Treatment of lateral knee joint pain with artificial lateral meniscus prosthesis after meniscectomy.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON57018

Source
ToetsingOnline

Brief title
Early ARtificial laTeral prostHesis (EARTH)

Condition

- Joint disorders

Synonym
post meniscectomy pain

Research involving
Human

Sponsors and support

Primary sponsor: ATRO Medical B.V.
Source(s) of monetary or material Support: Europese Unie en ATRO Medical B.V.

Intervention

Keyword: Artificial, Lateral, Meniscus, Prosthesis

Outcome measures

Primary outcome

• Safety assessed by device related (S)AEs within 12 months of surgery.

• Knee MRI (non-weight-bearing) at 12 months (extrusion measurement as measure for prosthesis integrity).

Secondary outcome

• The nature and frequency of all adverse events observed during the study including their timing, severity, and relatedness to the investigational device.

• Incidence of secondary surgical intervention of the index knee.

• Knee MRI (non-weight-bearing) at 12 months or explantation (extrusion measurement as measure for prosthesis and joint integrity including cartilage status).

Study description

Background summary

Meniscal tears are the most common knee injury, resulting in approximately 61 meniscectomies per 100,000 patients annually of which ~40% of the procedures is performed in lateral menisci.[1] In the Netherlands, in 2010, approximately 42,000 meniscectomies were performed annually and, in the US, approximately 500,000 patients are subject to partial or total meniscectomy. Meniscectomy results in impaired function of the meniscus and decreases the contact area by up to 75% and increase contact pressures by up to 300% [2]. Clinical and radiological studies have shown that most patients improve clinically post-meniscectomy, but that partial or complete loss of the meniscus promotes in 40% of the post-meniscectomy patients the early development and progression of Knee Osteoarthritis 5-20 years post-surgery [3]. Chatain, et al. [4] outlines that 14% of these post-meniscectomy patients demonstrates the rapid

onset of symptomatic unicompartmental pain in the meniscus-deficient knee, the so-called post-meniscectomy pain syndrome.

As no cure for the post-meniscectomy pain syndrome patient is currently available, most patients endure the remaining pain and experience gradual loss of their mobility. Therefore, patients have to adapt their daily life activities. The symptoms often have a profound effect on the quality of life (QoL), affecting both physical functioning and psychological parameters. There are no specific clinical guidelines for the post-meniscectomy pain syndrome but treatment is mostly conservative analogue to the treatment guidelines for knee osteoarthritis [5] of which the Standard of Care (SOC) treatment scheme is as follows:
• First line of treatment is a combination of non-pharmacological interventions such as exercise, education and weight loss programs, physical therapy and use of assistive devices. During this stage of the disease, physicians often recommend soft pain medication, such as paracetamol.
• Second line of treatment involves stronger pain medication, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and the even less-desirable opioids. Also, corticosteroid injections are applied directly into the knee joint. These treatments reduce pain but do not prevent continuous joint degeneration. This will eventually result in a more severe KOA, for which pharmacological pain intervention is no longer sufficient. With a mean age at KOA diagnosis of 54 years-old, the average time on pain medication preceding the third line of treatment is 13 years for the regular patient (K/L grade 2) [6].
• Third line and final treatment: once most articular cartilage is degenerated and first- and second-line conservative therapies are no longer effective to delay or prevent disease progression, surgical treatment is often necessary. The SOC surgical treatment for end-stage KOA is Total Knee Arthroplasty (TKA) or Unicompartmental Knee Arthroplasty (UKA). This highly invasive surgical intervention removes the diseased bone and cartilage from respectively one or both knee joint compartments, which is replaced with an artificial joint made of synthetic materials. TKA have demonstrated improved function, reduced pain and improved QoL for patients [7]. For ease of reading, TKA and UKA are grouped as *TKA* in the remainder of this document, unless specifically indicated separately. A distinct limitation of TKA is that it is a suboptimal treatment option in patients under the age of 65 years since younger active and high-demand patients are at a greater risk for prosthesis failure due to reduced durability of the TKA. Consequently, the patients are likely to outlive their prosthesis and a revision surgery is required to replace the original implant with a new knee replacement. This is a more complex procedure associated with higher complication rates, extended hospitalization, and unsatisfactory functional outcomes [8]. After the revision TKA no other treatment options are possible, leaving the patient immobile and wheelchair bound when the prosthesis stops functioning.

The development of the lateral meniscus prosthesis focuses on post-meniscectomy

pain syndrome patients, with limited underlying cartilage damage (Kellgren Lawrence scale 0-2), who remain with unicompartmental pain in the lateral meniscus-deficient knee and reduced mobility. Clinical and radiological studies have shown that most patients improve clinically, but that early onset osteoarthritis can develop later[9]. This is the patient group that now spends on average 13 years on a non-surgical regimen of pain medication [6]. Obviously, the non-surgical natural history of post-meniscectomy syndrome is very unfavorable, and the pain remains also on the longer term. This is also confirmed by the non-surgical control group in the study by McKeon et al. in which the patients with a non-operative treatment perform stable low[10]. Treatment options for patients with meniscus deficient knees are limited to transient conservative treatment options (i.e., first and second line of treatment of SOC). This treatment often falls short, and the pain remains on an unacceptable level in many patients. Furthermore, in a meniscus deficient knee the KOA progresses until it reaches end-stage KOA condition, then the only solution is a TKA whereby the degenerative (part of the) joint is removed and replaced. There is a large treatment gap between the first knee pain after meniscectomy and the eligibility for a TKA. Hence, there is a strong unmet need for a durable and cost-effective treatment solution that will relieve chronic knee pain and regain mobility in symptomatic post-meniscectomy patients. Such treatment could save the knee joint and delay or prevent the need for a knee joint replacement.

