

Ligamys

REHABILITATION GUIDELINES

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Dear Therapists

Sporting activities have become an integral part of our daily lives. If there is a cruciate ligament rupture, in many cases this has not only an impact on leisure activities, but may also lead to significant occupational restrictions. If the doctor and the patient opt for surgery, with the Ligamys surgery procedure there is an additional treatment option. This novel medical technology eliminates the need to replace an acutely ruptured cruciate ligament with a tendon graft. With the Ligamys implant, which was first used on patients in 2009, the torn cruciate ligament can be preserved. The knee is stabilised with a dynamic thread-spring system over the entire range of motion. Subsequently, the cruciate ligament can cicatrise; important proprioceptive nerve fibres are preserved. The therapy form offers good conditions for regaining optimal knee stability. The success depends, however, significantly on the physiotherapeutic aftercare.

The patient should receive targeted and individualised care throughout the rehabilitation period. The current rehabilitation scheme has been developed specifically for Ligamys patients and is, in addition to surgical treatment, the mainstay of a return to work and sport. The present scheme is adapted to the biological ligament healing, the principles of training science and the latest findings of cruciate ligament research.

Each rehabilitation phase comprises essential background information on cruciate ligament healing, therapeutic and training-related measures, information on important precautionary measures, and function-related objectives. In addition, criteria for returning to sports are described, and an easy-to-use test battery is provided.

We thank you for your commitment!

Your Ligamys team

1. The Ligamys surgery procedure

The anterior cruciate ligament (aka. ACL) has two central functions: first, the mechanical guidance of movements of the knee joint; and second, the sensory feedback in the proprioceptive control loop. The anterior cruciate ligament plays an important role in maintaining stability, especially in fast, complex movement sequences. A rupture disturbs the entire stabilisation mechanism of the knee joint.

Ligamys is a medical implant for anterior cruciate ligament ruptures. The knee joint is stabilised in such a manner that the torn ligament can grow together. In analogy to conventional cruciate ligament reconstruction, surgical treatment is recommended for patients doing sports that exert stress on the knee, have relevant concomitant injuries, or have instability (giving way) symptoms.

During Ligamys surgery, a polyethylene thread is implanted into the knee joint (Fig. 1). This is fixed in the femur by a small metal plate and in the tibia by a metal sleeve (monobloc). A spring system is integrated into the metal sleeve. This thread-spring system temporarily assumes the function of the cruciate ligament during the healing of the latter, and ensures that at every angle of movement the knee joint remains in a position that allows the torn ligament structures to grow together. The spring system absorbs the tensile forces that act on the thread during movements, whereby the thread always remains taut and strengthens the knee. At the same time, the spring mechanism absorbs force peaks, which could have a negative effect on the possible coalescence of the cruciate ligament. Ligamys was developed for temporary splinting. Its function decreases over time, while the healing cruciate ligament more and more resumes its original function.

The most important differences to conventional cruciate ligament reconstruction are:

1. Preservation of the patient's own cruciate ligament

In cruciate ligament reconstruction, the torn ligament is completely removed and replaced with a tendon transplant (usually with a part of a natural tendon, such as the hamstring tendon or patellar tendon). With Ligamys, the patient's own cruciate ligament and thus its anatomical position and physiological functioning are maintained.

2. The very small drill holes

The drill holes that pass through the knee joint are much narrower, with a size of 2.4 mm, than the 7–9 mm wide transplant canal required for cruciate ligament reconstruction.

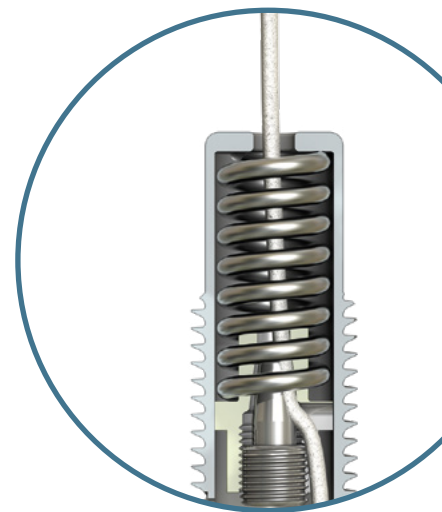
3. No tendon removal

The need for additional surgical removal of the tendon transplant is obviated. There is thus no risk of pain or physiological weakening at the donor site.

4. The short time window after the injury

The regenerative capacity of a torn ACL decreases over time, so Ligamys should be implanted within the first 21 days after the injury.

All Ligamys components can remain permanently in the knee. However, the monobloc in the tibia may be noticeable when the training activity is intensified, and be perceived as disturbing. In this case, it can be removed from the bone 6 months after surgery or later. This requires a minimally invasive procedure, which is usually performed on an outpatient basis. Thereafter, the sports activity should be reduced for two weeks (no high-impact training).



