BADAL X®

OTN Implants

Aftercare Guideline

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Contents

1. BADAL X Aftercare

Good quality and long lasting aftercare is a critical part of the treatment after the implantation of a bone anchored prosthesis. It is important that BADAL X aftercare is well performed according to a standard guideline. Trained and certified professionals under the supervision of the surgeon that implanted the BADAL X system are responsible for adhering to the guideline. It is important that at least a prosthetist, a physical therapist and a nurse are involved in the aftercare team. In some countries this multidisciplinary aftercare team can be accommodated under supervision of a physiatrist in a rehabilitation center. In other countries this team will be situated in an orthopedic workshop. In all circumstances, the surgeon is responsible for the organization, certification and accommodation of the aftercare team. OTN Implants values adequate aftercare and supports the training and certification of the multidisciplinary aftercare team in close collaboration with the surgeon that implanted the BADAL X system.

Tasks of the aftercare team members

Prosthetist:
- Pre-operative patient counseling regarding bone anchored prosthetics
- Accommodation of the multidisciplinary aftercare team
- BADAL X Connector installation
- Exo-prosthesis attachment and alignment
- Give advice in the choice of prosthetic parts and components based on activity level
- Organization of the connector maintenance and prosthetic alignment follow up program

Physiotherapist:
- Rehabilitation loading program
- Gait training
- Phasing out walking aids
- Adjusted loading instructions
- Life style recommendations

Nurse:
- Stoma care instructions
- Stoma problem management
- Recommendations for stoma maintenance and stoma care products
- Life style recommendations

Physiatrist/surgeon:
- Prescription of multidisciplinary aftercare
- Prescription of adjusted loading programs
- Diagnostics and treatment of pain during rehabilitation
- Diagnostics and treatment of stoma problems
- Organization of the implant maintenance follow up program

2. Exo-prosthesis installation and alignment

2.1 Exo-prosthetic parts and components

2.1.1 Use a compatible connector for the attachment of an exo-prosthesis

The BADAL X modular bone anchoring systems consists of 3 components:

1. An implant or fixture, applied by a surgeon in an operation room under sterile conditions
2. An adapter or abutment, applied by a surgeon in an operation room under sterile conditions
3. A connector, applied by either a surgeon or certified prosthetist in an out-patient clinical or orthopedic workshop setting

The Morse tapers of the three components are manufactured with high precision. Incompatibility of Morse taper fit must be avoided to prevent system failure and possibly harm to the amputee as end user. The combination of implant, adapter and connector are tested on mechanical safety by the manufacturer according to the European MDR guidelines. These validations are included in the medical device dossier and checked by the notified bodies. Legal manufacturers of bone anchoring devices attach great importance that components of a specific manufacturer are not exchanged with components of competing manufacturers. This is because a legal manufacturer of bone anchoring devices has no control and no security with respect to the compatibility (exactness and tolerances of Morse taper fittings) of components when components of competing manufacturers are combined. Combining components of competing manufacturers is possible when this is allowed by the manufacturer and included by the manufacturer in the Instruction For Use. If combining competing products is not allowed by the manufacturer but the doctor or end user (amputee) nevertheless decide to combine competing products, this is allowed according to the off-label use rule. In that case the doctor and end user (amputee) may deviate from the instructions for use from the manufacturer. This can only be done when there is a mutual agreement and acceptance (informed consent) between the doctor and end user (amputee) regarding the possible risks related to the off-label use of the medical device. This off-label use informed consent should be documented by the doctor in the medical chart of the end user (amputee).

2.1.2 Off label use of connectors

When an amputee with a bone anchored device asks his or her certified prosthetist to exchange the connector from one manufacturer for a connector from another manufacturer, the prosthetist may do this if the patient has an agreement from his surgeon that was responsible for the bone anchoring device implantation. This off-label use must be discussed by the surgeon with the patient and the informed consent documented by the surgeon. If that procedure has been followed, the prosthetist can exchange the connectors without any problems and the prosthetist can not be held liable in case of personal injury or costs because of a medical device failure as a result of off-label use.

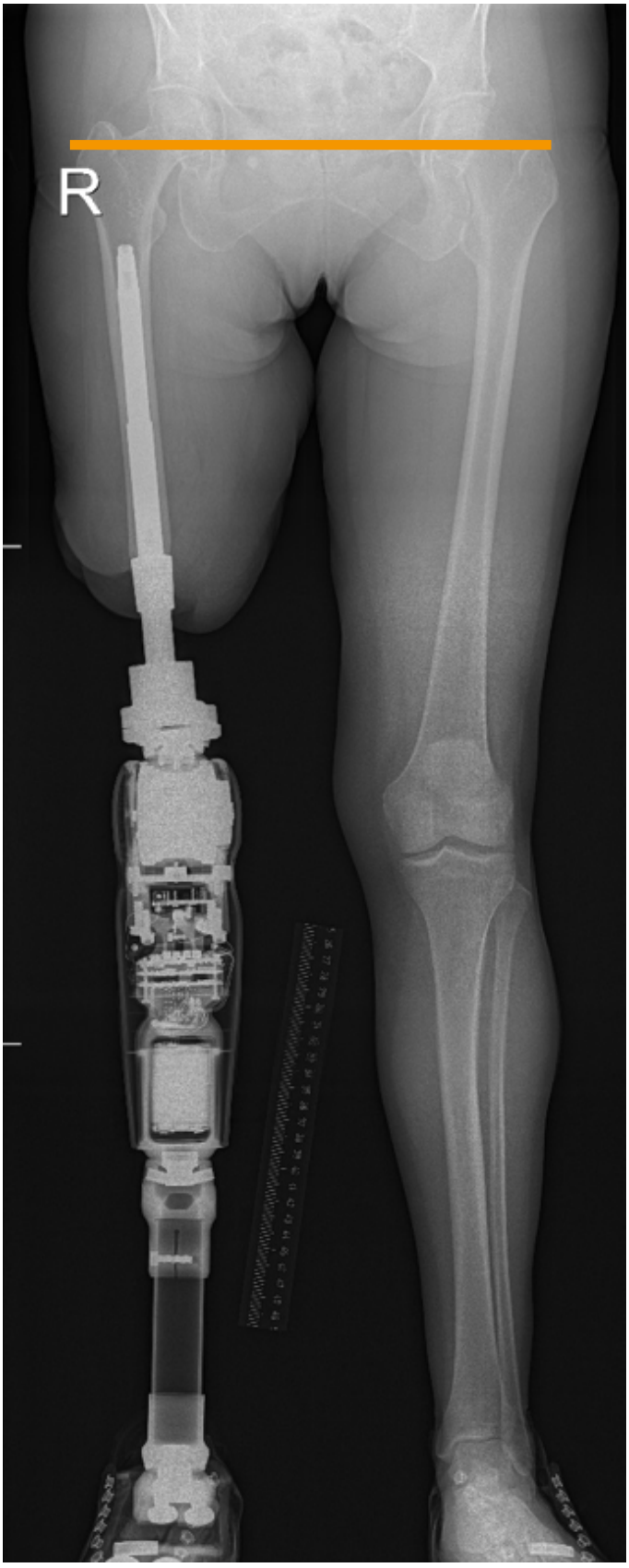
2.1.3 Use of other exo-prosthetic parts (e.g. knee/foot)

