

Lateral versus conventional fasciotomy for prevention of lateral femoral cutaneous nerve injury in total hip arthroplasty with direct anterior approach: a study protocol for dual-center, single-blind, randomized controlled trial

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Study protocol

Keywords: total hip arthroplasty, direct anterior approach, lateral femoral cutaneous nerve, ultrasonography

Posted Date: April 8th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-62883/v1>

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Abstract

Background; An incision for total hip arthroplasty (THA) via the direct anterior approach (DAA) is generally made outside of the space between sartorius and tensor fasciae latae muscles to prevent lateral femoral cutaneous nerve (LFCN) injury. Recent anatomical studies have revealed that the LFCN not only courses between the sartorius and tensor fasciae latae muscles, but it also branches radially while distributing in the transverse direction from the sartorius muscle to the tensor fasciae latae muscle. The latter is called the fan type, and studies suggest that damage to the fan type LFCN is unavoidable by conventional fasciotomy.

We previously demonstrated that injury to non-fan type LFCN occurred in 28.6% of patients who underwent THA by fasciotomy performed 2 cm away from the intermuscular space. This suggests that the conventional approach also poses a risk of LFCN injury for non-fan type LFCN. LFCN injury is rarely reported in the anterolateral approach (ALA), which involves incision of fascia further away than DAA. The purpose of this study is to investigate how the position of fasciotomy in DAA affects the risk of LFCN injury.

Methods; This is a prospective, randomized, controlled study. All patients are divided into the fan type and non-fan type using ultrasonography before surgery. Patients with the non-fan type LFCN will be performed by the conventional fasciotomy and the lateral fasciotomy in the order specified in the allocation table created in advance by our clinical trial center. The primary endpoint is the presence of LFCN injury. The secondary endpoints will be assessed based on patient-reported outcomes (PROs) at 3 months after surgery in an outpatient setting using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Japanese Orthopaedic Association Hip-Disease Evaluation Questionnaire (JHEQ), and the Forgotten-Joint Score-12 (FJS-12).

Discussion; We hypothesize that the incidence of LFCN injury due to DAA-THA can be reduced by making the incision further away from where it is typically made in conventional fasciotomy.

If our hypothesis is confirmed, it will reduce the disadvantages of DAA, improve patient satisfaction.

Trial registration; UMIN Clinical Trials Registry, UMIN000035945. Registered on 20 February 2019.

Background

Total hip arthroplasty (THA) is an effective surgical procedure that helps reduce pain and improve function of patients with hip disorders(1, 2). There are several surgical approaches for THA; in particular, an intermuscular and internervous approach known as direct anterior approach (DAA) causes less harm to the soft tissue compared with other approaches. Thus, DAA is associated with a lower risk of dislocation and rapid recovery of muscular strength after the procedure(3–6). However, it can result in injury to the lateral femoral cutaneous nerve (LFCN)(5, 7–10). LFCN is a pure sensory nerve that controls the anterolateral aspect of the thighs, and LFCN injury leads to hypesthesia and dysesthesia. Several

studies demonstrated that LFCN injury does not affect the function of hip joint following THA(7, 11, 12). However, even in such cases, sensory disturbance caused by LFCN injury may affect patient satisfaction.

The LFCN passes posterolaterally from the iliopsoas and under the inguinal ligament before it crosses between the sartorius and tensor fasciae latae muscles(13, 14). Thus, in order to prevent LFCN injury, an incision for DAA is generally made outside of the space between sartorius and tensor fasciae latae muscles. However, LFCN injury is reported in 0.1 to 81% of patients(1, 4, 7, 13). In addition to the LFCN that passes in between these muscles, Rudin et al. performed pathological examinations and identified a different type of LFCN that radially distributes in the transverse direction from the sartorius muscle into the tensor fasciae latae muscles(15). This type of LFCN that passes across the muscles is called the fan type, and studies suggest that damage to the fan type LFCN is unavoidable by conventional fasciotomy(15). We also previously demonstrated that injury to non-fan type LFCN (LFCN that passes in between the sartorius and tensor fasciae latae muscles) occurred in 28.6% of patients who underwent THA by fasciotomy performed 2 cm away from the intermuscular space(16). This suggests that the conventional approach also poses a risk of LFCN injury for non-fan type LFCN.

