Long term follow up after rotationplasty

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Primary Objective: To asses health-related quality of life and functional outcome after long-term follow up, in patients treated with a rotationplasty for primary malignant bone tumours or PFFD compared to above-knee amputation means.Secondary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON55093

Source
ToetsingOnline

Brief title
Long term follow up after rotationplasty

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Rotationplasty

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: filantroop: St Lodewijk-de Kort;Noordersingel 30;3755 EZ Eemnes

Intervention

Keyword: functional outcome, long-term follow-up, quality of life, rotationplasty

Outcome measures

Primary outcome

Health-related quality of life (HRQoL) and functional outcome after long-term follow up, in patients treated with a rotationplasty for primary malignant bone tumors or PFFD compared to above-knee amputation (for similar indications)

means.

1. Self-reported health-related quality of life (Qol), assessed with the 36-item Short Form Health Survey (SF-36).

2. Self-reported activity limitations, assessed with the Toronto Extremity Salvage Score (TESS) measuring functionality, and parts of the Prosthesis Evaluation Questionnaire (PEQ) measuring satisfaction with the prosthetic device. To objectify activity limitations, gait bionechanics4, and walking speed and energy cost are assessed with 3D gait analysis and a 6-minute walk test, respectively.

3. Impairments in ankle (now knee) joint function will be measured with the Ankle Osteoarthritis Score (AOS), Foot and Ankle Outcome Score (FAOS) and Visual Analogue Score (VAS). Additional physical examination will focus on knee angulation (genua valga/ vara) or foot defects, impingement, range of motion (American Orthopaedic Foot and Ankle Society (AOFAS) score) and muscle strength (Medical Research Council (MRC)). To objectify joint rejections osteoarthritis on plain radiographs are evaluated, using individual radiographic features.

Secondary outcome

Additional outcomes, at baseline, patient demographics (e.g. sex, ethnicity) will be recorded. Also, the leg prosthesis will be checked with respect to fit, alignment and proper functioning.

Confirm whether rotationplasty patients actually function better compared to above-knee amputation patients. And if this also results in a measurable better quality of life.

Study description

Background summary

The rotationplasty was first described (1930) by Borgreve as a treatment option for tuberculosis of the knee joint and popularized (1950) by van Nes to treat congenital femoral defects. Subsequently, this surgical technique was introduced in the treatment of osteosarcomas, as an alternative for above-knee amputations. A major advantage of rotationplasty compared to above-knee amputation is preservation of knee function with a better functional outcome, while maintaining surgical margins around the tumor. Further, complication rates after rotationplasty are low and additional surgeries exceptional. Rotationplasty does not result in a normal knee, but on short-term it allows higher walking speed, better gait, lower oxygen consumption and improved general efficiency compared to above-knee amputation or arthrodesis. As a consequence of these favorable factors, patients can participate in various sport activities. On the other hand, concerns were expressed about psychosocial consequences of the mutilating appearance of the rotated and shortened leg. Previous research did not confirm these expected adverse psychosocial effects. As a result of improved limb-sparing techniques within orthopedic oncology, such as endoprostetic replacements, auto- or allografts and combinations of these procedures, nowadays rotationplasty is rarely used. Rotationplasty is still indicated when limb-sparing surgery is not feasible after resection of a malignant bone tumor about the knee joint, or as a reconstruction modality to avoid more extensive amputation after a failed limb-salvage procedures. A similar functional outcome was found after endoprostetic reconstruction and rotationplasty, however patients with an endoprothesis might lead a more sedentary life due to fear of destroying the endoprothesis.

Rotationplasty has proven to be an effective, highly functional option in short- and mid-term studies. However, little is known on the long-term impact of life about this invasive procedure. The limited available information are small case series or case reports with a mean follow up of mostly 15-20 years. The main objectives of this cohort study, are to assess the long-term health-related quality of life, and physical and functional outcomes of patients after an rotationplasty, using a combination of self-administered questionnaires, physical examination, evaluation of osteoarthritis, and walking tests. Insights into these long-term outcomes are needed to better inform (new) patients about the consequences of rotationplasty and may change future procedures in favor or against this orphan surgical procedure.