The legal manufacturers of BADAL X; Baat Medical BV, OTN Implants BV and OTN Innovations, warrant the use of all commercially available exo-prosthetic components like knees and feet.

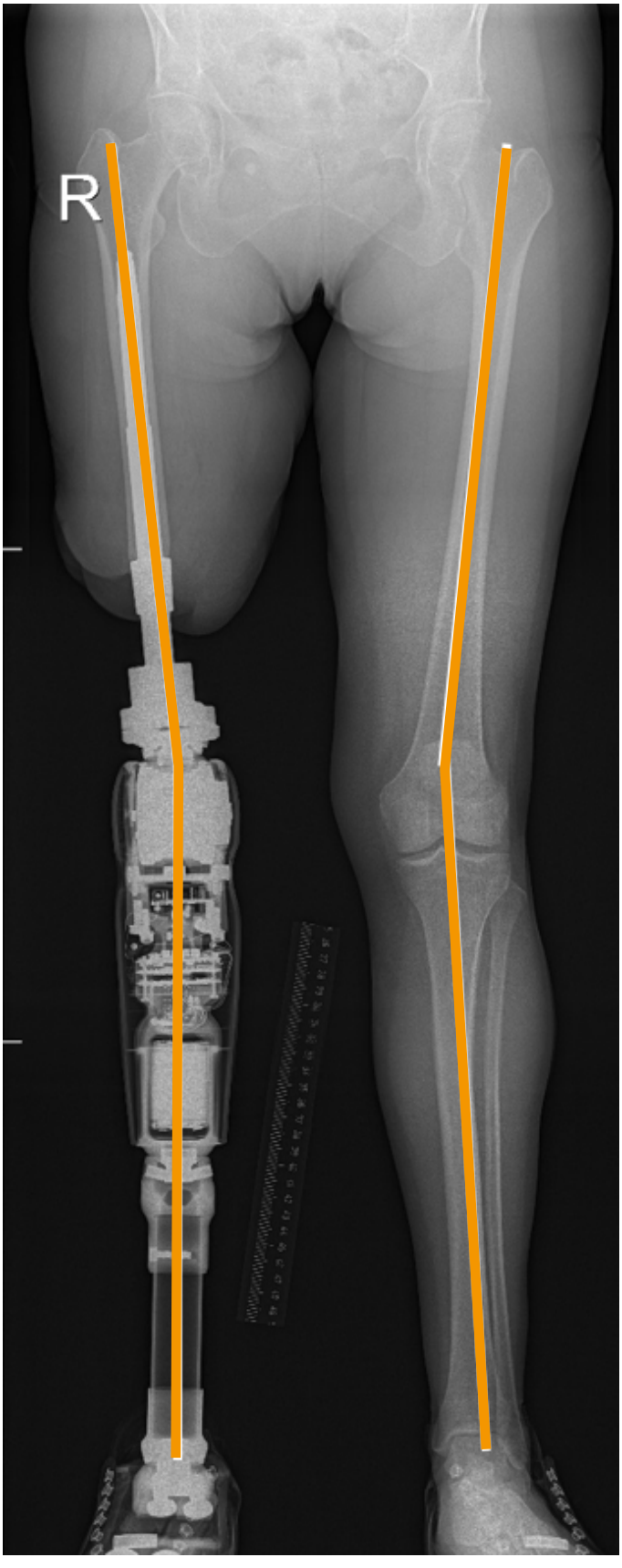
2.2 BADAL X exo-prosthesis installation instructions

Basic installation principles

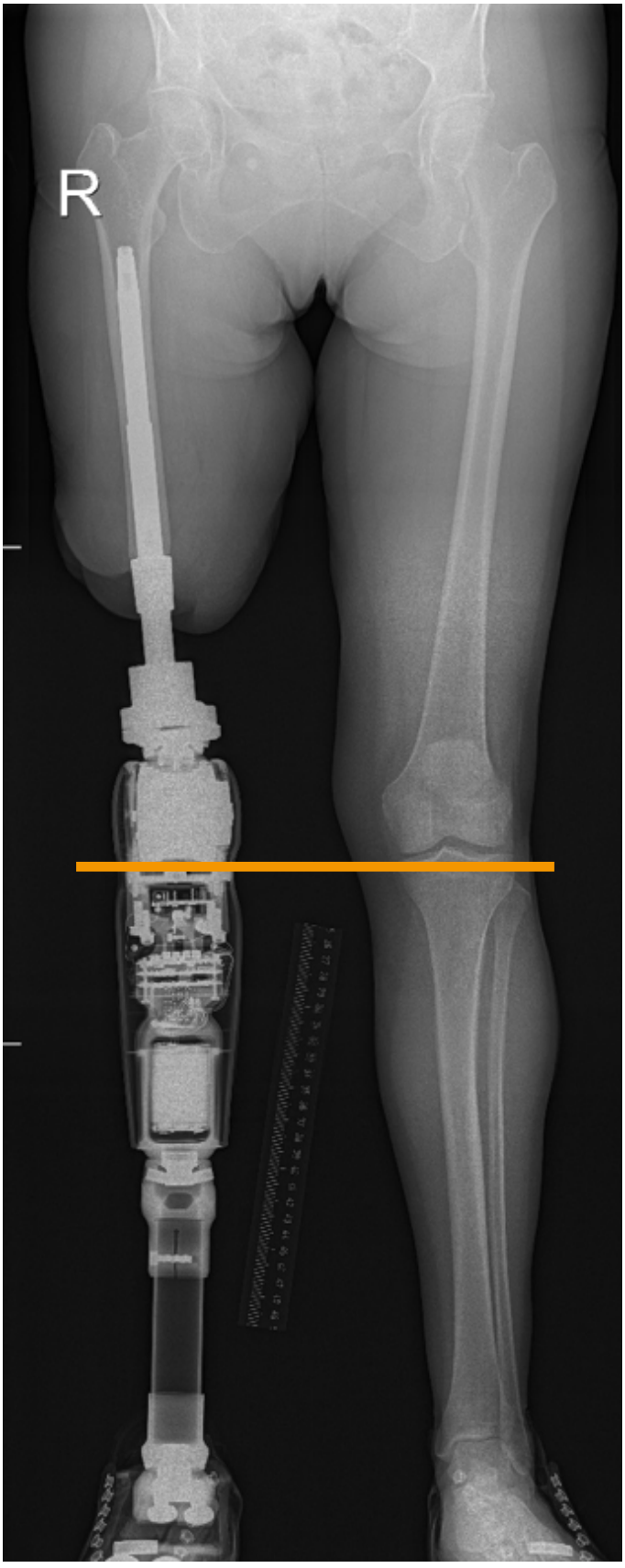
2.2.1 Make both legs exactly the same length