In the anterolateral approach (ALA), the incision is made further away from the fascia in order to reach the hip joint from between the tensor fasciae latae and gluteus medius. As with DAA, ALA is also an intramuscular approach, and thus enables preservation of the soft tissue and is associated with a relatively low risk of dislocation and rapid recovery of muscular strength after the procedure(17–21). However, as both the tensor fasciae latae and gluteus medius are supplied by a motor nerve called the superior gluteal nerve, damage to the superior gluteal nerve due to ALA may reduce muscular strength(22, 23). On the other hand, unlike DAA, LFCN injury is rarely reported after ALA(23).

Based on these findings, we hypothesized that the incidence of LFCN injury due to DAA-THA can be reduced by making the incision further away from where it is typically made in conventional fasciotomy. In this prospective study, we will investigate how the position of fasciotomy in DAA-THA affects the risk of LFCN injury.

Methods

Study design

This is a prospective, dual-center, single-blind, randomized, single-blind, randomized, controlled study.

Ethics

The study was approved by the research ethics board of Juntendo University Hospital in January 2019 and was subsequently registered in the University Hospital Medical Information Network (UMIN) clinical trials registry on February 20, 2019 (ID: UMIN000035945). The study team will explain about the study in writing and verbally, and voluntary written consent will be received from the study subjects.

Informed consent

The informed consent form was approved by the hospital's research ethics board. The consent form will be provided to study subjects, and the study team will explain about the study in writing and verbally. Voluntary consent will be received from study subjects in a written form. Study subjects will be informed immediately if any new information that may affect consent is obtained or if any changes to the study protocol that may affect consent is to be implemented. Study subjects will then have the opportunity to decide whether they wish to continue participating in the study. We will also revise the consent form, and upon approval from the hospital's research ethics board, we will provide the revised form to study subjects to receive consent.

Study setting

This study will be conducted in the Juntendo University Hospital and the Juntendo Tokyo Koto Geriatric Medical Center.

Eligibility criteria

Inclusion criteria

Prior to enrollment, patients must comply with all of the following:

- Age 20-90 years
- Primary THA via DAA
- Patients who provide written consent for participation after receiving sufficient explanation and understanding the study content.

Exclusion criteria

Patients are excluded if presenting any of the following:

- Trauma
- A history of hip surgery
- Purulent coxitis
- Failure to follow instructions of physicians
- Neurological disorder
- BMI of 35 or greater
- Patients deemed unsuitable for inclusion in the study by the principal investigator

Recruitment

After explaining about the study, consent will be received from study subjects that meet all of the inclusion and exclusion criteria. Study subjects will undergo preoperative ultrasound, and those with non-fan type LFCN will be registered for the study. We aim to recruit a total of 130 subjects, with 65 in each group (conventional and lateral fasciotomy). The flow chart of the study is shown in Figure 1. After consent, the study subjects will participate for 4 months, including 1 month of preoperative monitoring and 3 months of postoperative follow-up.

The trial flow chart is showed in Figure1.

Randomization

An assignment sheet will be created by the hospital's clinical trial center prior to the start of the study. According to the assignment sheet, subjects will be randomized to undergo either the conventional approach or the lateral approach using a fixed block size of 4.

Study timeline and data collection

After providing consent, study subjects will participate in the study for a total of 4 months, consisting of a 1-month pre-observation period and a 3-month post-observation period. The timeline for the assessment and data collection regarding primary and secondary outcomes is shown in Figure 2.

Ultrasonography of LFCN

Ultrasonography will be performed in the supine position using LOGIQ e Expert (GE health-care, Japan) with a 12-MHz linear array transducer according to the protocol developed by Zhu et al..