Study objective

Primary Objective:
To asses health-related quality of life and functional outcome after long-term follow up, in patients treated with a rotationplasty for primary malignant bone tumours or PFFD compared to above-knee amputation means.

Secondary Objective(s):
· To evaluate factors affecting health-related quality of life, occupation and sport activities with regard to the performed rotationplasty.
· To measure self-reported activity limitations of these patients by questionnaire*s and satisfaction with their external prosthesis. And to further objectify activity limitations after rotationplasty, as measured by gait biomechanics, walking speed and walking energy cost.
· Furthermore, impairments will be revealed by physical examination of hips, knee and ankles objectified by development of osteoarthritis on plain radiographs.

The outcomes with respect to gait biomechanics and walking energy cost can be compared to healthy reference values, but also to the values of patients with above-knee amputations. Measured joint angles and joint moments of the affected leg (rotationplasty) can be compared to the contralateral side and to general population means. This can provide insight into compensation mechanisms of the control lateral leg and into fall risk. Furthermore, osteoarthritis on performed radiographs can be related to joint loading during walking.

Study design

The study design is a cross-sectional follow-up study. All patient records of consecutive patients who had an arthroplasty between 1980-2005 at the Academic Medical Center (AMC) or *Onze Lieve Vrouwe Gasthuis* (OLVG) in Amsterdam are checked. We will score both deceased patients and survivors. Survivors (approximately N=30-50) will be approached to take part on this study by phone followed by a letter explaining the study including an informed consent. The

participants can either fill out the self-reported questionnaires (SF 36, TESS, PEQ, VAS, AOS, FAOS and social-/ prosthesis related questions) at home through internet (using Castor Electronic Data Capture) or on paper at the outpatient clinic.

The participants will visit the outpatient clinic to undergo a physical examination (hips, knee- and ankle function) and get plain radiographs of the formal ankle joint, now functioning as a knee (including the contralateral ankle to compare with) and of the pelvis (to compare osteoarthritis development of both hips). If they did not fill out computer based questionnaires at home, they can to do that during their one time visit at the outpatient clinic. This part of the study will be performed at the department of orthopaedic surgery of the AMC in Amsterdam, the Netherlands. When possible during the same visit, patients undergo a 3D gait analysis and 6-minute walking energy cost test performed at the department of rehabilitation of the AMC in Amsterdam, the Netherlands.
The duration of the study depends on the time needed for data collection, probably several months up to a year.

Study burden and risks

Both patients and controls will be asked to visit the Amsterdam AMC maximal two times to participate in the explained measurements.
The risks are negligible (plain radiograph) and the burden minimal (time coming to the hospital to answer the health-related quality of life questions (1 hour), to undergo a physical examination (30 minutes), a 6-minute walk test (30 minutes) and a 3D gait analysis (75 minutes)).
The study can only be done using these specific patients groups, because it is a rare disease and very rare surgical treatment.
The measurements are non-invasive. There will be no costs related to the study components. Traveling costs for the visits will be reimbursed by the research project. Questionnaires can be completed during the visit or by e-mail using *CASTOR EDC*

Potential risks:
Possible risks related to all study parts are considered minimal.
During the gait analysis and 6-minute walk test, patients walk on an obstacle free indoor track, and risks of falling are considered minimal. Patients can get tired during these tests (6MWT and 3DGA), however it is ensured that they receive enough recovery time during and in between tests.

Potential benefits:
Participants get the chance to receive more insight in their functionality and their external prosthesis is being checked by experts in the field. Also, they get the opportunity to express dissatisfaction and might come up with solutions to immediately improve their own quality of life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

· Treated with a rotationplasty or above-knee amputation for a primary musculoskeletal malignancy or PFFD at the AMC or at the OLVG in Amsterdam between 1980-2005.
· Being able to visit the AMC in Amsterdam once or twice.

Exclusion criteria

· To perform the walking energy cost measurements, patients need to walk 6 minutes. If they cannot maintain 6 minutes of walking, they are only excluded for that part of the study.
· Patients who cannot read and/ or write Dutch cannot participate the study.
· Patients with contra-indications for radiographs will be exempted to this

part of the study.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2020
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL72453.018.20