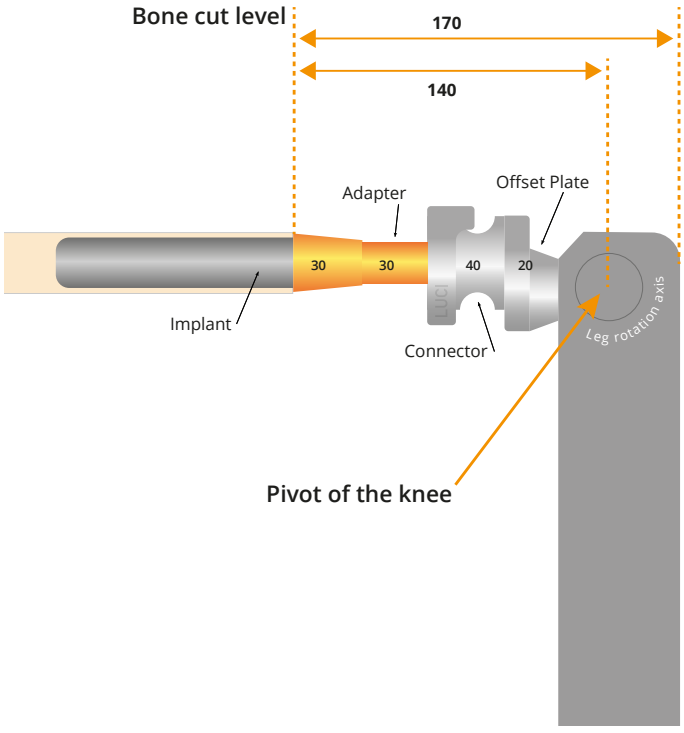


2.2.2 Aim at symmetrical varus/valgus leg/knee-axis in the exo-prosthesis



2.2.3 Keep pivot point of both knees at same height, see surgical technique

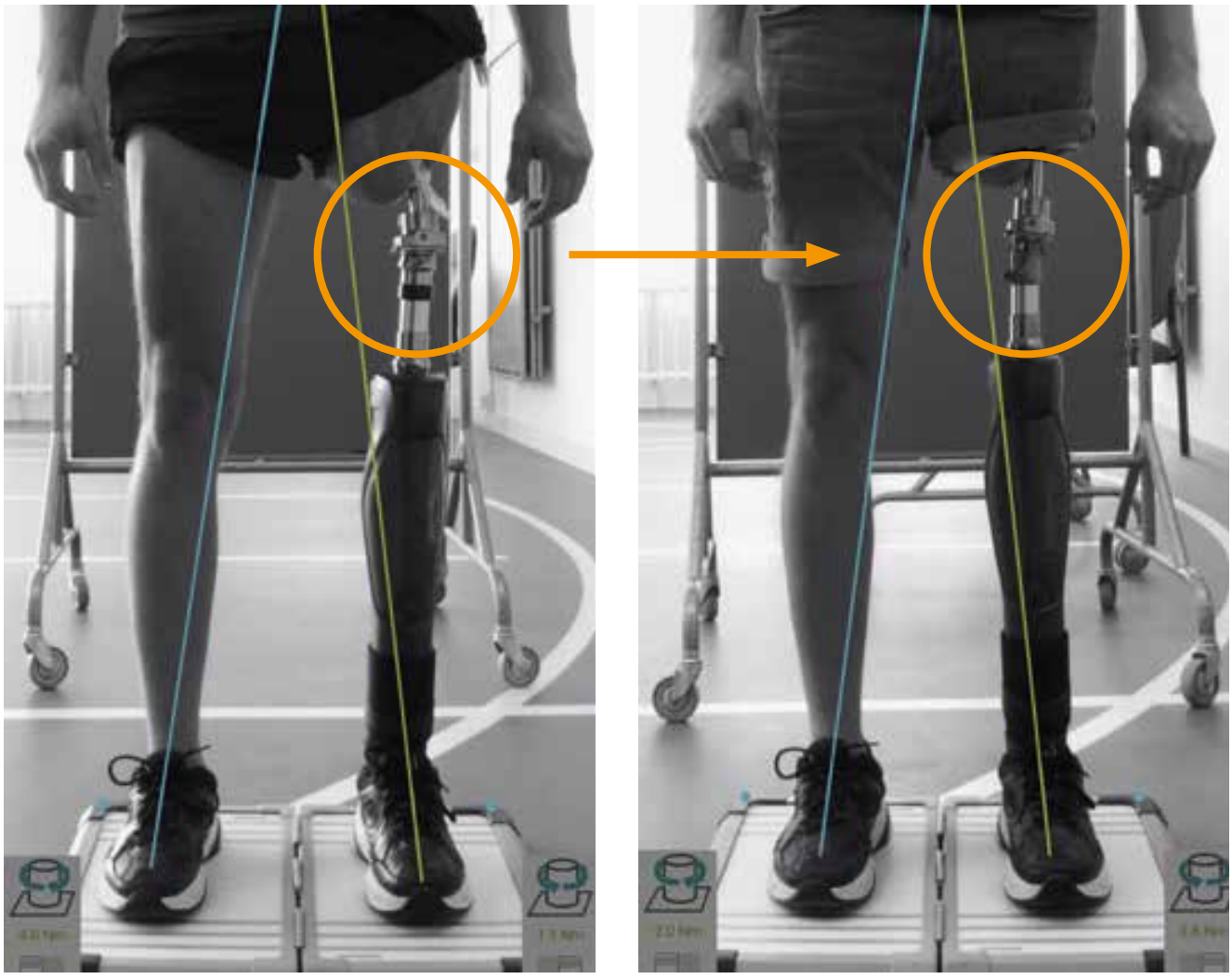


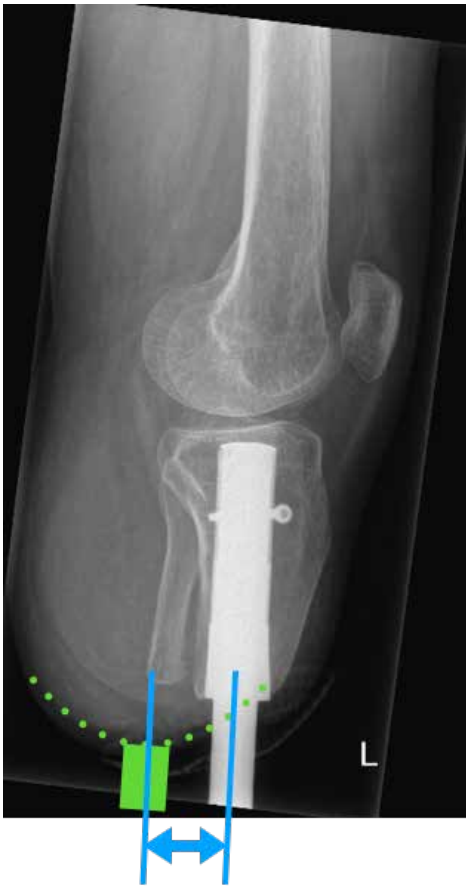


2.3 Particularities of TF bone anchoring prosthesis

2.3.1 Hip-flexion contracture often occurs after a transfemoral amputation

2.3.2 Hip-abduction contracture occurs due to muscular imbalance in subjects with short femur remnants



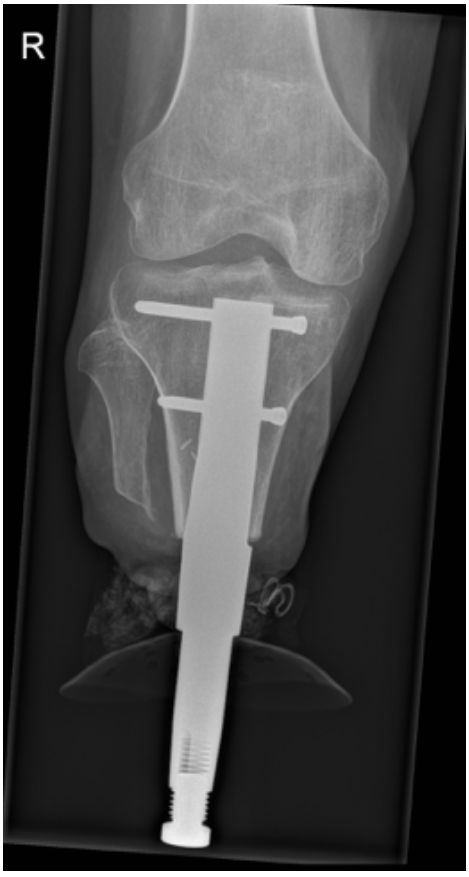


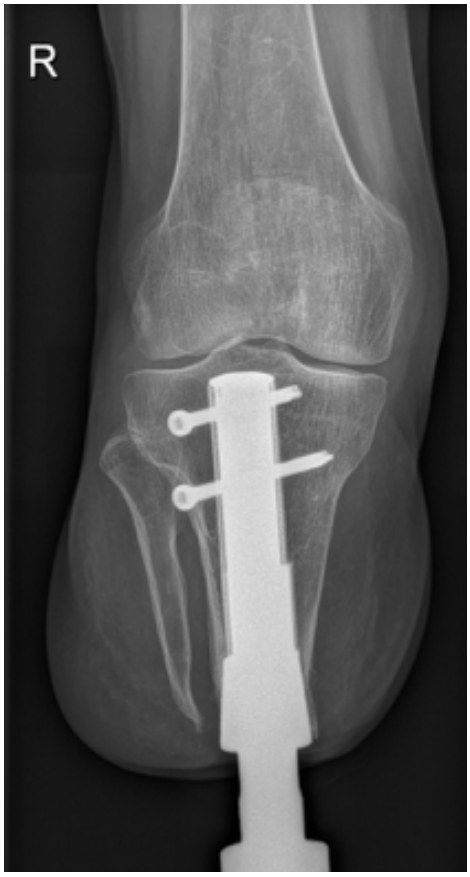
2.3.3 Hip-exorotation contracture occurs due to muscular imbalance m. iliopsoas (exorotation) vs m. tensor fasciae latae (endorotation)

2.4 Particularities of TT bone anchoring prosthesis