Metal sleeve with integrated spring (monobloc)

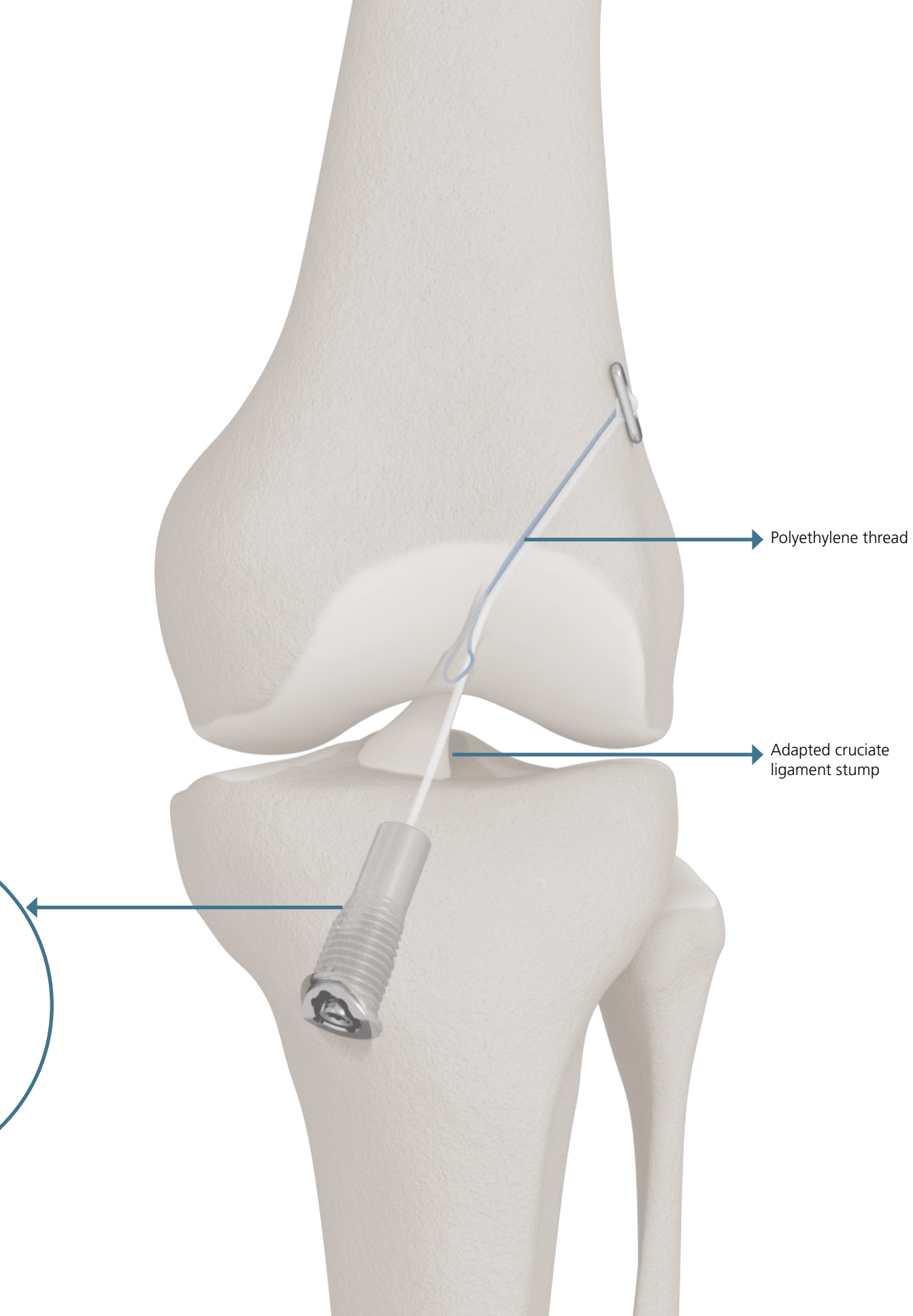
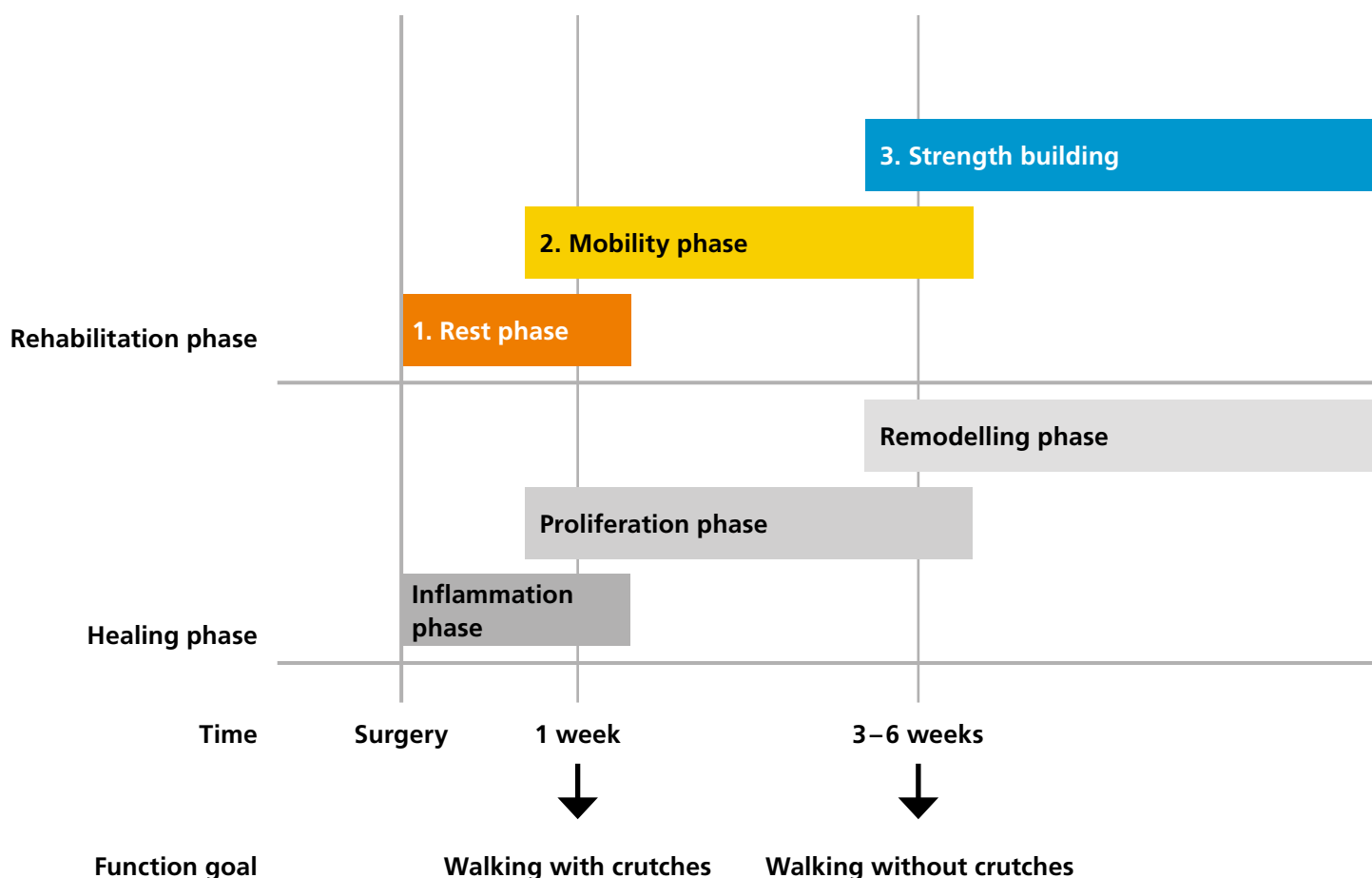