The LMP is intended to provide unicompartmental pain relief in the meniscus-deficient knee by simulating the function of the natural meniscus. The LMP is intended to restore the function of the natural meniscus and redistribute loads transmitted across the knee joint.

Study objective

The primary objective of the clinical investigation is to evaluate the safety of the LMP system within 1 year after implantation in terms of adverse events and prosthesis integrity. Outcomes: AEs and prosthesis extrusion on MRI 12 months post-operatively.

Secondary objectives are:
• To demonstrate clinical performance within 2 years in terms of pain relief and maintenance of function (Outcomes: KOOS, Pain VAS, OKS, Lysholm scale, Tegner Activity Scale).
• To record changes in general well-being (Outcomes: SF-36, EQ-5D-5L, WORQ).
• To identify wet biomarkers as objective measures for clinical status (urine, blood, synovial fluid)

Study design

Prospective, multi-center, open label, single arm clinical investigation

Intervention

Implantation with the lateral meniscus prosthesis (LMP) system.

Study burden and risks

The intended clinical benefits of the LMP system are:

• Pain relief in the lateral compartment of the knee
• Increased functional activity
• Symptom relief
• Improved Quality of Life

The following potential Adverse Device Effects have been identified:
• Pain discomfort and/or Range of Motion (RoM) impairment, caused by oversizing, undersizing or wrong placement of the meniscus prosthesis
• Pain discomfort and/or RoM impairment, caused by impingement of the meniscus prosthesis
• Breakage of the meniscus prosthesis, potentially leading to pain discomfort and requiring consecutive surgery to remove or replace the prosthesis
• Wear of the meniscus prosthesis, potentially leading to breakage, pain discomfort and/or synovitis
• Wear of the fixation tape, potentially leading to breakage and/or synovitis
• Impingement of implant components between the articular surfaces as a result of incorrect positioning during surgery or after implant failure, potentially resulting in changes to the cartilage and/or bone tissue
• Post-operative infection of the joint, which requires consecutive surgery with rinsing of the joint, prolonged antibiotics, and possible removal of the implant.
• Neurovascular damage during surgery: especially drilling of the posterior drill hole may damage the neurovascular structures posterior in the knee (popliteal nerve, artery, and vein)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Is aged 18 to 70 years (inclusive) at the time of screening
2. Has a history of partial or total meniscectomy
3. Has post-meniscectomy pain syndrome (defined as symptomatic unicompartmental pain in the meniscus- deficient knee without severe cartilage damage- Kellgren & Lawrence grade 3-4) in the lateral compartment as confirmed by patient history and MRI
4. Has a KOOS Pain of <= 75 at the time of screening
5. Failed conservative treatment options (non-operative treatments of the knee, i.e., self-management exercise programs, physical therapy, braces, pain medication, and intra-articular corticosteroids)
6. Has neutral alignment < ± 3° of the mechanical axis
7. Is willing to be implanted with the LMP System and to comply with instruction for use
8. Is able and willing to do the study required follow-up visits, questionnaires, X-rays, and MRI
9. Is able and willing to understand and sign the study Informed Consent Form
10. Is able to read and understand the national language of the country in which the clinical site is located.

Exclusion criteria

1. Has progressed knee osteoarthritis, Kellgren & Lawrence grade 3-4 in the lateral compartment

2. Has evidence of a modified Outerbridge Grade IV cartilage loss on the lateral tibial plateau or femoral condyle that potentially could contact the meniscus prosthesis
3. Has medial compartment pain and Grade III or Grade IV modified Outerbridge cartilage score in the medial compartment
4. Has a varus or valgus knee deformity of > 3°
5. Has a valgus alignment that is not passively correctable
6. Has a laxity level of more than Grade II (IKDC), primary or secondary to an injury of the anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL) and/or lateral collateral ligament (LCL) and/or medial collateral ligament (MCL).
7. Has significant trochlear dysplasia, patellar instability or symptomatic patellar misalignment
8. Has patellar compartment pain and Grade III or Grade IV modified Outerbridge cartilage score in the patellar compartment
9. Had an ACL reconstruction performed < 9 months prior to surgery
10. Has a BMI > 35 at the time of screening
11. Received any type of prosthetic knee implant made of artificial non-resorbable plastic, metal or ceramic, not including the lateral meniscus prosthesis
12. Has a knee flexion contracture > 10°
13. Has flexion < 90°
14. Had a knee alignment correction osteotomy < 9 months ago
15. Has insufficiency fractures or avascular necrosis of the lateral compartment

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2024
Enrollment:	16

Type:	Actual

Medical products/devices used

Generic name:	Lateral meniscus prosthesis (LMP) system
Registration:	No

Ethics review

Approved WMO Date:	26-09-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84929.091.23