2.4.1 Keep in mind that with tibia BADAL X, the tibia bone anchor is situated 10 to 20mm anterior to where the anchor is inserted in case of a socket attachment

2.4.2 Keep in mind that the BADAL X tibia implant longitudinal axis may be installed in varus/valgus during surgery





2.5 Luci Connector installation

2.5.1 Install connector male part

2.5.2 Attach abutment screw and tighten the M14/M12 screw with 20 Nm. Check and if necessary retighten the abutment screw at every follow up service interval

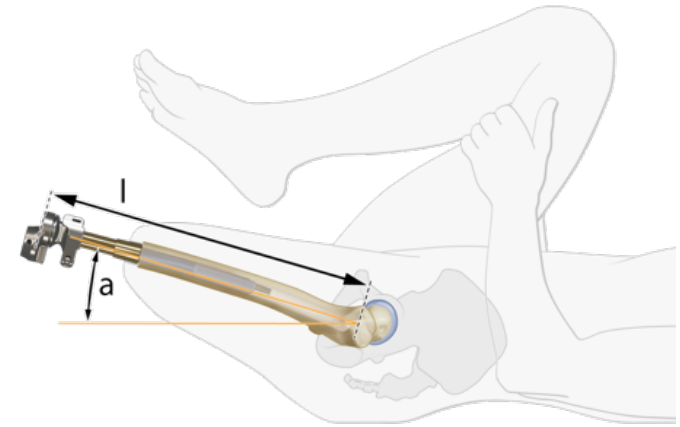
2.5.3 Attach connector female part

The lip of the Luci connector should point towards the gait direction.
The jaw width of the Luci connector should be 2.0 to 2.2 mm when closed without a male part.

