 (4.11)	0.521
	Postoperative day 1	15.75 (0.96)	15.50 (1.00)	0.767
	Postoperative day 3	18.25 (1.25)	18.75 (1.50)	0.628
	Postoperative day 14	21.25 (2.50)	22.25 (0.96)	0.938
	Postoperative 3 months	23.50 (2.38)	24.00 (1.41)	0.888
	Postoperative 6 months	26.00 (1.41)	24.50 (3.70)	0.424
	Postoperative 12 months	26.75 (2.36)	27.25 (4.35)	0.791
External rotation	Preoperative	21.00 (4.55)	20.75 (3.10)	0.815
	Postoperative day 1	21.00 (7.26)	22.25 (3.30)	0.791
	Postoperative day 3	23.50 (5.97)	24.25 (2.99)	0.888
	Postoperative day 14	27.25 (3.20)	26.75 (2.36)	0.988
	Postoperative 3 months	30.75 (2.63)	30.50 (2.38)	0.767
	Postoperative 6 months	33.25 (0.96)	34.50 (3.11)	0.424
	Postoperative 12 months	37.75 (2.63)	36.25 (4.79)	0.696
Pain VAA	Preoperative	7.61 (0.77)	7.38 (0.60)	0.443
	Postoperative day 1	7.38 (0.77)	6.94 (0.72)	0.097
	Postoperative day 3	7.05 (0.72)	6.55 (0.70)	0.041
	Postoperative day 14	5.00 (1.02)	4.44 (0.92)	0.097
	Postoperative 3 months	1.77 (0.80)	1.55 (0.85)	0.372
	Postoperative 6 months	0.66 (0.68)	0.72 (0.57)	0.743
	Postoperative 12 months	0.05 (0.23)	0.11 (0.32)	0.791
HHS	Preoperative	45.61 (12.77)	43.44 (12.91)	0.521
	Postoperative day 1	62.50 (10.07)	60.11 (6.46)	0.443
	Postoperative day 3	66.44 (9.03)	63.50 (7.17)	0.293
	Postoperative day 14	72.27 (8.33)	70.66 (6.22)	0.339
	Postoperative 3 months	82.44 (3.51)	82.38 (2.68)	0.815
	Postoperative 6 months	87.77 (3.47)	87.55 (3.56)	0.839
	Postoperative 12 months	92.16 (2.76)	92.66 (2.80)	0.988

# Changes in pain VAS and HHS within 12 months after operation

Comparisons between assessment time	VAS		HHS	
points	SuperPath	Posterolateral	SuperPath	Posterolateral
Preoperative compared with postoperative day 1	0.974	0.477	<0.001	<0.001
Preoperative compared with postoperative day 3	0.295	0.009	<0.001	<0.001

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Preoperative compared with postoperative day 14	<0.001	<0.001	<0.001	<0.001
Preoperative compared with postoperative 3 months	<0.001	<0.001	<0.001	<0.001
Preoperative compared with postoperative 6 months	<0.001	<0.001	<0.001	<0.001
Preoperative compared with postoperative 12 months	<0.001	<0.001	<0.001	<0.001
Postoperative day 1 compared with postoperative day 3	0.837	0.636	0.757	0.751
Postoperative day 1 compared with postoperative day 14	<0.001	<0.001	0.007	<0.001
Postoperative day 1 compared with postoperative 3 months	<0.001	<0.001	<0.001	<0.001
Postoperative day 1 compared with postoperative 6 months	<0.001	<0.001	<0.001	<0.001
Postoperative day 1 compared with postoperative 12 months	<0.001	<0.001	<0.001	<0.001
Postoperative day 3 compared with postoperative day 14	<0.001	<0.001	0.310	0.033
Postoperative day 3 compared with postoperative 3 months	<0.001	<0.001	<0.001	<0.001
Postoperative day 3 compared with postoperative 6 months	<0.001	<0.001	<0.001	<0.001
Postoperative day 3 compared with postoperative 12 months	<0.001	<0.001	<0.001	<0.001
Postoperative day 14 compared with postoperative 3 months	<0.001	<0.001	0.004	<0.001
Postoperative day 14 compared with postoperative 6 months	<0.001	<0.001	<0.001	<0.001
Postoperative day 14 compared with postoperative 12 months	<0.001	<0.001	<0.001	<0.001
Postoperative 3 months compared with postoperative 6 months	<0.001	0.009	0.420	0.267
Postoperative 3 months compared with postoperative 12 months	0.001	<0.001	0.004	<0.001
Postoperative 6 months compared with postoperative 12 months	0.193	0.127	0.542	0.280

# **Key safety findings**

No postoperative complications in either group.

# Study 3 Korytkin AA (2021)

#### Study details

Study type	Randomised controlled trial
Country	Russia (single centre)
Recruitment period	2018 to 2019
Study population	n=44 (SuperPath, n=20; mini posterior, n=24)
and number	Patient with non-inflammatory degenerative joint disease
Age and sex	SuperPath group: mean 56.75 years; 50% (10/20) male; BMI, mean 28.2 kg/m <sup>2</sup>
	Mini posterior group: mean 56.96 years; 46% (11/24) male; BMI, mean 29.04 kg/m <sup>2</sup>
Patient selection criteria	Inclusion criteria: patients had unilateral hip disease, were included if they were more than 20 years of age, with non-inflammatory degenerative joint disease, if they were able and available to attend follow up and were willing to sign the informed consent form.
	Exclusion criteria: BMI more than 40 kg/m², rapid disease progression and neuromuscular diseases.
Technique	Cementless acetabular component Dynasty® PC Shell and femoral component Profemur Z classic femoral stem with a cobalt chrome femoral head on Ultra high molecular weight Dynasty A-class poly liner (MicroPort Orthopedics, Inc. Arlington, TN, USA) were used. A 32-mm diameter head was used in 19 cases and 28-mm in 1 case of the SuperPath group, whereas in the mini posterior group, the 32-mm head was used in 23 cases and the 28-mm in 1 case.
	Patients were weight-bearing as tolerated on the day of surgery regardless of approach. Patients in the mini posterior group were given standard postoperative precautions to prevent dislocation, whereas the SuperPath group was not given any restrictions.
Follow-up	6 weeks
Conflict of interest/source of	Funding: The study was supported by MicroPort Orthopedics Inc. (Grant Number 04.02 T003).
funding	Conflict of interest: none.

#### **Analysis**

Follow-up issues: Forty-nine patients met the inclusion criteria and had surgery using one of the 2 approaches (22 in the SuperPath group and 27 in the mini posterior group). In the SuperPath group, 2 patients were lost to follow up. In the MPA group, 3 patients were not available: 2 patients chose not to participate, 1 patient was still using a walking aid at 6 weeks follow up.