Fig. 1 Knee with Ligamys implant

2. The Ligamys rehabilitation

In addition to the surgery, rehabilitation is the mainstay of Ligamys treatment. The overall goal of rehabilitation is the full return to sporting activities. Therapeutic success depends largely on targeted physiotherapeutic measures and consistent training. On the physical level, the resilience and function of the body should be fully restored and optimised. On the psychological level, the patient should be strengthened emotionally in order to regain confidence in himself/herself and his/her own knee, and reduce fears of movement.



The 4-phase rehabilitation scheme

The present 4-phase rehabilitation scheme (Fig. 2) was developed specifically for Ligamys patients. The loading intensities and training focuses are matched to the phases of the biological ligament healing, and the training of the basic motor skills to the principles of training science and the latest scientific findings from cruciate ligament research. The progression of the training pivotally depends on the functional status of the patient. Regardless of the time course, the patient should not move on to the next rehabilitation phase without having achieved the relevant goals.

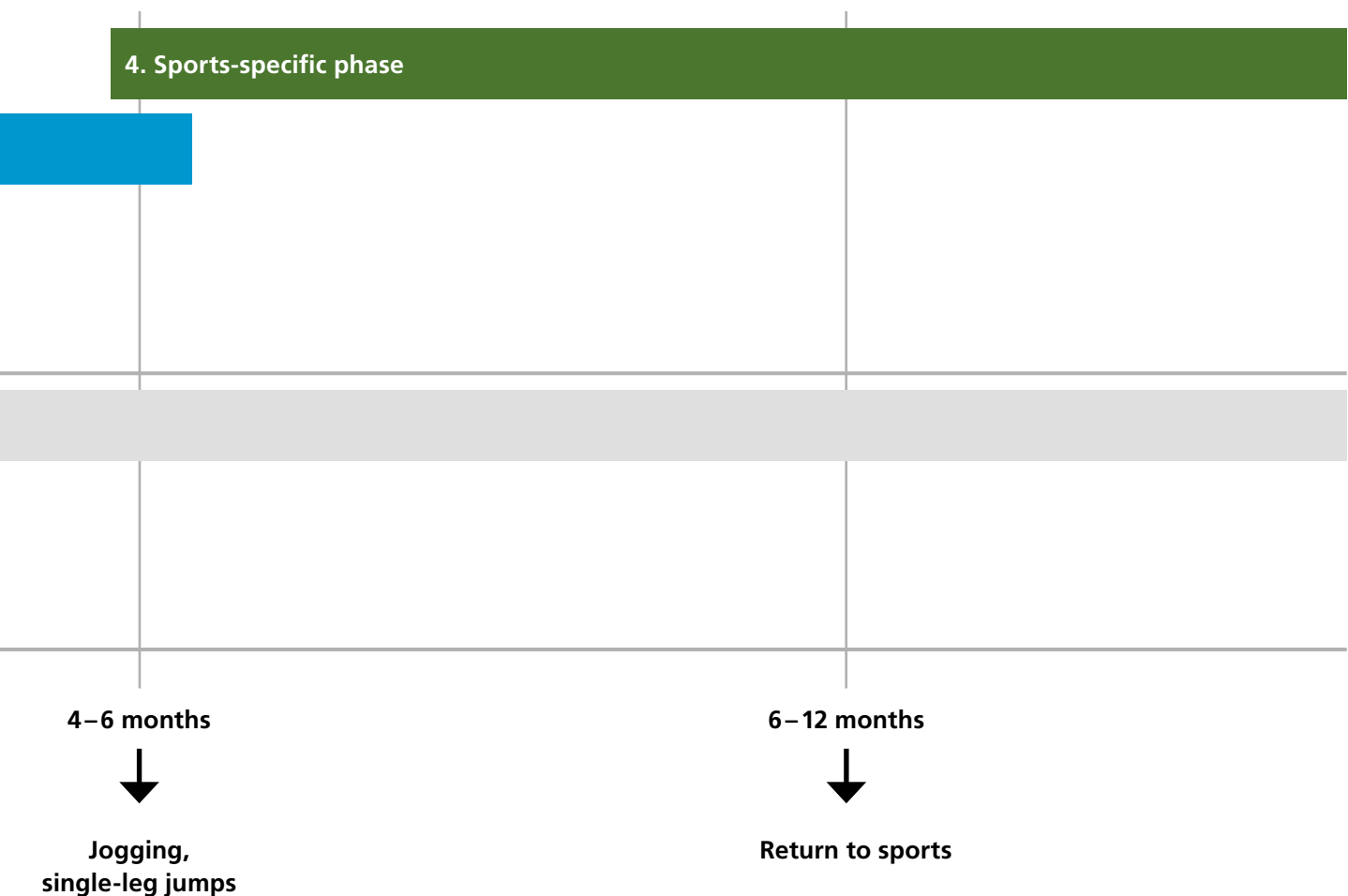


Fig. 2 The 4-phase rehabilitation scheme. The function goals are pivotal for the progression. The time specifications are to be understood as guidelines.

Important principles:

- **Good and open communication**

Rehabilitation involves the patient, the surgeon, the physiotherapist, and the patient's environment (e.g. trainers). Mutual information is a prerequisite for successful cooperation. The rehabilitation process should be based on a jointly defined objective.

- **Concomitant injuries may delay the rehabilitation process**

The present rehabilitation scheme is based on isolated cruciate ligament ruptures. Depending on the severity, localisation and type of treatment of the concomitant injury, the patient must comply with more stringent restrictions in the first two phases of rehabilitation (limitation of flexion/extension, consistent partial loading by crutches, etc.), which can delay the rehabilitation process. It is important that the therapist be initially informed about any concomitant injuries, surgical measures, and postoperative precautions, preferably by the attending physician.

- **Objective-based and individualised training**

The present time specifications are to be understood merely as guidelines. The durations of the four rehabilitation phases should be adapted to the individual situation and the knee function. The warning signals that the body sends must not be disregarded. Only when the existing exercises can be completed without pain and subsequent swelling in the knee, should the training be intensified. Transition to the next phase or return to the normal training routine takes place as soon as the relevant goals and criteria can be met.

- **Access to strength and endurance training equipment**

The rehabilitation requires physiotherapeutic care and consistent training over several months. The patient receives outpatient treatment in physiotherapy 1 to 3 times a week. In addition to manual treatment, the physiotherapist instructs and corrects the training and regularly reviews the progress made. For adequate training, access to strength and endurance training equipment (ideally in physiotherapy rooms) is recommended.

- **Progressive strength and coordination training**

The strength and coordination training of the lower extremities is the mainstay of a successful rehabilitation. Strength and coordination should be trained in parallel and coordinated. The building of these basic motor skills takes place in view of the healing process and according to the principles of training science (see Tab. 1).

Phase 1 – Rest phase

Wound healing phase: Inflammation

Time: 1 week from the day of surgery

Focus: Rest

The first phase of wound healing is the inflammation phase. The healing mechanism of the body is activated. The increased blood flow supports the degradation of dead tissue and clearance of microbes from the wound. Only «preliminary» tissue is synthesised. The resilience of the structures is still very low in this phase. The mechanical loading on the leg should be limited to a minimum. To allow optimal scarring of the adapted cruciate ligament stumps, the knee is held in the extended position by an orthosis for the first 4 days.

