**Cover page**

**Official Title:** *Autologous semitendinosus tendon as meniscal transplant – a pilot study*

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**Study protocol**

*Autologous semitendinosus tendon as meniscal transplant – a pilot study*

**Background, literature and own research:**

Meniscectomy leads to a very large extent to increased joint surface load and on biomechanical grounds osteoarthritis over time. Both current and older research shows that the more of the meniscus that has been resected, the greater the impact on the cartilage surfaces. Repair of a damaged meniscus has therefore gained more interest and especially in younger patients (<40 years) this is a treatment that is considered valuable in order to reduce future osteoarthritis risk.

In situations where the meniscus is irreparable, meniscectomy is still the only available method of treatment.

From an international perspective, meniscus transplants are a long-established method of treatment. The long-term results are decent based on both transplant survival and PROM (patient related outcome measures). In Sweden, however, meniscus transplantation with allograft from tissue bank has never been successful on a large scale and no centers today routinely use the method. In Sweden, there are also no tissue banks for transplants, but instead must be purchased from, for example, the USA or Belgium at a considerable cost.

An alternative to allograft has in recent years become synthetic menisci, where there are two alternatives on the market today. However, these are primarily indicated where there is still a certain amount of meniscus tissue left and are intended to act as a scaffold for the regeneration of meniscus tissue. Even these two types are costly. Medium and long-term results are rather slightly worse than with conventional meniscus transplant, but there are fewer studies published.

Therefore, in the light of the existing methods, there is a great potential for improvement in the area of meniscus transplantation, both in terms of cost but also availability and results.

Tendon grafts with autologous semitendinosus tendon have been used in various reconstructive orthopedic surgeries for about 25 years. In anterior cruciate ligament surgery, it is by far the most common transplant and according to the Swedish cruciate ligament register, it is used in > 97% of all primary operations, about 3,000 per year in Sweden. Also in other reconstructive surgeries where free tendon graft with collagen tissue is needed, it is the most common type of transplant, for example reinforcement reconstructions of the patellar tendon, quadriceps tendon, various tendon extensions, etc. The main reasons are the low morbidity after harvesting the tendon, the good tissue capabilities and the easy harvest of the tendon. Of course, this also means no additional cost because the patient's own tissue is used. When this tendon is used as a graft to the anterior cruciate ligament, there is a clear remodeling of the cells in the tendon which over time is gradually transformed into a more cruciate ligament-like character. This remodeling process is considered to depend on the load and positioning of the transplanted tendon when exposed to its new environment within the knee joint.

An earlier study is available where the semitendinosus has been used as a meniscus replacement, but in this study the procedure was performed on a few patients who were all on the waiting list for knee replacement surgery and thus already had pronounced osteoarthritis, active degenerative process in the knee joint. Thus, a group of patients who would never have been eligible for conventional meniscus transplant or meniscus replacement surgery. The fact that these tendons were not remodeled into neomenisci is therefore not surprising since the knee joints were already in a pronounced ongoing degenerative process. Furthermore, these

patients had a deviant alignment (load line through the knee) due to osteoarthritis and this in itself should be a contraindication for all types of meniscus replacement surgery.
The current pilot study aims to evaluate the possibility of replacing an injured or missing meniscus with a semitendinosus tendon as a transplant in patients who could otherwise benefit from meniscus replacement and thus could be relevant for conventional meniscus transplantation with one of the currently available grafts (meniscus allograft or synthetic meniscus replacement)

**Research questions**
Can the body's own semitendinosus function as a meniscus transplant?
Do patients who receive a neomeniscus of the semitendinosus experience reduced post meniscectomy problems?

**Hypothesis**
The semitendinosus tendon functions as a meniscus graft / neomeniscus and lead to better subjective knee function and quality of life than after meniscectomy.

**Purpose**
If meniscus replacement with the body's own semitendinosus works at least as well as now conventional replacement alternatives, this will be a very big gain from several perspectives. From a patient perspective, because one uses the body's own graft with good availability and with no risk of viral infection spreading. From a societal and cost perspective because the cost of the transplant is zero. If the method works and became generally acceptable, with a biomechanically functioning "neomeniscus", this would also mean great gains in an osteoarthritis prevention perspective in a large number of patients.