Study design issues: This prospective, randomised clinical trial tested the hypothesis that patients having THA using the SuperPath technique would achieve improved gait parameters with better functional and clinical results than patients operated on using the mini posterior approach. This trial also evaluated patients' hip kinetics and kinematic changes in walking performance. Two unbiased biostatisticians, blinded to patient

attribution and outcome, did the statistical work. Gait analysis was done by an independent researcher with expertise in such an analysis, who was blinded to patients' allocation, at the clinic biomechanical laboratory.

Based on the time to stopping use of a walking aid using mini posterior approach as 28.5 days, the total sample size of 52 patients (26 patients per group) with the probability of alpha errors at 0.05, with a power of 0.80 is sufficient to detect differences between groups. Patients who met the inclusions criteria were randomly assigned to either the mini posterior or SuperPath group according to a computed randomisation list, with numbered and sealed envelopes opened before the operation.

All procedures were done by a fellowship-trained surgeon. Early postoperative rehabilitation was the same for both groups and was done by the same physiotherapy team at the same institution and started the first day after surgery. Upon discharge, patients were advised to resume activities as they could tolerate.

Study population issues: At baseline, there was no statistically significantly difference between the 2 groups in terms of age, sex, BMI, disease duration, and VAS, HHS and HOOS scores.

Limitations: This study had a short-term follow up, patients were not blinded to the approach, and gain parameters were collected in the sagittal plane only (frontal and transversal planes were not included for comprehensive analysis).

## **Key efficacy findings**

Number of patients analysed: 44

Incision length: range 7 to 11 cm.

#### Surgical outcomes, mean±SD (range)

Variable	SuperPath (n=20)	Mini posterior (n=24)	P value
Operation time, minutes	63.2±9.87 (50 to 80)	61.7±14.1 (40 to 90)	0.33
Estimated blood loss, ml	177.5±54.95 (100 to 300)	204.16±83.29 (50 to 450)	0.1
Haemoglobin (g/ml)			
Preoperative	136.3±15.19 (110 to 166)	139.29±18.93 (106 to 173)	0.56
Postoperative day 5	110.15±14 (81 to 138)	117±18.85 (90 to 154)	0.17
Haematocrit, %			
Preoperative	42±3.87 (35 to 52.6)	41.19±6.13 (28.2 to 52.3)	0.56
Postoperative day 5	32.89±4.51 (24.1 to 43.6)	35.2±5.91 (27 to 46.7)	0.14
Hospital stay, days	8.85±1.66 (5 to 13)	8.66±1.63 (6 to 13)	0.35
Stay after operation, days	6.2±1.28 (3 to 8)	6.1±1.55 (3 to 11)	0.39

# Radiological evaluation of implant position

Variable	SuperPath (n=20)	Mini posterior (n=24)	P value
Cup anteversion, mean (range)	ge) 18° (range 16° to 21°) 19° (range 16° to 24°) All		All p>0.05
Cup inclination, mean (range)	elination, mean (range) 43° (range 32° to 48°) 44° (range 31° to 49°)		
Stem alignment			
Neutral	100%	96%	
>2º in varus		4%	

## Clinical and functional outcomes, mean±SD

Variable	Follow-up time	SuperPath	Mini posterior	P value
VAS	Preoperatively	5.7±2.03	5.4±1.81	0.63
	6 weeks	0.85±0.58	1.87±1.2	0.001
HHS	Preoperatively	45.6±11.3	46±11	0.79
	6 weeks	78.6±9.18	68.8±15.1	0.01
HOOS	Preoperatively	40.1±10.3	41.3±15.7	0.75
Symptoms		44.5±11.2	46.8±16.6	0.57
Pain		46±11.3	43.3±18.3	0.55
FDL (function – daily living)		43.1±12.1	44.6±18.8	0.06
FSR (function – sport and recreational activities)		26.8±21.9	32±25.7	0.47
Quality of life		20±12.4	25±19.7	0.31
HOOS	6 weeks	81.3±10.9	72.47±13.5	0.01
Symptoms		86.7±10.3	79.8±12.2	0.04
Pain		89.1±9.7	80.4±15.3	0.02
FDL (function – daily living)		80.4±11.9	71.7±15.3	0.04
FSR (function – sport and recreational activities)		80.3±21.7	74±27.3	0.39
Quality of life		60.3±17.9	45.05±23.6	0.01

Overall, all the patients were satisfied with the results.

# Spatio-temporal parameters of gait

Parameter	SuperPath	Mini posterior	P value
Gait velocity, km/h			
Preoperatively	3.02±0.72	2.92±0.85	0.66
6 weeks	3.00±0.92	2.69±1.00	0.28
Stance phase, %			
Preoperatively	65.13±5.25	65.63±4.27	0.73

6 weeks	66.01±4.20	68.36±6.17	0.14
Swing phase, %			
Preoperatively	34.01±5.78	34.37±4.27	0.82
6 weeks	33.99±4.20	31.64±6.17	0.14
Double step length			
Preoperatively	1.00±0.19	1.01±0.22	0.84
6 weeks	1.03±0.22	0.94±0.26	0.26
ROM hip			
Preoperatively	25.66±6.74	27.26±8.01	0.47
6 weeks	26.29±5.46	25.79±6.20	0.77
ROM knee			
Preoperatively	51.95±8.66	50.88±9.21	0.69
6 weeks	51.59±9.70	48.58±10.28	0.32
ROM ankle			
Preoperatively	24.99±6.70	24.82±4.08	0.92
6 weeks	26.07±6.22	27.12±4.83	0.53

Comparison of the mean differences in gait velocity between preoperative and the 6 weeks postoperative outcomes, revealed improvement in the SuperPath group over the mini posterior group (p=0.06).

For kinematics, flexion/extension ROM, hip joint excursion statistically significantly improved in the SuperPath group, compared to the mini posterior group (p=0.04). Knee joint excursion consequently improved for the SuperPath group (p=0.31).

#### Stance phase before and after the operation

Parameter	SuperPath		ter SuperPath Mini posterior			
	Involved side	Contralateral side	P value	Involved side	Contralateral side	P value
Preoperation	65.13%±5.25%	69.36%±4.46%	0.009	65.63%±4.27%	68.89%±3.93%	0.01
6 weeks after the operation	66.01%±4.2%	68.47%±5.35%		68.36%±6.17%	70.95%±8.35	

# **Key safety findings**

No major complications were seen in either group.