First, the transducer will be placed perpendicular to the body axis and 1-2 cm away from the outer edge of the inguinal ligament. At this location, images of the sartorius and tensor fasciae latae muscles will be collected, and LFCN in between the muscles will be identified. While keeping the LFCN in the imaging field, the probe will be moved distally between the sartorius and tensor fasciae latae muscles (Figure3-A). The LFCN will be defined as a structure in between the sartorius and tensor fasciae latae muscles that is characterized by low signal intensity (nerve bundle) surrounded by oval or spindle-shaped high signal intensity (perineurium)(24). Fan type and non-fan type LFCN will be defined based on the pathological findings reported by Rudin et al. Specifically, non-fan type LFCN will be defined as a structure with one main nerve surrounded by multiple smaller branches(Figure 3-B), and fan type LFCN will be defined as a structure with three or more branches of similar size or two or more nerves branching out from one main nerve(Figure 3-C).(15).

Surgical procedures of THA

In all cases, THA will be performed under general anesthesia by one of 5 experienced (>50 cases) hip surgeons(10, 25). Study subjects will be placed in the supine position, and the procedures will be performed with traction beds and intraoperative fluoroscopy(26). The skin incision will be made 2 cm

distally from the superior anterior iliac spine; specifically, the incision will begin 2 cm away from the superior anterior iliac spine and in parallel to the line that connects the superior anterior iliac spine with the head of the fibula. The total length of the incision will be 10 cm. The same techniques will be used to set up the surgical field and place the implants for both groups. The same implant will be used for both groups.

Interventions

The conventional approach involves incision of the skin, followed by incision of the fascia just below the site of skin incision. The lateral approach, on the other hand, proceeds outside from the site of skin incision, and involves incision of the fascia at a site 2 cm lateral from the conventional site of incision. Incision of the fascia will be performed to the extent that both approaches can be viewed in the surgical field.

Withdrawal criteria

Study subjects will be withdrawn from the study if the principle investigator and the study team decide that it is impossible to continue the study activities under the following criteria. If this applies, the subject will be given the explanation for their withdrawal. Subjects will continue to receive the standard of care that they need after study withdrawal.

- If withdrawal from the study is requested or if the consent is withdrawn by a study subject,
- If a subject develops any unexpected postoperative complication,
- If the study is terminated, or
- If the principle investigator decides that the study should be terminated for reasons other than those listed above.

Outcomes And Measurements

Primary outcomes

The primary outcome of the study is LFCN injury. Nerve injury will be assessed 3 months after the surgery during an outpatient visit using a patient-based questionnaire. Based on previous studies, we defined LFCN injury as having 1) no sensation, 2) numbness, 3) tingling, or 4) pain in the lateral aspect of the thigh except at the site of wound(13).

Secondary outcomes

The secondary endpoints will be assessed based on patient-reported outcomes (PROs) at 3 months after surgery in an outpatient setting to examine the extent to which LFCN injury affects the QOL. PROs will be evaluated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (pain,

stiffness, and function subscales), the Japanese Orthopaedic Association Hip-Disease Evaluation Questionnaire (JHEQ), and the Forgotten-Joint Score-12 (FJS-12).

The WOMAC was first described by Bellamy and Buchanan in 1986. It uses a scoring system with a total score of 0 (poor) to 96 (excellent), and has since been used worldwide to evaluate hip and knee osteoarthritis. The JHEQ is a self-administered questionnaire that takes into consideration the Asian lifestyle in terms of hip disorders with a total score of 0 (poor) to 84 (excellent). The FJS-12 is another self-administered questionnaire measuring the PROs on the ability of the patient to forget about their prosthetic implant in everyday life, and has a total score of between 0 (poor) and 84 (excellent)(26). The lowest and highest scores for WOMAC are 0 and 96, whereas those of JHEQ are 0 and 84; thus, the lowest and highest scores for each questionnaire were converted to 0 and 100.

Sample size

According to previous studies, the incidence of LFCN injury due to THA with the DAA is 28.6% in non-fan type patients(16). In total, 130 patients, 65 hips each operated on using the conventional approach and the new approach, are considered necessary assuming that the incidence of adverse events is reduced from 29% to 15% by employing the new approach using the chi-square test.