Measures

- 4 days fixed orthosis in extended position
- Learning how to use crutches. The loading depends on the complaints *
- Relief of pain and swelling (elevated position, much rest, little walking around)
- From the 5th day on: Removal of the orthosis
Improvement of knee mobility (active mobilisation) * and continued placement in extended position

* Unless otherwise prescribed. In case of concomitant injuries, more restrictive precautionary measures may apply

Please note!

- In the first 4 days: Avoid flexion of the knee joint and activation exercises of the quadriceps muscle
- No provocation of additional pain due to movement/strain (signs of inflammation should not increase)
- Cold treatment only in mild form (do not use ice)



Fig. 3 In the first days after surgery, rest and relaxation are in the foreground.

Fig. 4 From the 5th day on, the patient begins with light, independent mobilisation exercises.



Criteria for the transition to phase 2

The patient is usually discharged home after 1 to 2 days of hospitalisation. At this point, the patient can safely move with crutches. He/she is instructed about the further procedure, and he/she knows the precautionary measures and home exercises. He/she is registered for outpatient treatment in a physiotherapy practice with strength training equipment.

Phase 2 – Mobility phase

Wound healing phase: Proliferation

Time: up to 3–6 weeks after surgery

Focus: Mobility of the knee joint

The patient starts outpatient treatment in physiotherapy. In the knee, the number of inflammatory cells slowly decreases, and the next wound healing phase begins. This becomes apparent when swelling and pain abate and mobility increases. In the proliferation phase, the formation of new tissue is in the foreground. In addition to the blood supply, physiological loading stimuli have an important positive influence on the healing process. They ensure that the injured tissue is not just «repaired» (scar tissue), but «regenerated» (newly formed tissue functionally and structurally equivalent to the original tissue), and that the tissue fibres are properly organised from the beginning and functionally restored. However, as the newly formed tissue is still very unstructured and nonspecific, its load-bearing capacity and elasticity are still lower than those of the original tissue were.

In this phase, moderate active mobilisation of the knee joint is very important. It should be noted that Ligamys patients occasionally have limited extension. In most cases, this becomes noticeably better after approx. 6 weeks, when the tension of the thread-spring system decreases.

Measures

- Gait training up to full loading *
- Relief of pain and swelling
(elevated position, heat/cold treatment, massage)
- Improvement of knee mobility
(primarily active mobilisation, patellar mobilisation, stretching)
- Activation of the quadriceps muscle by closed-chain exercise
- Building of muscle strength endurance by closed-chain exercise (leg press)
- Start of balance training
- Training with bicycle ergometer

* Unless otherwise prescribed. In case of concomitant injuries, more restrictive precautionary measures may apply. The course of phase 2 may have to be extended accordingly.

Please note!

- Still exert care when mobilising extension (up to the normal position in comparison to the opposite side)
- Dose the load so that signs of inflammation do not increase



Fig. 5 The leg press is a very good training device and should be used as early as possible.



Fig. 6 With simple aids (e. g. a folded towel), the patient can do sensorimotor training at home as well.



Criteria for the transition to phase 3

The patient has mastered normal walking and climbing stairs without crutches. He/she can cope with daily living without pain, work out on the bicycle ergometer at low resistance and stand on one leg on a moving surface.

Info Box 1:

Leg axis control

In all rehabilitation exercises, good leg axis control is of central importance. The physiotherapist always monitors and analyses the quality of movement and, if necessary, introduces additional training measures to improve it.

Proper axis control means:

- The knee and hip joints remain on a vertical line
- The position of the trunk and hip remains stable
- The leg axes are identical in interlateral comparison

The following compensation movements should be avoided:

- The trunk tilts to the side of the supporting leg
- The pelvis sags to the opposite side
- The knee joint buckles (varus position)

The quality of movement can be optimised by improved activation of the thigh muscles, in particular of the vastus medialis, posterior tibialis and gluteus medius. External rotation and abductor training as well as trunk strength training are recommended.



Fig. 7 Knee joint buckling



Fig. 8 Correct leg axis control



Fig. 9 Leg axis control exercise



Fig. 10 Leg axis control exercise with integrated trunk training

Info Box 2:

Effects of meniscal suture on rehabilitation

In more than 50 % of cruciate ligament ruptures, a concomitant meniscal injury is present. Whether and how a meniscal rupture must be surgically treated, depends on the location and extent of the rupture. There are two techniques to this end: While in case of a suture the ruptured meniscus can heal again, in partial resection all damaged parts are removed. Whenever possible, the meniscal suture is preferred. Current research results show that this leads to better long-term results in terms of knee function.¹

In contrast to meniscal resection, the meniscal suture needs longer and more intense rest than the cruciate suture does. This usually means that the attending physician prescribes a limitation of knee flexion and consistent use of crutches for several weeks. With regard to the present rehabilitation programme, the course of phase 2 may be extended. In case of meniscal resection, the rehabilitation process does not change.



Fig. 11 Treatment of a concomitant meniscal injury with a meniscal suture may prolong the rehabilitation process.