## Study 4 Rasuli KJ (2015)

#### Study details

Study type	Non-randomised comparative study
Country	Canada (single centre)
Recruitment	SuperPath: 2013 to 2014
period	PATH: 2009 to 2011
Study population	n=99 (SuperPath, n=50; PATH, n=49)
and number	Patients with degenerative hip arthritis
Age and sex	SuperPath group: mean 68.1 years; 38% male; BMI, mean 29.4 kg/m²
	PATH group: mean 68.2 years; 47% male; BMI, mean 29.6 kg/m²
Patient selection criteria	Inclusion criteria: patients had a diagnosis of degenerative hip arthritis, failed nonoperative therapy, and were candidates for THA.
	Exclusion criteria: patients presented with a femoral neck fracture, severe acetabular defect likely to need grafting or augmentation, metastatic disease, or had simultaneous bilateral procedures.
Technique	SuperPath and PATH techniques were used.
Follow-up	SuperPath: mean 7.9 months
	PATH: mean 24.7 months
Conflict of	WG: Active consultant for Microport, receiving fees for technique training.
interest/source of funding	RKJ: no conflicts of interest to declare

#### **Analysis**

Study design issues: This study assessed the early outcomes of 2 micro-posterior approaches (SuperPath and PATH) when done by a non-developer surgeon. The surgeon had 4 years of experience doing primary THA exclusively through a Hardinge approach and had experience with the posterior approach for trauma and revision THA. He does about 250 joint replacements per year, of which 50% are THA. This study also evaluated the learning curve associated with the SuperPath and PATH approaches to assess whether the outcomes reported in the literature are likely to be reproducible by surgeons incorporating these innovative techniques into their own practice.

Clinical outcomes included operative time and length of stay, postoperative blood transfusion, acetabular cup abduction and anteversion (evaluated using the first postoperative anteroposterior pelvis and a modified protractor).

Study population issues: No significant statistical difference was identified between the 2 groups in terms of age, gender, BMI or preoperative haemoglobin.

Other issues: This study did not compare the outcomes of the SuperPath approach with more traditional approaches used in THA. Other limitations of this study included small sample size, lack of long-term follow up and lack of functional results.

# **Key efficacy findings**

Number of patients analysed: 99

#### Comparison of clinical outcomes between groups

Comparison items	SuperPath	PATH	P value
Mean operation time, minutes	114.5±17.5	101.7±18.3	0.0002
Mean length of stay, days	2.2±0.9	3.0±0.8	<0.0001
Discharged home by percentage of patients discharged by postoperative day 1, %	20	0	
Discharged home by percentage of patients discharged by postoperative day 2, %	64	27	
DC by percentage of patients discharged by postoperative day 3, %	96	78	
Discharged directly home, %	90	81.6	>0.05
Short-term inpatient rehabilitation, %	2	14.3	
Planned convalescence, %	8	4.1	
Patients having tranexamic acid, %	92	40.8	>0.05
Postoperative blood transfusion, %	4.0	6.1	>0.05
Radiographic outcomes			
Mean acetabular cup anteversion, °	23.5±8.2	13.1±7.1	<0.0001
Mena acetabular cup abduction, °	39.0±8.4	42.9±7.6	<0.05

For operation time, the correlation coefficient for the SuperPath cohort was significant (-0.467, p<0.001) but not for the PATH cohort (-0.0246, p=0.088).

Mean length of stay in short-term rehabilitation was calculated for the PATH (10.6±3.1) group but not for the SuperPath approach as only 1 patient attended short-term rehabilitation (7 days) in the SuperPath group.

# **Key safety findings**

## Intraoperative and postoperative complications

Approaches	Overall complications	Intraoperative complications	Postoperative complications
SuperPath	4.0%	1 femoral calcar fracture (case 5): extension of the skin incision, piriformis release and cerclage wiring, weight- bearing as tolerated	1 transfusion reaction (case 21): recovered with supportive care
PATH	4.1%	1 femoral calcar fracture (case 10): extension of the skin incision and cerclage wiring, weight-bearing as tolerated	1 dislocation at 6 weeks (case 26): modular neck revision and soft tissue capsular repair

Case 21 returned to hospital following discharge complaining of fatigue. The patient was found to be anaemic (haemoglobin 74 g/L) and had a blood transfusion. Subsequently, this patient developed an acute haemolytic transfusion reaction, but recovered with supportive measures.

No superficial or deep infections were found in the SuperPath or PATH group.

# Study 5 Mas Martinez J (2019)

#### Study details

Study type	Non-randomised comparative study
Country	Spain (single centre)
Recruitment period	2016 to 2017
Study population	n=90 (SuperPath, n=30; posterior, n=60)
and number	patients with hip arthrosis
Age and sex	SuperPath group: mean 56 years; 66.7% (20/30) male; BMI, mean 27.5 kg/m <sup>2</sup>
	Posterior group: mean 60 years; 66.7% (40/60) male: BMI, mean 27.9 kg/m²
Patient selection criteria	Inclusion criteria: patients with a diagnosis of hip arthrosis and indication for cementless hip replacement surgery.
	Exclusion criteria: patients with femoral or acetabular defects, acetabular protrusion, femoral fracture, or neurological condition with impaired gait.
Technique	THA using the SuperPath or posterior approach was done.
	SuperPath group: Profemur L stem and Procotyle® cup (MicroPort Orthopedics Inc., Arlington, TN, USA) were used. The bearing surface used was the ceramic-ceramic in 5 patients, ceramic-polyethylene in 17 patients and the metal-polyethylene in 8 patients. The size of the femoral head was 28 mm in 8 patients, 32 mm in 15 patients and 36 mm in 7 patients.
	Posterior group: stem Accolade and Trident® cup (Stryker, Kalamazoo, MI, USA) were used. The bearing surface used was the ceramic-ceramic in 5 patients, ceramic-polyethylene in 44 patients and the metal-polyethylene in 11 patients. The size of the femoral head was 28 mm in 10 patients, 32 mm in 28 patients and 36 mm in 22 patients.  No postoperative drains were used.
Follow-up	1 year
Conflict of	None
interest/source of funding	TOTIC

#### **Analysis**

Follow-up issues: Patients were assessed at 3 months, 6 months and 1 year after operation. No patients were lost to follow up.

Study design issues: This prospective, observational cohort study (cohort-paired) determined the short-term results of patients that had a THA intervention using the SuperPath approach, and compared the results with patients operated for THA using conventional posterior approach. The hypothesis was that the SuperPath approach would make it possible to obtain results similar to those of the posterior approach.

Outcomes included hip function outcomes (measured using HHS, Merle d'Aubigné Hip Score, WOMAC for pain and for function, SF-12 physical and mental scales, HOS-AVD and iHOT-12 scales), pre- and post-operative variables and radiological evaluation.

After the operation, walking with crutches or a walker was authorised after assessing the radiological control and postoperative laboratory results. The patient was told not to do any activities that increased pain in the operated hip. The suture was removed after 2 postoperative weeks.

Study population issues: At baseline, there was no statistically significant difference between the 2 groups in terms of age, sex, BMI, ASA, preoperative haemoglobin and haematocrit.

Study limitations: Different stem-stem models were used in the 2 groups. The surgeon-dependent distribution of patients into the SuperPath or posterior approaches.