Information disclosure

The study was registered in the public University Hospital Medical Information Network (UMIN) clinical trials registry. The results will be presented at the Japanese Orthopaedic Association Annual Meeting and published in an orthopaedic journal. Data that will be presented will only consist of those that have been processed statistically; thus, personal health information of the study subjects will not be made available.

Harms

There is no expected harm to the study subjects that is directly attributed to study participation. The study team will provide appropriate care immediately after observing any adverse events, and report such events in clinical notes and case report forms. If treatment is required for such adverse events, the study team will notify the study subject.

Declaration of interests

The study will be conducted using internal funding within the Orthopaedics and Sports Medicine Departments. The study did not receive any other funding or benefits from external source (i.e. industry), and will be conducted independently from external organizations. As such, there is no conflict of interest that can affect the analysis or results of the study.

According to the Juntendo University Regulations of Management of Conflicts of Interest, the principle investigator and study team will report any conflict of interest and receive approval by the management committee.

Data monitoring

In accordance with the Standard Operating Procedures for the Storage of Materials and Information in Medical Research with Human Subjects, the principle investigator will store the following important documents related to the study electronically for 5 years from the end (or after termination) of the study: copy of the application form, notification documents from the Hospital Director, copies of applications and reports, assignment sheet, consent form (data will be deleted if consent is not obtained), copy of the case report form, and any other forms and records that are needed to ensure reliability of the data. Upon completion of this 5-year period, all documents will be deleted appropriately.

Statistical analysis

To assess the impact of LFCN injury on patient QOL, we will use Mann–Whitney U tests to compare differences in the PROs between patients reporting neuropraxia versus those with no symptoms, and $p < 0.05$ will be regarded as significant. All statistical analyses will be performed using SPSS 22 for Mac (SPSS Inc, Chicago, IL).

Data protection

In order to protect the confidentiality of personal health information, a study ID that does not contain any identifying information will be assigned to each subject. The principle investigator will follow the Standard Operating Procedures for the Storage of Materials and Information in Medical Research with Human Subjects. All data will be stored electronically or within the Orthopaedics Department of our hospital for 5 years from the end (or after termination) of the study. Upon completion of this 5-year period, all documents will be deleted or discarded appropriately.

Audits

Monitoring and audits will be performed according to the Standard Operating Procedures for Monitoring and Audits in Medical Research with Human Subjects of the Clinical Research Support Center.

The institutional research ethics board will review the study on an annual basis and evaluate whether the study activities can continue. Amendments to the study documents will be submitted each time and approved by the research ethics board. If any severe adverse events are identified within the hospital, the study team will report to the Hospital Director immediately. The research ethics board will then determine whether the study activities need to be terminated.

Discussion

Surgical approaches for the placement of hip prosthesis can be classified as posterior, lateral, and anterior. DAA and ALA are anterior approaches that do not involve dissection of the tendon to reach the hip joints. Thus, they are advantageous over other approaches in terms of functional recovery following the placement of hip prosthesis(3, 4, 6, 18, 27). Although both DAA and ALA are intramuscular

approaches, ALA is associated with a risk of motor paralysis as it involves approaching between the tensor fasciae latae and gluteus medius, which are supplied by the superior gluteal nerve(22, 23). On the other hand, the risk of motor paralysis is minimal in DAA as it is the only approach that involves the inter-innervated area where the sartorius and tensor fasciae latae muscles are supplied by the femoral and superior gluteal nerves, respectively(23, 28). Thus, we selected DAA over ALA for the purpose of this study.

However, injury to the LFCN, a sensory nerve, has been reported as a complication of DAA(5, 7-10). Although several studies demonstrated that LFCN injury does not affect the function of hip joint following THA, sensory disturbance caused by LFCN injury may affect patient satisfaction(7, 11, 12). In a previous study, we examined patient-based postoperative outcomes by administering FJS-12 to patients who underwent DAA-THA and demonstrated that patients who developed LFCN injury had a significantly poorer outcome than those without injury(13). This suggested that although LFCN injury does not cause significant harm to the hip function, it significantly affects patient satisfaction. Thus, we believe that it is important to develop strategies to minimize LFCN injury.