Phase 3 – Strength-building phase

Wound healing phase: Remodelling

Time: up to 4–6 months after surgery

Focus: Strengthening of the thigh muscles, knee stability

The third and final phase of wound healing is the remodelling phase. If the tissue was adequately loaded by that time, the cruciate ligament has already developed into a relatively stable structure. Its resilience and elasticity is significantly increased. The focus is now on the qualitative transformation into original tissue.

In treatment, the loading can and should be significantly increased. The progression of the training of the basic motor skills is based on the principles of training science.²

Measures

- Building of strength and coordination (Table 1)
- Start of strength measurement in closed-chain training.
Performance of multiple repetition tests (3–8 RM) on the leg press is recommended (page 24)
- Integration of sports-specific elements
- Integration of whole-body training (especially for the trunk)

Phase	Strength	Coordination
2–3	Strength endurance Intensity: 40–60 % of maximum force Scope: 15–20 repetitions; 2–5 sets	Balance training Walking, climbing stairs, standing on one leg, and others
3	Hypertrophy Intensity: 70–85 % of maximum force Scope: 8–12 repetitions; 3–8 sets Variation: concentric phase on both legs, eccentric phase on one leg (= braking overload)	Gait training heels-to-butt, skipping, running backwards, and others
3	Intramuscular coordination Intensity: 85–100 % of maximum force Scope: 1–5 repetitions; 2–5 sets	Jumping training Plyometric, reactive, single-leg, and others
4	Sports-specific, deficiency-oriented training	

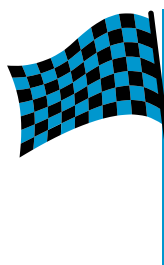
Table 1: The training focus of the strength-building phase is on the parallel development of strength and coordination.

Please note!

- No strength training of the quadriceps muscle in open-chain training («leg extension» with additional weight) before the 3rd month. This restrictive approach is chosen in view of the currently inconsistent research results.³



Fig. 12 and 13 At the end of this phase, the patient masters even complex forms of training with good leg axis control.



Criteria for the transition to phase 4

The patient can jog for about 30 minutes without complaints and skip on one leg with good leg axis control. In the strength test, he/she achieves a Limb Symmetry Index of 90 % (page 26).

Phase 4 – Sports-specific phase

Wound healing phase: Continuation of remodelling

Time: up to 6–12 months after surgery

Focus: Sports-specific rehabilitation training

The duration of the sports-specific phase varies depending on sport, level, and training effort. The complete remodelling of the healing cruciate ligament into original tissue is not fully completed yet even after one year; it may take several months more. The duration of the remodelling process depends on various factors, including how the previous phases of wound healing have progressed. The knee can now be loaded in controlled situations without restrictions. ⁴

Measures

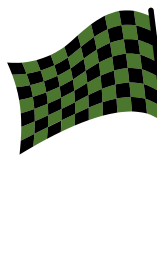
- Individual specialisation
- Training focuses on individual objectives and existing deficiencies
- Regular performance control for status determination and progress measurement, see Back to Sports test battery (chapter 4)

Please note!

- Avoid sudden and extreme performance increases due to the risk of injury and overload
- Do not exercise in uncontrolled situations (e.g. tackles)



Fig. 14 and 15 In this phase, the focus is on individual, sports-specific exercises.



Criteria for the completion of rehabilitation

The patient completes the rehabilitation at the end of this phase. He/she will receive clearance to fully return to sports once the clearance criteria are met (chapter 3).

3. Back to sports – Assessment

The overall goal of rehabilitation is to return to the usual sports. This means that the patient is able to practise his/her favourite sports again without discomfort.

The time when the patient has completed his/her rehabilitation program and resumes sporting activities will depend on the stress on the knee joint caused by the sport and the patient's level of performance. Some sports, such as swimming or cycling, can be resumed even during ongoing rehabilitation. Other, knee-stressing sports, such as soccer, handball or gymnastics, are possible only after completion of rehabilitation.

During the last, sports-specific rehabilitation phase, the physiotherapist performs a regular performance control to determine the status and progress. For this purpose, an easily applicable test battery with quantitatively measurable evaluation criteria was developed, which can be carried out with minimal material expenditure (chapter 4).

The physiotherapist decides together with the doctor and the patient when the rehabilitation is completed and unrestricted return to sports is possible. Regardless of the type of sport, the following conditions should be fulfilled:

1. Passing the Back to sports test battery (chapter 4)
2. Sports-specific training without discomfort in the affected knee
3. Clearance by the supervising physiotherapist/doctor based on a holistic assessment related to the sport
4. Approval by the patient: Complete confidence in his/her knee joint

Info Box 3:

Long-term prognosis of cruciate ligament patients

Scientific studies have shown that after the first cruciate ligament rupture the risk of further knee injury is increased.⁵ The patient should be informed by the physiotherapist about this situation. Ideally, after completing rehabilitation, he/she will have better knee stability and be in better physical condition (e.g. trunk strength) than before the cruciate ligament rupture. This can reduce the risk of injury. It is also advisable to permanently integrate a specific, preventive leg strength and coordination training into the everyday training.