## **Key efficacy findings**

Number of patients analysed: 90

#### Pre- and post-operative variables

Variables	SuperPath	Posterior	P value
Mean operation time, minutes	69.5±7.1	56.1±5.2	0.001
Mean pre-operative haemoglobin, g/dl	14.8	14.6	0.61
Mean postoperative haemoglobin	11.2±1.3	12.5±1.5	0.07
Mean haemoglobin decrease	3.4±1.0	2.5±0.8	0.04
Mean pre-operative haematocrit	42.1	42.9	0.83
Mean postoperative haematocrit	32.1±3.3	35.6±4.8	0.03
Mean haematocrit decrease	10.3±3.2	7.7±3.0	0.04
Mean blood loss, ml	977.85±285.1	752.46±299.3	0.03
Mean hospital stay, days	2.2	2.4	0.23

None of the patients needed autologous blood transfusion.

#### Clinical assessment results

Outcomes, mean±SD	SuperPath	Posterior	P value
Preoperative			
HHS	48.8±7.1	50.0±14.5	0.75
Merle d'Aubigné hip score	5.1±1.8	5.7±1.9	0.38
WOMAC pain	38.2±14.6	41.3±12.9	0.20
WOMAC function	31.8±13.8	39.5±14.7	0.08
SF-12 physical	39.8±12.3	41.7±12.6	0.27
SF-12 mental	46.1±13.7	47.6±14.7	0.29

HOS-AVD	38.6±13.5	39.2±13.1	0.90
iHOT-12	15.2±15.1	22.2±18.7	0.27
3 Months			
HHS	91.6±8.8	93.7±5.4	0.51
Merle d'Aubigné hip score	10.7±1.4	11.0±1.3	0.55
WOMAC pain	87.2±14.1	85.8±16.1	0.49
WOMAC function	85.4±12.6	79.7±14.6	0.24
SF-12 physical	82.4±13.7	85.5±13.5	0.95
SF-12 mental	82.7±12.4	81.8±14.2	0.92
HOS-AVD	84.2±14.7	75.1±18.8	0.15
iHOT-12	78.2±15.6	63.5±22.8	0.04
6 months			
HHS	90.2±12.8	92.4±9.3	0.21
Merle d'Aubigné hip score	10.1±2.1	10.6±1.4	0.41
WOMAC pain	96.2±12.5	92.7±12.9	0.57
WOMAC function	92.9±12.9	89.6±14.6	0.28
SF-12 physical	85.5±13.6	86.3±13.0	0.50
SF-12 mental	84.7±15.4	82.6±14.4	0.57
HOS-AVD	82.3±17.7	80.5±19.7	0.77
iHOT-12	76.0±24.8	70.6±22.5	0.74
12 months			
HHS	98.2±2.0	96.2±5.6	0.24
Merle d'Aubigné hip score	11.8±0.4	11.3±0.8	0.14
WOMAC pain	97.0±11.6	91.2±12.8	0.42
WOMAC function	93.0±13.6	91.6±13.4	0.44
SF-12 physical	88.6±10.5	79.0±13.5	0.04
SF-12 mental	85.6±12.0	76.1±15.3	0.02
HOS-AVD	89.8±13.1	84.2±18.0	0.42
iHOT-12	78.5±18.3	76.8±14.9	0.53

The hip function surveys showed statistically significant increases between the preoperative values and those at 12 months in both groups (p<0.001).

#### Radiological evaluation at 3 months

Mean angle of acetabular inclination: SuperPath 47.6° compared with posterior 45.9°, p=0.41

All the femoral stems were implanted in neutral position. There were no recorded cases of mobilisation of prosthetic components.

IP overview: Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

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### **Key safety findings**

#### SuperPath:

• Intraoperative acetabular fracture: n=1

The patient having treatment with teriparatide for osteoporosis presented fracture of the acetabular background during the impaction of the cup component. The external rotators were removed and the approach was converted to a conventional posterior approach. Given that osseous acetabular circumferential stability existed, a cemented stem was implanted. Evolution at 12 months follow up was satisfactory, with a Harris Scale score of 82 points and Merle scale score of 10 points.

Progressive pain in the buttock on the affected side at 6 months: n=1
 Complete radiolucency of the stem without implant mobilisation was detected in the radiological control, and the patient was pending surgical revision.

#### Posterior:

Hospital readmission at 14 days postoperation for periprosthetic infection: n=1
 This event needed debridement and replacement of mobile components. Evolution was good at 1-year follow up, with a Harris Scale score of 84 points and a Merle scale score of 10 points.

There were no cases of prosthetic dislocations or thromboembolic complications during follow-up in either cohort.

#### Study 6 Qultmann H (2019)

#### Study details

Study type	Case series
Country	Germany (single centre)
Recruitment period	2016 to 2017
Study population	n=150
and number	Patients with osteoarthritis of the hip
Age and sex	Mean 69 years; 35% (52/150) male; BMI, mean 27 kg/m²
Patient selection criteria	Not reported
Technique	Cementless THA using the SuperPath approach.
Follow-up	16 months
Conflict of interest/source of funding	HQ: consultant for MicroPort Orthopedics for surgical observation services

#### **Analysis**

Study design issues: This paper described the SuperPath technique and reported preliminary results. For postoperative management, full weight bearing was allowed as tolerated by pain and there were no restrictions of postoperative movement.

Study population issues: Limited baseline data were presented.

### **Key efficacy findings**

Number of patients analysed: 150

Operation time: 81 minutes (range 58 to 121 minutes)

Inclination angle: 39.3° (range 28° to 50°)

Leg length difference: 5 mm or less

Anteversion angle at a standard supine anteroposterior pelvis view: mean 17.1° (range 6.2° to 31.9°, SD 4°)

Position of the stem measured between the stem axis and the long axis of the femur: mean 0.17° varus (range 2.7° valgus to 3.3° varus, SD 0.9°)

Length of hospital stay: 9.9 days (because of regulations of the hospital). Most of the patients were able to leave the hospital earlier.

IP overview: Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis

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There was no radiological loosening of the components after a mean of 16 months.

### **Key safety findings**

Complications: n=4 (only the first related to the surgical technique)

Subluxations: n=2 (in both patients, there was no complete dislocation because the head was captured by the closed capsule).

- 1 patient: subluxation happened at 3 weeks after the surgery during elevated sitting. This patient had a closed reduction and was doing fine 1 year after the surgery.
- 1 patient: subluxation happened in the operating room after turning the patient onto the back. This
  needed immediate exchange of the head to a longer one. This demented patient walked without
  crutches after a few days without any complaints.

Wound dehiscence: n=1 (the patients had a new skin closure at day 8).

Femoral diaphyseal fracture at 4 weeks postoperation: n=1 (the patient was retransferred from the rehabilitation clinic and needed cerclage wiring of the femur and exchange of the stem).