In order to prevent LFCN, an incision for DAA is generally made outside of the space between the sartorius and tensor fasciae latae muscles. However, even with this technique, 32% of our patients developed LFCN injury(13). In a subsequent study, we excluded fan-type LFCN based on ultrasound findings because injury to fan-type LFCN is considered unavoidable. In this study, we noted injury to non-fan type LFCN in 28.6% of cases(16). Based on pathological findings, Ropars et al. suggested that damage to the nerves can be prevented by approaching as laterally and distally as possible(29). Therefore, we hypothesized that the risk of injury to non-fan type LFCN can be reduced by approaching similar to ALA such that the incision further away from what is typically performed in conventional fasciotomy. If this approach is successful at preventing nerve injury, it will overcome one of the few limitations of DAA. We believe that this will be greatly beneficial to patients undergoing THA.

Trial Status

We are actively recruiting at the time of submission. Patient recruitment started on June 2019 and the study is scheduled for completion in March 2021. The date of enrolment of the first participant to the trial was 3 June 2019. This protocol is version 1.0, dated 20 February 2019. The study is scheduled for completion in March 2021.

Abbreviations

THA: Total hip arthroplasty; DAA: Direct anterior approach; LFCN: Lateral femoral cutaneous nerve; BMI: Body mass index; QOL: Quality of life; PROs: patient-reported outcomes; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; JHEQ: Japanese Orthopaedic Association Hip-Disease Evaluation Questionnaire; FJS-12: Forgotten-Joint Score-12

Declarations

Acknowledgements

The authors would like to thank Tamaki Nara, Yuta Jinnai and Seiya Ishii for their intellectual contributions and support.

Authors' contributions

HT and TB originated the idea for the study, contributed to its design and developed the intervention protocol. KK is supervisor of the project. TB, TW, YH, SB and YO are the operator who will conduct this study at the hospital. YJ and NY will perform the statistical analysis. The authors read and approved the final manuscript.

Funding

No external funding will be used. This study is supported by the Advanced Research Foundation, the Juntendo University Hospital, Tokyo, Japan. There is no role for funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Availability of data and materials

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Ethic approval and consent to participate

This study was approved by the research ethics committee of Juntendo University Hospital on January 2019 (reference number:18-236). We have obtained informed consent from all study participants.

Consent for publication

The pictures of LFCN will be used to confirm the LFCN distribution. Therefore, written consent will be obtained using our trial documents from all participants.

Competing interests

The authors declare that they have no competing interests.