4. Back to sports – Test battery

The Back to sports test battery includes the following recognised test forms for assessing the patient's physical condition after cruciate ligament rupture:

1) Lysholm Score ⁶

2) One Repetition Maximum (1-RM) Test ⁷

3) Hop test ⁸

The Lysholm Score is a patient questionnaire for the subjective assessment of knee function. The 1-RM test and the hop test are two active function tests for assessment of strength and stability. The goal is for the patient to reach at least a value of 90 for each test and thus pass the test battery.

Detailed instructions on how to perform the test battery, questionnaire and test protocol can be downloaded from the website www.ligamys.com.

Lysholm Score

The internationally recognised Lysholm score is determined via a written questionnaire. This consists of 8 questions with predefined answer alternatives, giving a maximum total score of 100 points. The following 8 dimensions are evaluated: limping, aids, blocking, instability, pain, swelling, climbing stairs and squatting. The questionnaire is filled out by the patient himself/herself. In case of >90 points, knee function is rated as sufficient.

Note: The various dimensions of the questions allow specific problems/deficiencies to be revealed. All poor ratings should be discussed individually with the patient and, if necessary, communicated to the attending physician.

One Repetition Maximum (1-RM) test

To determine the maximum single-leg strength, the One Repetition Maximum (1-RM) is determined using a leg press. The 1-RM stands for the weight that can be moved once with maximum effort. The weight is increased until it can no longer be pushed away. The highest weight that could still be lifted is evaluated. The assessment is based on the Limb Symmetry Index of the two 1-RM values (see Info Box 4).

Note: The strength test on the leg press can be used early in the rehabilitation phase (from phase 3 – Strength-building). To simplify this, a multiple repetition test (3–8 RM) can be used.

Hop test

To determine the active stabilisation capacity, as well as the speed strength and explosive strength, four types of single-leg jumps are used. Here, jumping and landing must be completed stably on one leg.

- 1. Long jump:** The patient jumps on a single leg as far as possible
- 2. Time jumping:** The patient performs single-leg long jumps over a distance of 6 meters as rapidly as possible
- 3. Triple jump:** The patient traverses the largest possible distance with 3 sequential single-leg jumps
- 4. Oblique triple jump:** The patient jumps three consecutive single-leg jumps as far as possible with the additional task of skipping the line obliquely each time

The assessment of the jumping performance in the interlateral comparison is carried out by means of the Limb Symmetry Index from the mean value of two valid tests (see Info Box 4). For the final assessment, the mean value is formed from the Limb Symmetry Indexes of the four jumping forms.