# Study 7 NJR (2020a, 2020b, 2020c)

### Study details

Study type	Non-randomised comparative study (unpublished registry data)
Country	UK (multiple centres)
Recruitment	Profemur L Classic Stem: 2014 to 2020
period	Profemur L Modular Stem: 2004 to 2020
	Procotyl L Cup: 2004 to 2020
Study population and number	Profemur L Classic Stem: n=432,625 (782 patients having 829 primary THAs in which Profemur L Classic Stem was used; 431,843 patients having 501,339 primary THAs using all other cementless stems)
	Profemur L Modular Stem: n=433,020 (3,874 patients having 4,233 primary THAs in which Profemur L Modular Stem was used; 429,146 patients having 497,935 primary THA using all other cementless stems)
	Procotyl L Cup: n=683,939 (5,991 patients having 6,568 primary THAs in which Procotyl L Cup was used; 677,938 patients having 795,951 primary THAs using all other cementless cups)
	Patients with osteoarthritis, rheumatoid arthritis, avascular necrosis, fractured neck of femur, CDH/DDH or others
Age and sex	<ul> <li>Profemur L Classic Stem:</li> <li>Profemur L Classic Stem: mean 61.3 years; 46.9% male; BMI, median 28 kg/m²</li> <li>All other cementless stems: mean 65.3 years; 44.4% male; BMI, median 28 kg/m²</li> <li>Profemur L Modular Stem:</li> <li>Profemur L Modular Stem: Mean 63.4 years; 43.7% male; BMI, median 28 kg/m²</li> <li>All other cementless stems: mean 65.3 years; 44.4% male; BMI, median 28 kg/m²</li> <li>Procotyl L Cup:</li> <li>Procotyl L Cup: mean 63.9 years; 43.8% male; BMI, median 28 kg/m²</li> <li>All other cementless cups: mean 66.1 years; 43.6% male; BMI, median 28 kg/m²</li> </ul>
Patient selection criteria	Not reported
Technique	THA procedures with the use of the Profemur L Classic Stem, Profemur L Modular Stem, Procotyl L Cup or other cementless implants.
Follow-up	Profemur L Classic Stem - implantation time: mean 2.3 years (maximum 6.5 years)
	Profemur L Modular Stem - implantation time: mean 8.1 years (maximum 16.5 years)
	Procotyl L Cup - implantation time: mean 6.2 years (maximum 16.5 years)
Conflict of interest/source of funding	Not reported

### **Analysis**

Study design issues: These NJR implant reports summarised usage and outcomes associated with the Profemur L Classic Stem, Profemur L Modular Stem and Procotyl L Cup. They also compared the outcomes of these implants with all other cementless implants in NJR.

Study population issues: The reports included patients with various indications, although most had osteoarthritis. All patients had primary THA procedures. It was unclear how many procedures used the SuperPath approach. There is some patient overlap between reports.

### **Key efficacy findings**

Number of patients analysed:

- Profemur L Classic Stem: n=432,625 (782 patients having 829 primary THAs in which Profemur L Classic Stem was used; 431,843 patients having 501,339 primary THAs using all other cementless stems in NJR)
- Profemur L Modular Stem: n=433,020 (3,874 patients having 4,233 primary THAs in which Profemur L Modular Stem was used; 429,146 patients having 497,935 primary THA using all other cementless stems in NJR)
- Procotyl L Cup: n=683,939 (5,991 patients having 6,568 primary THAs in which Procotyl L Cup was used; 677,938 patients having 795,951 primary THAs using all other cementless cups in NJR)

### **Key safety findings**

# Revisions associated with the Profemur L Classic Stem, Profemur L Modular Stem and Procotyl L Cup

	Profemur L Classic Stem	Profemur L Modular Stem	Procotyl L Cup
Death	1.0% (n=8)	13.9% (n=590)	10.6% (n=696)
Revision	1.3% (n=11)	5.0% (n=210)	2.8% (n=187)
Unrevision	97.7% (n=810)	81.1% (n=3,433)	86.6% (n=5,685)
Total	100% (n=829)	100% (n=4,233)	100% (n=6,568)

#### **Profemur L Classic Stem findings**

Reasons for revision of primary procedures in which the classic stem was used – all bearing types

	Expected revisions**	P value
2	0.44	0.073
1	2.27	0.734
0	0.013	1
3	2.01	0.46
0	1.11	0.634
1	0.38	0.318
2	1.23	0.35
	1 0 3 0	1 2.27 0 0.013 3 2.01 0 1.11 1 0.38

Periprosthetic fracture socket	0	0.11	1
Malalignment stem	0	0.45	1
Malalignment socket	1	0.53	0.413
Wear of acetabular component	0	0.13	1
Lysis stem	0	0.05	1
Lysis socket	0	0.04	1
Implant fracture stem	1	0.08	0.076
Implant fracture socket	0	0.18	1
Implant fracture head	0	0.04	1
Dissociation of liner	0	0.14	1
Other/reason not recorded	0	0.43	1
Total revised	11	8.56	0.388

<sup>\*</sup>Multiple reasons may be listed for one revision procedure.

Cox proportional hazards model for revision risk ratio of Profemur L Classic Stem / all other cementless stems in NJR, with endpoint as any revision

Adjustment	Hazard ration (95% CI)	P value
All bearings, Unadjusted	0.92 (0.51 to 1.66)	0.779
All bearings. Adjusted for age, gender, year cohort and indications.	1.29 (0.71 to 2.33)	0.405

#### **Profemur L Modular Stem findings**

Reasons for revision of primary procedures in which Profemur L Modular Stem was used – all bearing types

Reason for revision	Revised*	Expected revisions**	P value
Unexplained pain	34	26.45	0.142
Dislocation/subluxation	38	23.99	0.007
Adverse soft tissue reaction	33	37.46	0.511
Infection	37	21.60	0.002
Aseptic loosening – stem	23	31.93	0.129
Aseptic loosening – socket	16	16.14	1
Periprosthetic fracture stem	19	18.35	0.814
Periprosthetic fracture socket	1	2.31	0.734
Malalignment stem	11	5.05	0.02
Malalignment socket	15	10.15	0.151
Wear of acetabular component	7	8.32	0.861
Lysis stem	6	5.53	0.828

<sup>\*\*</sup>Based on all NJR cementless stems, adjusted for age group, gender, indications and implantation year.