2.5.4 Adjust correct clamp force with clamp screw

2.5.5 Secure clamp screw with lock screw

2.5.6 Perform the Thomas-Test and measure hip flexion contraction angle (a) femur length (L):



Choose offset plate with size table

Offset Plate size Table

	Hip flexion angle a (degrees)			
L	**0**	**5**	**10**	**20**
150	0	10	20	60
200	0	20	40	60
250	0	20	40	60
300	0	20	40	60
350	0	40	60	60

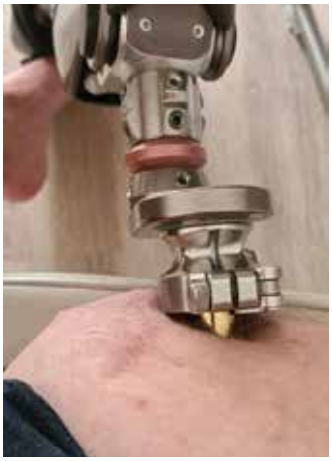
2.5.7 Fixate offset plate with M36 thread and install correct rotation mode

Body weight	MOB1	MOB2	MOB3	MOB4	MOB4+
50	5NM	5NM	6NM	7NM	8NM
55	5NM	5NM	6NM	7NM	8NM
60	5NM	5NM	6NM	7NM	8NM
65	5NM	5NM	6NM	7NM	8NM
70	5NM	5NM	6NM	7NM	8NM
75	5NM	6NM	6NM	7NM	9NM
80	5NM	6NM	7NM	8NM	9NM
85	5NM	6NM	7NM	8NM	9NM
90	5NM	6NM	7NM	8NM	9NM
95	6NM	6NM	7NM	8NM	9NM
100	6NM	6NM	7NM	8NM	9NM
105	6NM	6NM	7NM	8NM	10NM
110	6NM	7NM	7NM	9NM	10NM
115	6NM	7NM	8NM	9NM	10NM
120	7NM	7NM	8NM	9NM	10NM
125	7NM	8NM	8NM	9NM	10NM
130	7NM	8NM	8NM	9NM	10NM

2.5.8 Secure rotation angle with lock screw according to body weight/mobility table at 5 to 10 Nm

2.5.9 Fixate prosthetic components (knee/foot) into pyramid Euro-4-receiver at 15 Nm

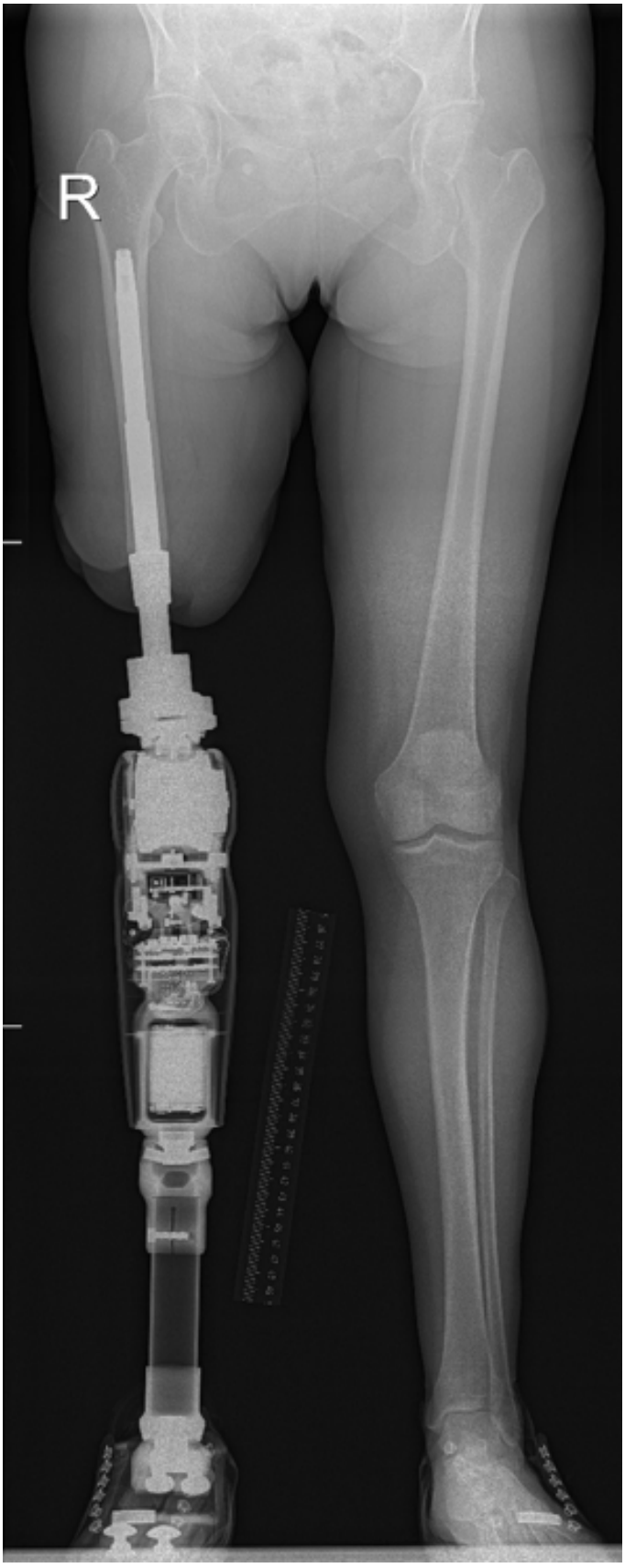
2.5.10 If necessary use extra parts to fill the gap between offset plate and Knee/Foot



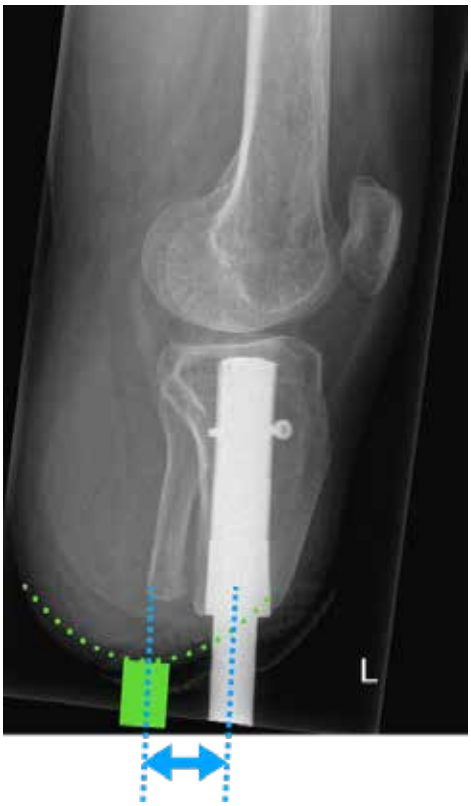
2.5.11 Check and re-adjust endo/exo rotation with M36 lock screw according to body weight mobility table at 5 to 10 Nm