**Design**
Patients (n = 15) between 20-50 years of age, who have previously undergone total or subtotal meniscectomy medially or laterally, lack of significant osteoarthritis (Ahlbäck 0-1), alignment according to HKA +/- 3 degrees varus / valgus. Furthermore, they should show symptoms that would constitute an indication for meniscus transplantation, ie. medial or lateral disorders that are accentuated by increased load (status post meniscectomy symptoms). The procedure is performed with the usual harvesting of the semitendinosus tendon via a 3 cm long incision over the pes anserinus (tendon attachment to the tibia below the knee joint). Tendon from the ipsi or contralateral side will be used. Transplantations are then performed arthroscopically or via so-called mini-open surgery in the same way as conventional meniscus transplantation. Similar to meniscus transplantation, the two ends of the new meniscus are fixed via 5-6 mm wide drill channels in the tibia corresponding to the meniscus roots. In the middle corpus part also one or more suture anchors with just under 2 mm at the drill channel. The remaining part of the circumferential meniscus is fixed to the capsule with accepted meniscus suture technique (all inside, inside out and outside in).
Antibiotics and thrombosis prophylaxis will be given according to usual surgical procedures. Postoperatively, partial weight bearing will be allowed. A hinged knee brace will be used that allows 0-30 degrees of mobility for 3 weeks, 0-60 for another 3 weeks and 0-90 for another 2 weeks. After 8 weeks open brace for another 4 weeks. Full weight bearing will be allowed after 6 weeks. The protocol mimics that used in previous meniscus transplants / meniscus replacement surgeries.

**Outcome**

Evaluation will take place with a clinical examination and MRI after 3, 6, 12 resp. 24 months in accordance with follow-up after meniscus transplant. HKA and usual X-ray at 6 months postoperatively and thereafter if necessary according to the clinical routine for osteotomy and meniscus transplantation.
Established and validated function scores regarding knee-related quality of life (KOOS), EQ5D, Global score, Lysholm score, activity score according to Tegner and knee-specific score according to IKDC will be performed preoperatively and 6, 12 and 24 months postoperatively. Usual clinical status with range of motion, tenderness, swelling, stability will be performed in connection with the return visits 6 weeks, 3 months, 6 months, 12 months and 24 months. Only for any reason (complication or other new injury) will new arthroscopic surgery be performed.

**Inclusion in the study**
If the patient meets all the criteria, participation in the study is offered. Inclusion takes place via written information and consent.

*Inclusion criteria*
- Previously undergone total or subtotal meniscectomy medially or laterally
- Absence of significant osteoarthritis (Ahlbäck 0-1)
- Alignment acc. HKA +/- 3 degrees varus / valgus
- Symptoms that would be an indication for meniscus transplantation, ie. medial or lateral disorders that are accentuated by increased load (status post meniscectomy symptoms).

*Exclusion criteria*
- Significant osteoarthritis (Albäck> 1)
- Alignment acc. HKA> 3 degrees varus / valgus
- Ligamentary knee joint instability eg untreated cruciate ligament instability.

**Logistics**
Patients who meet the inclusion criteria will receive information about and be offered to participate in the study. The patient will undergo surgery as above. Patients are called for return visits after 6 weeks, 3 months, 6 months, 12 months and 24 months when the usual clinical status with range of motion, tenderness, swelling, stability will be carried out. The patient may fill in validated function scores preoperatively and 6, 12 and 24 months postoperatively as follow-up MRI will also be performed.
The information is collected in a deidentified database.
The doctors responsible for the study, Erik Rönnblad and Karl Eriksson, calculate outcomes and test the hypothesis. The results will be published in a scientific journal.

**Data collection**
- Data collection regarding knee function and health-related quality of life takes place via standardized questionnaires filled out by the patient at 6, 12 and 24 months postoperatively.
- Evaluation of healing and possible morphological transformation of the graft will be ascertained by MRI.

**Analysis**
Statistical analytical expertise will be consulted.

**Schedule**
Define hypothesis (autumn 2016).
Ethics application (winter 2016)

Data collection (2017-2021)
Clear and analyze data (continuously 2019-2021)
Interpret results (2021)
Writing Article (2021)

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