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Figures

Figure 1

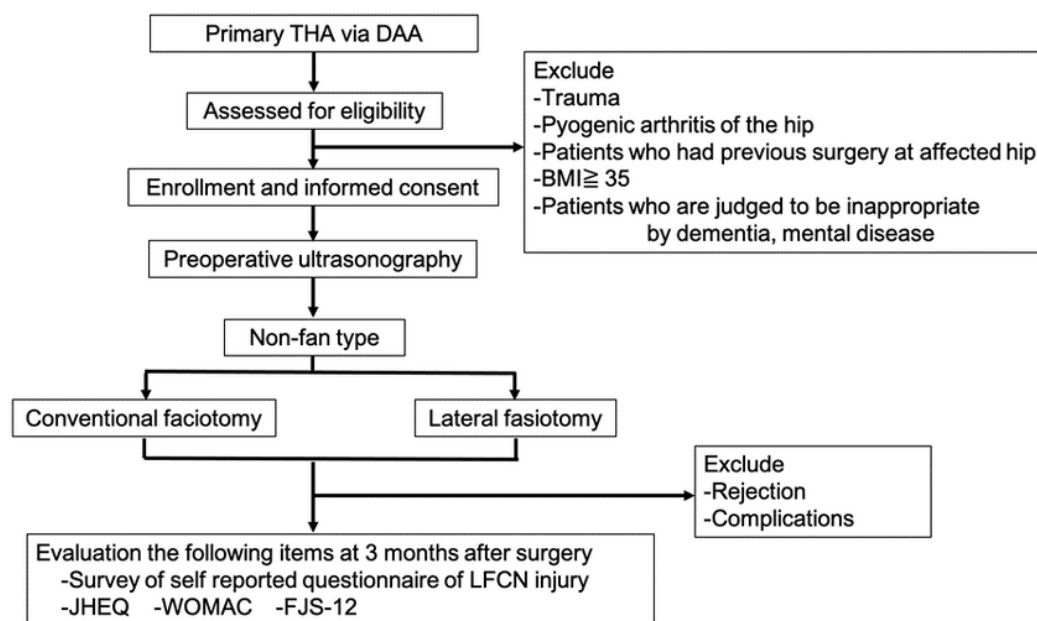


Figure 1

Flow chart of the trial protocol.

Figure 2

TIMEPOINT	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	
	1 month preoperation	0	Surgery day	3 months Follow up
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
Conventional approach			X	
Medial approach			X	
ASSESSMENTS:				
Radiography	X			X
Ultrasonography		X		
WOMAC	X			X
JHEQ	X			X
FJS-12				X
Presence or absence of neuropathy				X
Observation of adverse events			←→	

Figure 2

The schedule of enrolment, intervention, and assessments. WOMAC Western Ontario and McMaster Universities Osteoarthritis Index, JHEQ Japanese Orthopaedic Association Hip-Disease Evaluation Questionnaire, FJS-12 Forgotten-Joint Score-12.

Figure 3-A

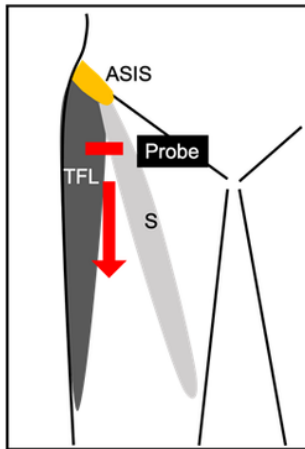


Figure 3-B

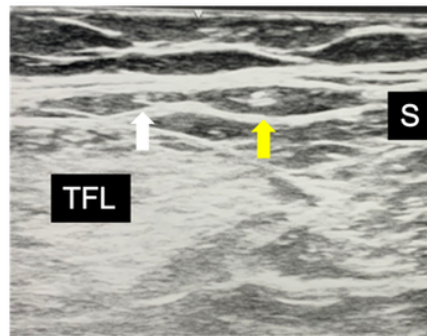


Figure 3-C

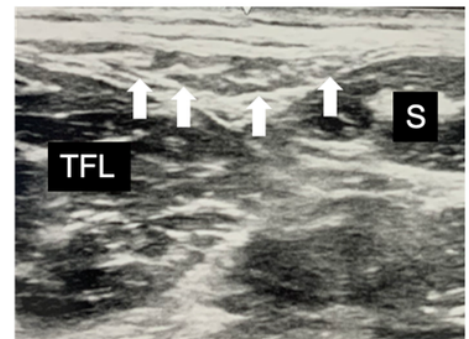


Figure 3

A: Schematic diagram showing the initial location of the probe. The probe is moved from the proximal to distal hip joint along the region between the sartorius and tensor fasciae latae muscle (Arrow). ASIS: Anterior superior iliac spine, TFL: Tensor fascia latae, S: Sartorius Figure3-B: Transverse ultrasound image of the non-fan type within the intermuscular space between the sartorius and the tensor fascia latae. (Yellow arrow: main branch, White arrow: thin branch) TFL: Tensor fascia latae, S: Sartorius Figure3-C: Transverse ultrasound image of the fan type within the intermuscular space between the sartorius and the tensor fascia latae. (Arrows: several nerve branches) TFL: Tensor fascia latae, S: Sartorius,

Supplementary Files

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