2.5.12 Install approximately 7 degrees valgus in TF amputees with pyramid receiver:

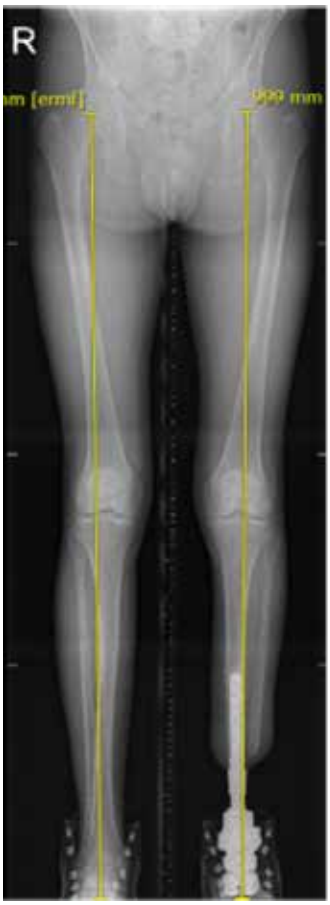
Aim at leg axis symmetry use total leg Xrays

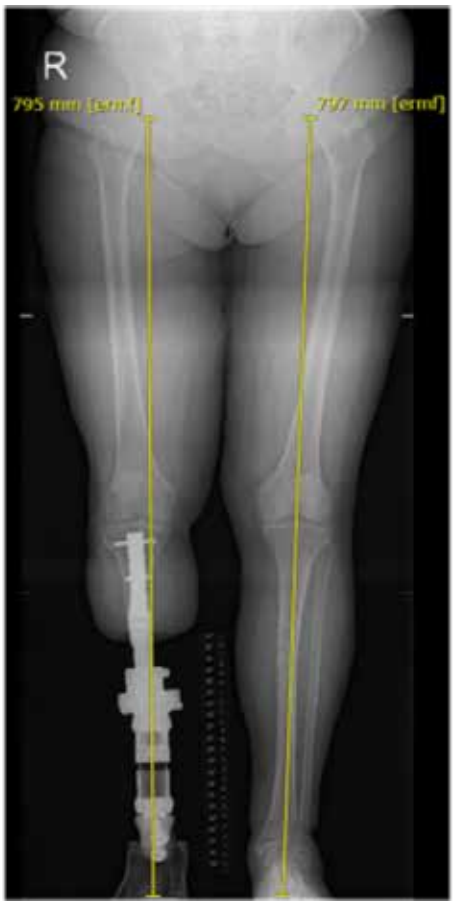


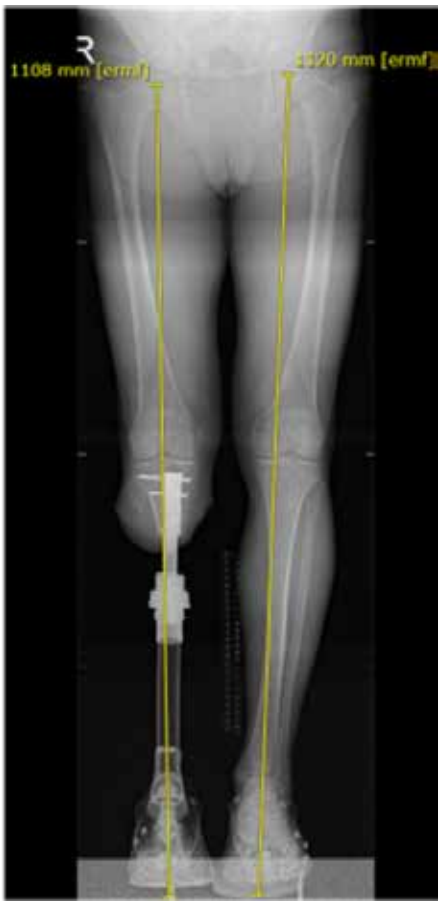
2.5.13 If necessary use 10-20mm offset plate for dorsal translation in TT amputees



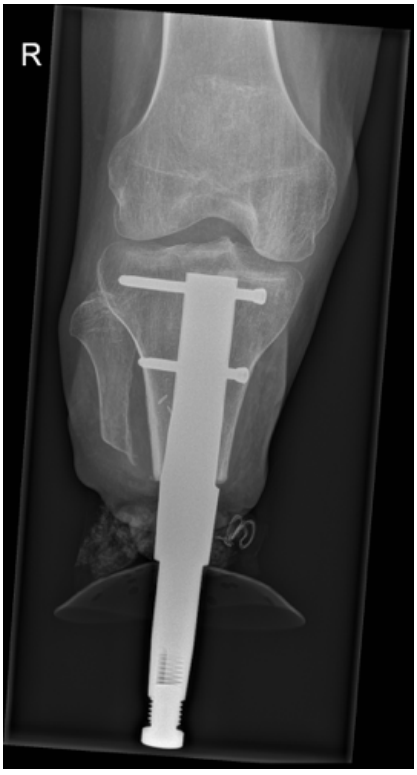
2.5.14 Check and adjust valgus/varus symmetry in TT amputees with use of total leg Xray

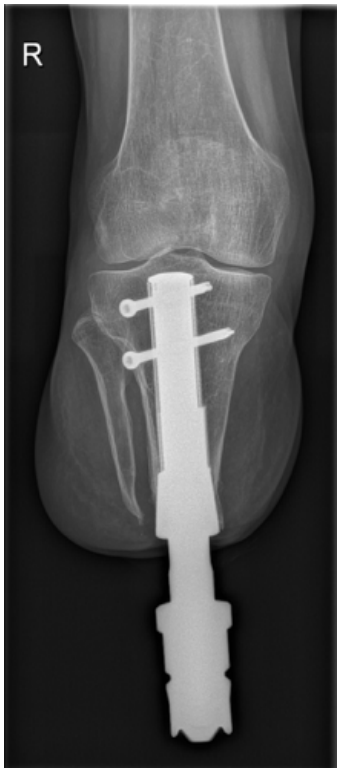






2.5.15 Adjust alignment in case of deviating position of the implant





3. Stoma Care

BADAL X requires regular care of the stoma, i.e. the skin opening through which BADAL X protrudes. Stoma care should become part of the daily routine and will be a lifelong task. Stoma care instructions are preferably given by a certified BADAL X stoma care nurse.