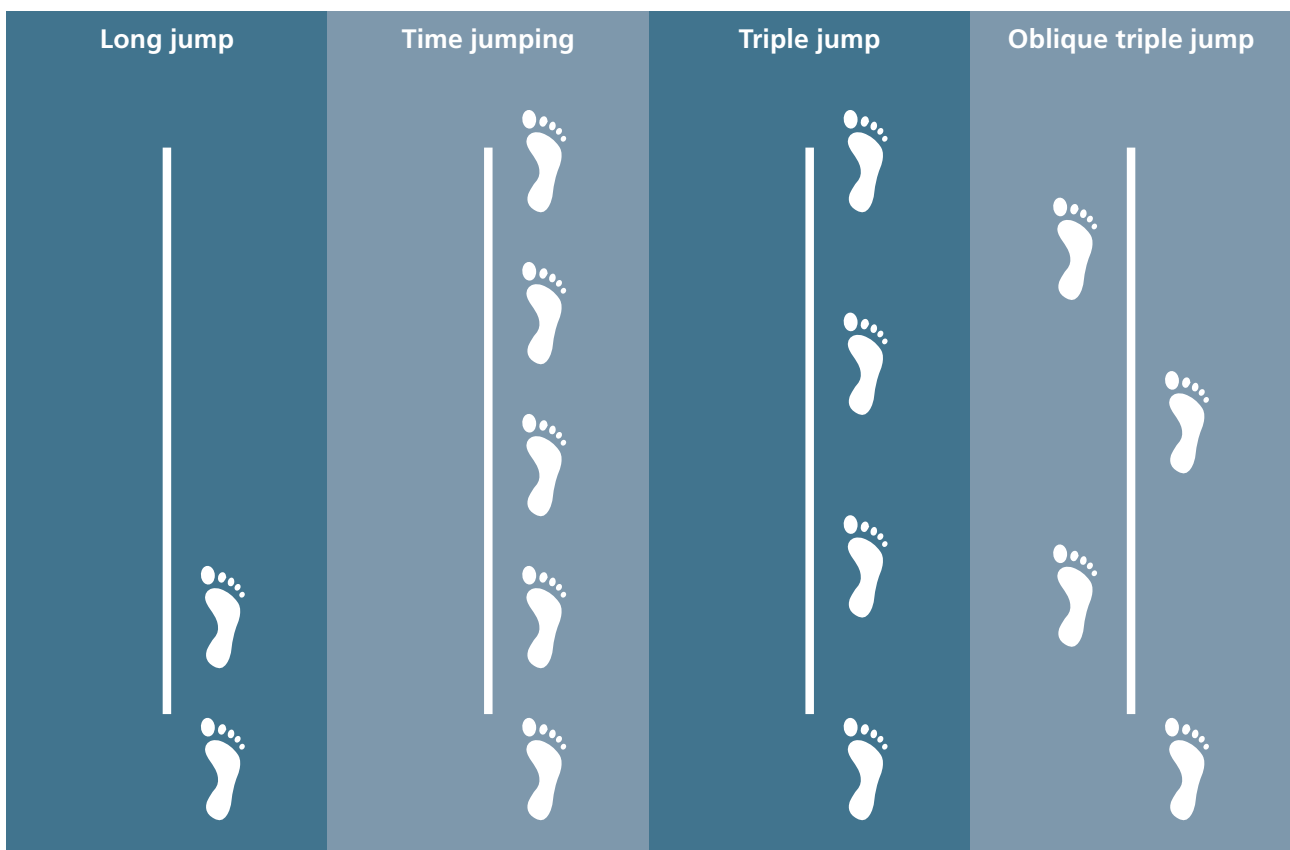


Fig. 16 Hop test with four types of single-leg jumps

Info Box 4:

Evaluation of knee function using the Limb Symmetry Index (LSI)

The two active function tests are evaluated using the so-called **Limb Symmetry Index (LSI)**, which compares the performance of the surgically treated leg with that of the healthy leg, taking the performance of the healthy leg as a reference (= 100 %).

Assessment:

In case of an **LSI ≥ 90 %**, the knee function is rated as **sufficient**. If the dominant leg (=supporting leg in coordination exercises, takeoff leg) has been operated on, a value above 100 % should be striven for.

Note:

In active function tests, attention should additionally be paid to good leg axis control.

Example:

Strength measurement healthy leg = 80 kg

Strength measurement operated leg = 65 kg

$100/80 \times 65 = 81 \%$ LSI

Assessment: The surgically treated leg reaches 81 % of the performance of the healthy leg. This is still insufficient.

5. Contact and further information

On the website www.ligamys.com, all documents for rehabilitation and further information about Ligamys are available. The instructions for performing the Back to sports test battery and the test protocol, as well as the summary of the rehabilitation guidelines, are available for download.

Contact email address for enquiries:

ligamys@mathysmedical.com

6. Short version of the rehabilitation scheme

Phase 1 – Rest phase

Wound healing phase: Inflammation

Time: 1 week from the day of surgery

Focus: Rest

Measures

- Orthosis in extended position for the first 4 days
 - Learning how to use crutches. The loading depends on the symptoms *
 - Relief of pain and swelling (elevated position)
 - Active mobilisation from the 5th day on *
 - Registration for outpatient physiotherapeutic treatment
- * Unless otherwise prescribed. In case of concomitant injuries, more restrictive precautionary measures may apply.

Please note!

- No activation exercises of the quadriceps muscle during the first 4 days

Function goals

- Walking on crutches

Phase 2 – Mobility phase

Wound healing phase: Proliferation

Time: up to 3–6 weeks after surgery

Focus: Mobility of the knee joint

Measures

- Gait training up to full loading
- Improvement of knee mobility
- Activation of the quadriceps muscle by closed-chain exercise
- Building of muscle strength endurance by closed-chain exercise
- Balance training
- Bicycle ergometer

Please note!

- Still exert care when mobilising extension (up to the normal position in comparison to the opposite side)

Function goals

- Walking without crutches
- Free from discomfort in everyday life
- Exercise on a bicycle ergometer without discomfort
- Standing on one leg on a moving surface

Phase 3 – Strength-building phase

Wound healing phase: Remodelling

Time: up to 4–6 months after surgery

Focus: Strengthening of the thigh muscles, knee stability

Measures

- Building of strength and coordination
- Start of strength measurement in closed-chain training
- Integration of sports-specific elements and total body training

Please note!

- Strength training of the quadriceps muscle in open-chain training («leg extension» with additional weight) not before the 3rd month

Function goals

- Jogging without discomfort
- Skipping on one leg
- 90 % Limb Symmetry Index in strength test

Phase 4 – Sports-specific phase

Wound healing phase: Continuation of remodelling

Time: up to 6–12 months after surgery

Focus: Sports-specific rehabilitation training

Measures

- Individual sports-specific specialisation
- Regular performance control (Back to Sports Test Battery)

Please note!

- Avoidance of uncontrolled sport situations (e. g. tackles)

Function goals

- Fulfilment of the Back to Sports approval criteria

Back to sports

Before rehabilitation is completed and the patient fully returns to his/her normal training routine, the following conditions should be met:

1. Passing the Back to sports test battery
2. Sports-specific training without discomfort in the affected knee
3. Clearance by the supervising physiotherapist/doctor
4. Approval by the patient: Complete confidence in his/her knee joint

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8. Symbols



Manufacturer



Caution

CE 0123 CE marking for medical devices of Risk Class Ir, Is, Im, II and III



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