Lysis socket	9	5.33	0.121
Implant fracture stem	13	2.58	<0.001
Implant fracture socket	3	3.30	1
Implant fracture head	1	0.88	0.587
Dissociation of liner	1	3.39	0.274
Other/reason not recorded	10	9.81	0.872
Total revised	210	176.14	0.012

### Components revised

Components revised	Number of procedures	Profemur L Modular Stem	All other cementless stems in NJR
Femoral only	44	21%	24%
Acetabular only	57	27%	33%
Both femoral and acetabular	80	38%	31%
Neither femoral nor acetabular revision recorded***	29	14%	12%

<sup>\*\*\*</sup>Includes isolated head and/or liner exchange

Cox proportional hazards model for revision risk ratio of Profemur L Modular Stem / all other cementless stems in NJR, with endpoint as any revision

Adjustment	Hazard ration (95% CI)	P value
All bearings, Unadjusted	1.18 (1.03 to 1.35)	0.017
All bearings. Adjusted for age, gender, year cohort and indications.	1.20 (1.04 to 1.37)	0.010
Excluding metal-on-metal, unadjusted.	1.33 (1.13 to 1.55)	<0.001
Excluding metal-on-metal. Adjusted for age, gender, year cohort and indications.	1.29 (1.10 to 1.51)	0.002

### **Procotyl L Cup findings**

Reasons for revision of primary procedures in which Procotyl L Cup was used – all bearing types

Reason for revision	Revised*	Expected revisions**	P value
Unexplained pain	23	24.63	0.84
Dislocation/subluxation	25	29.37	0.516
Adverse soft tissue reaction	11	25.05	0.003
Infection	38	27.02	0.042
Aseptic loosening – stem	22	27.89	0.296
Aseptic loosening – socket	8	13.56	0.17

Periprosthetic fracture stem	29	24.81	0.365
Periprosthetic fracture socket	1	2.97	0.382
Malalignment stem	7	5.51	0.515
Malalignment socket	9	10.39	0.875
Wear of acetabular component	2	6.32	0.105
Lysis stem	3	4.27	0.806
Lysis socket	1	3.46	0.277
Implant fracture stem	19	3.27	<0.001
Implant fracture socket	3	3.36	1
Implant fracture head	1	0.99	0.629
Dissociation of liner	0	3.48	0.056
Other/reason not recorded	9	9.92	1
Total revised	187	179.45	0.574

#### Components revised

Components revised	Number of procedures	Procotyl L Cup	All other cementless cups in NJR
Femoral only	65	35%	22%
Acetabular only	37	20%	25%
Both femoral and acetabular	63	34%	43%
Neither femoral nor acetabular revision recorded***	22	12%	10%

Cox proportional hazards model for revision risk ratio of Procotyl L Cup / all other cementless cups in NJR, with endpoint as any revision

Adjustment	Hazard ration (95% CI)	P value
All bearings, Unadjusted	0.86 (0.75 to 1.00)****	0.046****
All bearings. Adjusted for age, gender, year cohort and indications.	1.04 (0.90 to 1.20)	0.570
Excluding metal-on-metal, unadjusted.	1.16 (1.00 to 1.35)	0.052
Excluding metal-on-metal. Adjusted for age, gender, year cohort and indications.	1.16 (1.00 to 1.35)	0.053

<sup>\*\*\*\*</sup>Hazard ratio varied with time

### Validity and generalisability of the studies

- Studies were conducted in China (n=2), Canada (n=1), Germany (n=1), Russian (n=1) and Spain (n=1). UK data came from the NJR, even though the data were for patients who had primary THAs with various approaches for various indications.
- Patients were followed up no longer than 16 months (6 months in 1 study; 8 months in 2 studies; 1 year in 2 studies; 16 months in 1 study), and long-term data were reported in the NJR implant summary reports (maximum implantation time, 16.5 years).
- There was variation in patient selection (inclusion criteria). The mean age ranged from 56 to 69 years and mean BMI ranged from 23 to 30 kg/m<sup>2</sup>.
- Not all the studies identified the implants used and comparative studies used different implants as well as surgical approaches.
- Of the 3 randomised controlled trials:
  - Patients were blinded in one trial (Meng 2021) but not blinded in the other 2 trials (Korytkin 2021; Xie 2017).
  - A power analysis was done in the research planning phase in 1 trial (Korytkin 2021).
  - Intention-to-treat analysis was used in 2 trials (Meng 2021; Xie 2017) but not in the other trial (Korytkin 2021).
- Postoperative rehabilitation plays an important role in muscle strengthening and mobility. Of the 6 included studies, 2 studies provided some information relating to postoperative rehabilitation (Korytkin 2021; Meng 2021).
- Length of hospital stay varied widely across the studies and social issues might play a role.

### Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

### **Related NICE guidance**

Below is a list of NICE guidance related to this procedure.

#### Interventional procedures

 Minimally invasive total hip replacement. NICE interventional procedures guidance 363 (2010). Available from https://www.nice.org.uk/guidance/ipg363

#### **Technology appraisals**

 Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip. NICE technology appraisal guidance 304 (2014). Available from https://www.nice.org.uk/guidance/ta304

#### **NICE** guidelines

- Joint replacement (primary): hip, knee and shoulder. NICE guideline 157 (2020). Available from <a href="https://www.nice.org.uk/guidance/ng157">https://www.nice.org.uk/guidance/ng157</a>
  - 1.8.1 Consider a posterior or anterolateral approach for primary elective hip replacement.

The committee were unable to make recommendations on the direct anterior, direct superior and supercapsular percutaneously assisted (SuperPath) surgical approaches. They made a <u>recommendation for research on surgical approaches in primary elective hip replacement</u>.

The evidence review underpinning recommendation 1.8.1 and the research recommendation in the NICE guideline is available from <a href="https://www.nice.org.uk/guidance/ng157/evidence/m-hip-replacement-approach-pdf-315756469336">https://www.nice.org.uk/guidance/ng157/evidence/m-hip-replacement-approach-pdf-315756469336</a>

Osteoarthritis: care and management. NICE clinical guideline CG177 (2014).
 Available from https://www.nice.org.uk/guidance/cg177

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### Additional information considered by IPAC

#### Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Two professional expert questionnaires for supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis were submitted and can be found on the <u>NICE website</u>.

### Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

#### **Company engagement**

A structured information request was sent to one company who manufacture a potentially relevant device for use in this procedure. NICE received one completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

### Issues for consideration by IPAC

- Ongoing trials:
  - Randomised Control Trial Comparing Short-term Outcomes After
     <u>Direct Anterior and SuperPATH Approaches</u>; NCT03746925; Canada;

     RCT; estimated enrolment n=100; estimated study completion date
     April 2021.
  - A prospective pilot, randomised controlled trial to compare two approaches for total hip arthroplasty: supercapsular percutaneously assisted approach (SuperPATH) versus conventional posterior approach; UK; RCT; estimated enrolment n=60.
- In addition to the safety outcomes stated in the main summary above,
   some papers, that used the SuperPath approach in indications other than

hip osteoarthritis or various indications (where the outcomes for hip osteoarthritis were not presented separately), reported extra complications:

- Official of the original of the original of the original of the super original of the original or
- Mitchell et al. (2019) retrospectively reviewed of 37 patients with displaced femoral neck fragility fracture treated with THA using the SuperPath approach. During postoperative follow up, there were no incidents of symptomatic heterotopic ossification and no superficial or deep wound infections. There were 4 cases of intraoperative nondisplaced calcar fracture. Postoperative medical complications included 1 case of respiratory failure and subsequent discharge to hospice, 5 cases of urinary retention, 1 case of atrial fibrillation and 1 case of delirium.
- Xu et al. (2019) determined the proportion of hidden blood loss, and to compare hidden blood loss of patients who had the SuperPath approach and the conventional posterior approach (the Moore approach). This was a non-randomised comparative study of 130 patients with displaced femoral neck fractures (Garden type III or IV) who had hip hemiarthroplasty. Postoperative complications in the SuperPath group included deep venous thrombosis (1.92%, 1/52), pneumonia (1.92, 1/52) and urine storage (1.92, 1/52).
- Yan et al. (2017) compared the early effectiveness between SuperPath approach and traditional Hardinge approach in THA. This was a non-randomised comparative study of 154 patients (173 hips) with non-inflammatory joint disease having initial THA. In the SuperPath group, great trochantern fracture (n=1) and dislocation of the hip joint (n=2) were found. No injury of nerve or blood vessel, deep vein thrombosis, infection and prosthesis loosening were reported in the 2 group.
- Kay et al. (2021) evaluated early results of patients having primary, elective THA using the SuperPath approach. In this case series, there were 214 patients with primary osteoarthritis, avascular necrosis, dysplasia, posttraumatic arthritis, rheumatoid arthritis and femoral neck non-union. Complications included intraoperative calcar fracture (n=3),

- periprosthetic femur fracture (n=1), early femoral revision (n=1), superficial infections (n=3), and wound necrosis (n=1).
- Tottas et al. (2020) compared the minimal invasive (MIS) SuperPath approach with the standard modified Hardinge approach at the base of muscle damage due to serum markers, functional results and other perioperative and postoperative data. This was a non-randomised comparative study of 48 patients with osteoarthritis, dysplasia, protruzio and osteonecrosis. Deep venous thrombosis was reported in 1 patient in each group.

#### References

- 1. Xie J, Zhang HX, Wang L et al. (2017) Comparison of supercapsular percutaneously assisted approach total hip versus conventional posterior approach for total hip arthroplasty: a prospective, randomized controlled trial. Journal of orthopaedic surgery and research 12(1): 138
- 2. Meng WK, Gao L, Huang Z et al. (2021) Supercapsular percutaneously-assisted total hip (SuperPath) versus mini-incision posterolateral total hip arthroplasty for hip osteoarthritis: a prospective randomised controlled trial. Ann Transl Med 9 (5): 392
- Korytkin AA, Novikova YS, El Moudni YM et al. (2021) A prospective randomised comparison of earlier function after total hip arthroplasty with a mini posterior approach or supercapsular percutaneously-assisted total hip approach: a gait analysis study. HIP International
- 4. Rasuli KJ and Gofton W (2015) Percutaneously assisted total hip (PATH) and supercapsular percutaneously assisted total hip (SuperPATH) arthroplasty: learning curves and early outcomes. Ann Transl Med 3 (13):179
- 5. Mas Martinez J, Sanz-Reig J, Morales-Santias M et al. (2019) Comparative cohort study of the SuperPath approach and the conventional posterior approach in primary cementless hip replacement surgery. Revista espanola de cirugia ortopedica y traumatologia 63(5): 346-54
- 6. Quitmann H (2019) Supercapsular percutaneously assisted (SuperPath) approach in total hip arthroplasty: Surgical technique and preliminary results. Operative Orthopadie und Traumatologie 31(6): 536-46
- 7. NJR (2020a) Implant summary report for Profemur L Classic Stem. Unpublished.
  - NJR (2020b) Implant summary report for Profemur L Modular Stem. Unpublished.
  - NJR (2020c) Implant summary report for Procotyl L Cup. Unpublished.

### Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	28/06/2021	Issue 6 of 12, June 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	28/06/2021	Issue 6 of 12, June 2021
International HTA database	28/06/2021	-
MEDLINE (Ovid)	28/06/2021	1946 to June 25, 2021
MEDLINE In-Process (Ovid) & MEDLINE ePubs ahead of print (Ovid)	28/06/2021	1946 to June 25, 2021 June 25, 2021
EMBASE (Ovid)	28/06/2021	1974 to 2021 June 25

#### Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

#### Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

#### Literature search strategy

Number	Search term
1	Osteoarthritis, Hip/
2	(hip* adj4 (osteoarthriti* or osteo-arthriti* or osteoarthrotic or osteoarthros*)).tw.
3	(hip* adj4 degenerati* adj4 (arthriti* or disease*)).tw.
4	(Osteonecrosis adj4 (femor* or femur* or hip*)).tw.

5	(coxarthros* or cox-arthros* or "malum coxae senilis").tw.
6	or/1-5
7	arthroplasty, replacement, hip/
8	Hip Prosthesis/
9	((femor* or femur* or hip*) adj4 (prosthe* or implant* or CoCr or Cobalt Chrome)).tw.
10	(hip adj4 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial* or arthroplast* or hemiarthroplast*)).tw.
11	THA.tw.
12	or/7-11
13	((tissue* or muscle* or capsul*) adj4 (spar* or preserv*)).tw.
14	((direct* or superior*) adj4 (technique* or procedur* or approach*)).tw.
15	(supercapsular or super-capsular or superior-capsular).tw.
16	((micro or mini) adj4 posterior*).tw.
17	Minimally Invasive Surgical Procedures/
18	(mini* adj4 invas* adj4 (technique* or procedur* or surg* or method* or therap* or treatment*)).tw.
19	(mini* adj4 surg* adj4 (technique* or procedur* or method* or therap* or treatment*)).tw.
20	or/13-19
21	SuperPath.tw.
22	Profemur*.tw.
23	Procotyl*.tw.
24	or/21-23
25	6 and 12 and 20
26	25 or 24
27	animals/ not humans/
28	26 not 27

## **Appendix**

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the <u>summary of the key evidence</u>. It is by no means an exhaustive list of potentially relevant studies.

#### Additional papers identified

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non- inclusion in summary of key evidence section
Branco CB, Sousa RM, Soursa D et al. (2021) Comparison of short-term outcomes between minimal invasive superpath approach and conventional posterior approach in total hip arthroplasty: a randomized controlled trial. International Journal of Research in Orthopaedics 7(3): 431-7	Randomised controlled trial  n=22 (SuperPath, n=11; posterior, n=11)	Despite the longer surgical time seen with the SuperPath approach, it managed to significantly decrease the length of hospital stay and obtained better results in improving pain in the short term (1 month).	Poor quality study at high risk of bias with 22 participants, participants not randomly allocated, follow-up only short-term.
Cardenas-Nylander C, Bellotti V, Astarita E et al. (2016) Innovative approach in total hip arthroplasty: supercapsular percutaneously-assisted. Hip international: the journal of clinical and experimental research on hip pathology and	Case series  n=21 (patients with non-inflammatory joint disease)	The SuperPath potentially minimises morbidity, reducing transfusion rates, allowing rapid recovery, shortening hospital stay and could save a significant cost to the healthcare system.	Small sample, limited efficacy and safety outcomes reported; and outcomes for hip osteoarthritis not reported separately.