3.1 Post-operative stoma-care management

In the first hours and weeks after BADAL X implantation the stoma might bleed easily and the skin around the stoma will look a bit red. The stoma opening is quite large in the first weeks after implantation and the inside of the stoma will be covered with a white-yellow layer. In this early phase the stoma will produce transparent to yellow-green wound fluid. These are all normal phenomena and will disappear once an epithelial layer has formed on the inside of the stoma. It is important to rinse the stoma well with plenty of lukewarm tap water and try to remove the white-yellow layer as much as possible. This should be done at least twice a day.

In the long run, the stoma tightens around the implant and produces no or very little stoma fluid. The colour of the stoma fluid is transparent to slightly yellow. Often when there is more movement of the soft tissues around the stoma, for example during walking or cycling, this may cause a higher discharge of stoma fluid. While at rest and while sitting, virtually no stoma fluid is released. The stoma fluid contains proteins and this will adhere to the implant as a plaque layer. Plaque is a good breeding ground for bacteria, similar as tooth plaque it should be removed at least twice a day with water and soap.

3.2 Washing out the stoma

The stoma only needs a light cleaning using tap water and ordinary soap. Use a cotton gauze or the Oral B Oxyjet to remove stubbornly adhering plaque from the implant. If dirt gets into the stoma, rinse it out thoroughly with normal water. Hand showers (hand bidets) are practical otherwise, just rinse off with the shower head or use the Oral B Oxyjet.

4. Stoma problems management

4.1 Hypergranulation and keloid scar tissue formation

Because of soft stoma tissue rubbing against the metal implant, the stoma wall tissue may grow excessively and hypergranulation or keloid (scar tissue) may form. This is a physiological (normal) response of the human body like calluses on the hands of craftsmen. Only if keloid is a problem for cleaning the stoma can it be excised with local anesthetic. Problems with hypergranulation can be treated with hydrocortison-vaseline cream 1%.

4.2 Stoma irritation

The signs of stoma irritation are: local redness of the skin around the stoma and/or pain and/or yellow/green stoma fluid. The area of local redness of the skin may be progressive and is than called cellulitis. In some cases the inflammation blood measure CRP may be slightly increased. This can be a sign of local bacterial inflammation (cellulitis). The cause is often an excessive amount of the staphylococcus aureus bacteria in combination with micro-injuries of the epithelium at the inner stoma wall. Stoma irritation is in the first place treated by improving or intensifying cleaning of the stoma. Wash out the stoma twice daily with water and soap and use when the stoma is tight, the Oral B Oxyjet. This Oral B Oxyjet provides a strong tiny water beam with micro bubbles which is very effective to remove bacteria and plaque that adheres to the implant. If that does not work, rinse the stoma after washing with a local antiseptic alcohol solution.

4.3 Stoma pain

4.3.1 Cause of stoma pain

4.3.1.1 Nerve pain; develops when sensory nerves growth and make contact with the wall of the stoma.

4.3.1.2 Mechanical pain; develops when the soft stoma inner wall tissue rubs against a sharp or rough surface of the implant. Sometimes the bone may retract a little and this may expose the rough surface of the implant.

4.3.1.3 Dry stoma pain: develops when the skin and/or stoma wall adheres with the implant.

4.3.1.4 Stoma Irritation: see 4.2

4.4.2 Treatment of stoma pain

4.4.2.1 Nerve Pain: administer a few drops of lidocaine hydrochloride gel 2% (200mg/g) deep inside the stoma, using the silicon application tips. Repeat this procedure if necessary every hour. This gel acts as a lubricant. It contains lidocaine which makes the inner-wall of the stoma a little numb.

4.4.2.2 Mechanical pain: A BADAL X stem or DCA sleeve can be placed to cover sharp or rough edges/surfaces

4.4.2.3 Dry stoma: Apply a few mililiters of lidocaine hydrochloride gel 2%, using the silicon Medela Finger Feeder application tips on the syringe and administer the gel deep inside the stoma and repeat this procedure if necessary every hour.

4.4.2.4 Stoma irritation: treatment see 4.2

5. Rehabilitation loading program

5.1 Joint range of motion, pelvic shift and strength training

To encourage a normal pattern of axial load during gait, pelvic shift and hip abductor activation (tilt) are trained during the mid stance phase using standard bathroom scales. Hip mobility, hip strength and core stability are trained functionally once daily. Hip strength is trained with an elastic resistance band, starting with two sets of 10 repetitions using a resistance that produces muscle fatigue. The number of repetitions is gradually increased to four sets of 20 and then increased further by changing the resistance band. Core stability is trained using core-specific floor exercises, preferably 30-60 minutes once daily.

5.2 Prosthetic loading

Prosthesis loading starts three weeks after single stage surgery procedure or one week after the second stage of two stage surgical procedure. After exo-prosthesis attachment and alignment using LASAR® (Otto Bock), the aim is to provide a narrow support base in the frontal plane in order to reduce the amount of pelvic shift needed during the gait stance phase. Initially, gait training is performed using parallel bars and subsequently using crutches. Weight bearing is increased based on acceptable levels of muscle/attachment pain. Alternating walking velocities and walking on uneven surfaces can be trained with the use of video analysis for visual feed back. When an acceptable two-point gait with two canes is reached, the patient can proceed to unaided gait training, and more complex gait skills such as slope walking, negotiating obstacles, and dual tasks. Rehabilitation is concluded when the patient is able to walk without crutches, perform complex gait, climb stairs and eventually ride a bike.

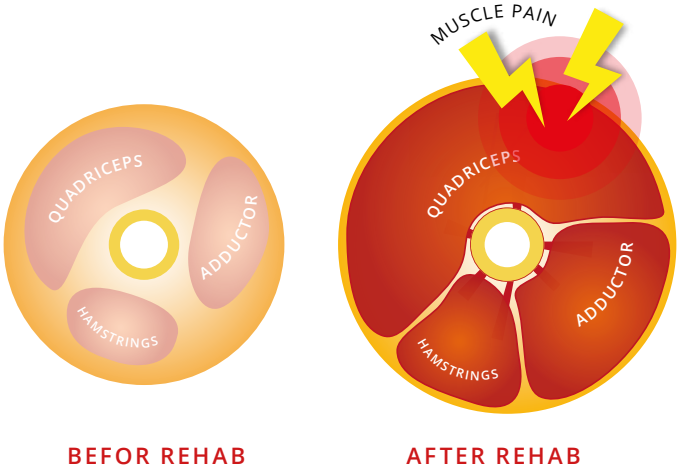
5.3 Advanced prosthesis training

Patients may receive advanced prosthesis training if they have specific work-related requirements or receive new prosthetic parts, especially micro-processor controlled prosthetic knees. Several sessions are required with close collaboration between prosthetist and physiotherapist for gait re-education, micro processor adjustments and prosthetic alignment.

Rehabilitation program
Week 1: prosthetic fitting and progressive weight bearing until 100% body weight.
Week 2: Gait training between parallel bars.
Week 3: Gait training with two crutches; 3 points and 2 points gait.
Week 4: Advanced gait training without walking aids and fine-tuning prosthesis.

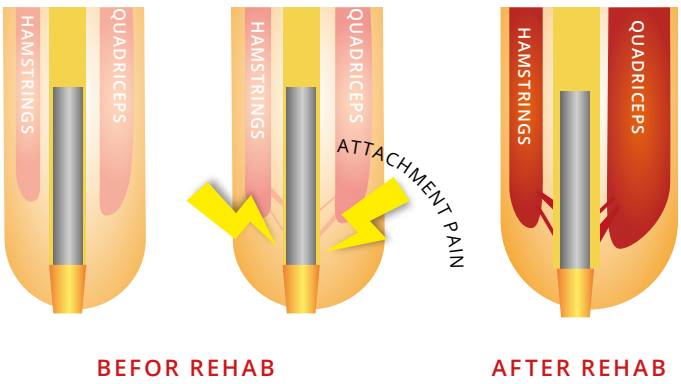
Muscle pain

Muscle pain might occur quite frequently in the first year after BADAL X implantation. Particularly in transfemoral BADAL X users. Before BADAL X implantation, amputees with transfemoral socket prostheses use the socket for passively stabilizing the femur during stance and gait. After BADAL X implantation, there is no socket and therefore the users must actively stabilize the femur with their remaining thigh muscles. The thigh muscles are no longer used to this intensive use and are weakened and atrophic due to years of socket use (see picture). The rehabilitation will therefore often be accompanied by enormous muscle pain, which, however, is only temporary. The thigh muscles become stronger through use and increase in volume.
In case of severe muscle pain, the intensity of training/loading can be reduced by using crutches or painkillers can be used such as acetaminophem and/or NSAIDs.



Attachment pain

Attachment pain is a typical pain sensation in the first year(s) after BADAL X implantation in transfemoral BADAL X users. The origin of this pain is similar to muscle pain. BADAL X users must actively stabilize the femur with their remaining thigh muscles. However, the thigh muscles are not yet firmly attached to the tip of the femur. During the rehabilitation with active use of thigh muscles stabilizing the femur, a strong muscle attachment is



formed between the thigh muscles and the tip of the femur. In the beginning of the rehabilitation this muscle attachment is rather weak and can easily be overused, which causes the typical pain sensation in the area just proximal from the stoma at the ventral part of the stump. The complaints are only temporary but can return if the user suddenly starts walking much more than usual. The treatment is similar to muscle pain; If necessary, reduce rehabilitation intensity, use crutches and/or use painkillers.

6. Follow up and BADAL X maintenance instructions

The BADAL X certified prosthetist designated by the treating BADAL X surgeon, is responsible for the proper execution of the aftercare program and maintenance instructions. Failure to properly follow the aftercare program and maintenance can be harmful to the user of the BADAL X system and can also lead to unnecessary and/or premature failure of the BADAL X device. The Manufacturer of the BADAL X device can not be held liable for harm or device failure when the aftercare program is not executed according to the following follow up and maintenance instructions:

6.1 3 months follow up and maintenance instructions

1. Remove the M12/M14 abutment screw with hexa 6 screw driver by holding the Luci male part with a spanner size 20. Check tightening torque of internal M6 locking screw and use the torque wrench with hexa 4 bit to tighten the internal M6 locking screw with 15 Nm. Replace the M12/M14 abutment screw and tighten to 20 Nm with the torque wrench with hexa 6 bit and spanner 20.
2. Check Luci connector condition: excessive wear of the Luci male part is a sign of incomplete clamping function.
3. If necessary adjust the Luci clamp force.
4. Evaluate gait pattern: In the frontal plane check adequate pelvis shift to the amputated side without trunk lateral flexion to the amputated side. Check the gait width and hip abduction in transfemoral amputees.
5. If necessary adjust prosthetic alignment with total leg Xray and aim at leg axis symmetry:
   - In TF amputees try to reduce offset size and if necessary adjust varus/valgus.
   - In TT amputees adjust varus/valgus if necessary

6.2 Annual follow up and maintenance instructions by orthopedic technician

1. Check adequate performance of stoma care. If necessary refer to stoma nurse for re-education.
2. Check Luci connector condition: excessive wear of the Luci male part is a sign of incomplete clamping function. If necessary adjust the Luci clamp force.
3. Evaluate gait pattern: In the frontal plane check trunk lateral flexion to the amputated side. Check the gait width and hip abduction in transfemoral amputees.
4. In TF amputees: try to reduce offset size and if necessary adjust varus/valgus.
5. In TT amputees: adjust varus/valgus, in case of medial/lateral knee pain, if necessary use total leg Xray.

7. Life style recommendations

7.1 Life style

It is recommended to inform BADAL X users of the health benefits of an active life-style. Stimulate the users to enjoy walking, cycling, swimming, fitness and other sports and leisure activities. Smoking and obesitas are associated with a higher incidence of soft tissue problems and stoma irritation. Advocate weight loss and smoking cessation.

7.2 Swimming

Swimming is allowed with BADAL X. The BADAL X system is water resistant and water is good for the BADAL X stoma. Swimming in lakes, rivers and sees is therefore recommended.

7.3 Warnings

In the first 3 years after BADAL X implantation, it is strongly recommended to avoid activities that may provoke high impact forces on the amputated limb. After a limb amputation the bone quality deteriorates. This osteoporosis is disadvantageous for the mechanical strength and increases the risk of fractures of the bone proximally from the BADAL X implant. After about three years, the bone has regained strength and more intensive activities can be tolerated.

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