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therapy 26suppl1: 34-7			
Chow J and Fitch DA (2017) Inhospital costs for total hip replacement performed using the supercapsular percutaneously-assisted total hip replacement surgical technique. International orthopaedics 41(6): 1119-23	Non-randomised comparative study  n=2,092 (SuperPath, n=419; other THRs, n=1,673)	The use of this tissue-sparing surgical technique resulted in reductions in inhospital costs, length of stay, and readmissions when compared to all other THRs done in a large hospital system in the United States.	This study compared the in-hospital costs of the SuperPath technique to all other THRs done in a large hospital system.
Della Torre PK, Fitch DA and Chow JC (2015) Supercapsular percutaneously- assisted total hip arthroplasty: radiographic outcomes and surgical technique. Ann Transl Med 3 (13):180	Case series n=66	All components in this case series were well seated and position deemed optimal. Leg lengths were measured to within 5 mm of the contralateral side and mean acetabular abduction angle was 40.13° (SD 6.30°).	This study reported radiographic outcomes and described surgical technique. Limited efficacy data were reported.
Ge YZ, Chen ZX, Chen QS et al. (2021) A systematic-review and meta-analysis of the SuperPath approach in hip arthroplasty. BioMed Research International.	Systematic review and meta-analysis n=6 studies	SuperPath, as a minimally invasive approach with its reduced tissue damage, quick postoperative recovery, and early rehabilitation, demonstrates the short-term advantages of hip arthroplasty. As the evidence in favour of the SuperPath technique were limited in a small	Of the 6 included studies, 3 studies (Xie et al., 2017; Martinez et al. 2019; Meng et al., 2019) were for hip osteoarthritis. These 3 studies are included in the main summary.

Hu Y, Wang MC, Meng Y et al. (2021) Less blood loss in supercapsular percutaneously assisted versus posterolateral total hip arthroplasty. Journal of orthopaedic surgery and	Non-randomised comparative study  n=263 (SuperPath, n=85; posterolateral THA group, n=178)	number of studies and short duration of follow-up, more research is needed to further analyse its long-term effect.  SuperPath resulted in less perioperative blood loss and a lower transfusion rate than conventional THA.	This study determined the blood loss during SuperPath and compared the blood loss with conventional posterolateral THA. Preoperative diagnoses included femoral neck fracture, necrosis of femoral head and hip osteoarthritis. The outcomes for
research 16(1): 217  Jiang H, Wang LH, Jin YX et al. (2020) Supercapsular percutaneously assisted total hip arthroplasty versus conventional posterior approach: Comparison of early functional results. Acta orthopaedica et traumatologica turcica 54(5): 511-5	Non-randomised comparative study  n=58 (SuperPath, n=28; conventional posterior approach, n=30)	Compared with the conventional posterior approach, the SuperPath approach provided better early functional results with less postoperative pain and shorter hospitalisation time. However, the operation time was longer in the SuperPath approach group.	osteoarthritis were not reported separately.  Preoperative diagnoses included femoral neck fracture, aseptic necrosis of the femoral head or osteoarthritis. The outcomes for osteoarthritis of the hip were not reported separately.
Kay A, Klavas D, Haghshenas V et al. (2021) Two year follow up of supercapsular percutaneously assisted total hip arthroplasty. BMC musculoskeletal	Case series n=214	SuperPath approach is safe for use in primary THA resulting in a low dislocation rate.	Preoperative diagnoses included primary osteoarthritis, avascular necrosis, dysplasia, post-traumatic arthritis, rheumatoid arthritis and femoral neck non-union. The outcomes for osteoarthritis of the

disorders 22(1): 478			hip were not reported separately.
Qurashi S, Chinnappa J, Lord SJ et al. (2017) Driving after microinvasive total hip arthroplasty. The Journal of arthroplasty 32(5): 1525-9	Case series n=94	Brake reaction time reached preoperative values by day 2 following microinvasive THA. Patients may be suitable to drive earlier than the previously recommended 6 weeks postoperation.	Hip pathology included osteoarthritis, dysplasia and avascular necrosis. This study evaluated patients' ability to drive in the early postoperative period following THA using the SuperPath approach by assessing break reaction time.
Qurashi S, Chinnappa J, Rositano P et al (2016) SuperPath® minimally invasive total hip arthroplasty - an Australian experience. JISRF Reconstr Rev 6(2).	Case series n=100	SuperPath is a safe technique of hip arthroplasty with excellent functional recovery and patient satisfaction.	Preoperative hip pathology included osteoarthritis, avascular necrosis, postseptic arthritis, ankylosing spondylitis and developmental dysphasia of the hip. The outcomes for osteoarthritis were not reported separately.
Ramadanov N, Bueschges S, Liu K et al. (2020) Comparison of short-term outcomes between SuperPath approach and conventional approaches in hip replacement: a systematic review and meta-analysis of randomized controlled trials. Journal of orthopaedic surgery and research 15(1): 420	Systematic review and meta-analyses n=726 (12 RCTs)	SuperPath approach showed better results in decreasing incision length and early pain intensity as well as improving short-term functional outcome. Long- term outcomes of SuperPath approach need to be investigated.	Preoperative diagnoses were osteoarthritis, femoral neck fracture, and avascular necrosis of the femoral head. The outcomes for osteoarthritis of the hip were not reported separately.

Ramadanov N, Bueschges S, Liu K et al. (2021) Comparison of short-term outcomes between direct anterior approach (DAA) and SuperPath in total hip replacement: a systematic review and network meta- analysis of randomized controlled trials. Journal of orthopaedic surgery and research 16(1): 324	Systematic review and meta-analysis n=1,392 (16 RCTs)	The findings suggested that the short-term outcomes of THA through SuperPath were superior to DAA. SuperPath showed better results in decreasing operation time, incision length, intraoperative blood loss, and early pain intensity. DAA and SuperPath were equal in functional outcome and acetabular cup positioning.	Preoperative diagnoses were osteoarthritis, femoral neck fracture, and avascular necrosis of the femoral head. The outcomes for osteoarthritis of the hip were not reported separately.
Tottas S, Kougioumtzis IE, Tsigalou C et al. (2020) Supercapsular percutaneously assisted total hip arthroplasty versus lateral approach in total hip replacement. A prospective comparative study. Journal of Orthopaedics 21: 406-15	Non-randomised comparative study  n=48 (SuperPath, n=25; Hardinge, n=23)	This study revealed some advantages in favour of the SuperPath approach comparing with the standard modified Hardinge approach, mainly in terms of less muscle damage and less perceived pain postoperatively. More research is needed to further elucidate its efficacy.	Small sample.  Preoperative diagnoses included osteoarthritis, dysplasia, protruzio and osteonecrosis. The outcomes for osteoarthritis of the hip were not reported separately