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Research Article

# Post-Surgical Rehabilitation Management after Megaprosthesis Arthroplasty of Lower Limb

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## Abstract

**Background:** Megaprosthesis (MP) is a modular prosthetic system designed for skeletal reconstructions after major resections. Rehabilitation plays a pivotal role in the recovery and subsequent maintenance of the highest possible quality of life. However a standardised rehabilitation protocol for MPs patients has not been yet established. Our literature search highlighted the lack of any recognized rehabilitation protocol for patients undergoing MPs implantation.

**Aim:** Because of the growing employment of these implants in both oncology and non-oncology, standard guidelines for patient's management are needed. In this work, we will focus on the rehabilitation protocol of patients undergoing a lower limb MP surgery, in particular proximal femur, distal femur, and proximal tibia MP surgeries.

**Design:** In this clinical study we assigned for each patient a rehabilitation protocol. Depending on the type of surgical treatment used and the main pathology, the limb salvage technique can sacrifice different anatomical structures. The rehabilitation path should also be differentiated according to the articular head affected by the resection.

**Setting:** This study takes place from July 2016 to January 2020, at the U.O. Ortopedia e Traumatologia II, Division of AOUP in Pisa (Italy).

**Population:** One hundred twenty two patients underwent MP or composite lower limb prosthesis implantation. Among them, 57 underwent proximal femur surgery, 41 distal femur surgery, and 24 proximal tibia surgery.

**Methods:** Our rehabilitation protocol was designed to support the patients from the onset of the disease. The rehabilitative treatment is specific for each resectioned segment, but the underlying pathology must be considered. Depending the main pathology, the surgical technique can sacrifice different anatomical structures so the rehabilitation path will be differentiated case by case.

For the evaluation of functional results, we have applied a scheme that uses two questionnaires in combination. To a pathology-specific score (WOMAC) we added a generic score that analyzes the quality of life, studying the physical and mental state (SF-36)26.

**Results:** The functional results resulting from the application of these protocols, customized on the patient, are very satisfactory as well as the long-term survival of the prosthetic implant. At Womac score that is not always optimal is often associated with a good SF-36 score. This shows how patients are generally satisfied with the results obtained, not so much in relation to the complete functional recovery but especially in relation to the underlying pathology and the possibility of performing normal daily activities in total autonomy.

**Conclusion:** Standardised rehabilitation protocols can provide local structures with guidelines for the management of the ever-increasing number of these patients. This is crucial to obtain a therapeutic continuity, an indispensable factor for improving surgical efficacy in terms of functional relapses, and for achieving and maintaining functional results that ensure the patients a good quality of life.

**Clinical rehabilitation impact:** Currently there is a gap in the literature about a standardized rehabilitation protocol for patients undergoing megaprosthesis implantation by lower limb resection. The progressive increase in the number of cases makes it increasingly necessary to draw up standard guidelines for patient management. We present in detail the standardized rehabilitation protocol that is used in our center.

**Key words: Megaprosthesis; Rehabilitation; Bone cancer; Post operative; Guidelines**

## Introduction

Megaprosthesis (MP) is a modular prosthetic system originally designed for skeletal reconstructions after major resections for the treatment of primary and secondary bone cancers; it provides an alternative to either massive bone grafts obtained from the Bone Banks or to fresh osteo-articular transplants [1]. MPs reproduce the anatomy of the resected bone portion, allowing the restoration of bone segments ranging from 10 cm to 48 cm in length [2], up to the entire segment. The modularity of MP makes it versatile for the reconstruction of different skeletal segments, meeting biomechanical requirements and achieving good functional results with fast recovery times. Therefore, MPs have rapidly become the preferred reconstructive method in oncological orthopaedics, and notably, they have been recently employed also in complicated cases of non-oncological patients [3,4].

In oncology, the latest improvements in diagnostic methods and medical therapies allow an early stage detection of primitive bone

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pathologies, thus enabling surgical radicalization. Moreover, these medical advances permit to chronicise non-primitive neoplastic pathologies of the bone, resulting in a significant increase of bone metastases detection along with the need for their resection [5,6]. In more recent years, MPs are often employed in the treatment of non-oncological pathologies. The increasing life expectancy has resulted in a higher demand of hip and knee prosthetic implants; this led to a significant increase of the number of prosthetic revision interventions and observations of the so-called 'complex' clinical cases. MPs offer the surgeon a valuable alternative in cases where

Severe bone loss has occurred, such as in repeated prosthetic revision surgery or complicated periprosthetic fractures, or even in those of severe post-traumatic joint subversions [7]. MPs represent a real therapeutic innovation for the so-called 'difficult' patients, who can thus hope for a good functional recovery and the achievement of a fair level of activity [8].

Analogously to the diffusion of MPs, composite prostheses are gaining attention due their expanding role especially in the reconstruction of the proximal femur and the proximal tibia. By composite prosthesis we mean an implant consisting of a massive homoplastic bone graft coupled with a conventional prosthesis. This method combines the advantages of both massive osteoarticular transplantation and prosthetic reconstruction: the former allows to restore an adequate metaepiphyseal "Bone Stock" and to achieve a suitable reinsertion of the muscles; the latter provides a stable and reliable joint surface over time, avoiding subchondral fractures which represent one of the most frequent complications after massive bone transplants. Although composite prostheses offer excellent functional results, they also present high complications rates, thus remaining limited to selected cases such as young patients with higher functional demand and life expectancy [9].

Rehabilitation plays a pivotal role in the recovery and subsequent maintenance of the highest possible quality of life, through the restoration of physical, psychological, and social states closest to the pre-existing ones at the onset of the disease. However, due to the low incidence of oncological, primary and secondary pathologies, whose treatment is further constrained to few highly-specialised medical centres, a standardised rehabilitation protocol for MPs patients has not been yet established [10]. Our literature search on this topic, carried out on the main search engines (PubMed, MedLine, Embase, Cochrane Library, PEDro), highlighted the lack of any recognized or published rehabilitation protocol for patients undergoing MPs implantation. Because of the growing employment of these implants in both oncology and non-oncology, standard guidelines for patient's management are needed. Large resection prostheses are available for each body district therefore each of them requires a specific rehabilitation protocol depending on the district involved.

Rehabilitation has become an integral part of the therapeutic path of the patient with MP. Importantly, it should be scheduled at the onset of the disease to actively follow the patient during the different therapeutic phases. Functional rehabilitation, carried out in a correct and professionally adequate way, is a fundamental aspect to guarantee the achievement of a suitable overall psychophysical well-being.

In this work, we will focus on the rehabilitation protocol of patients undergoing a lower limb MP surgery, in particular proximal femur, distal femur, and proximal tibia MP surgeries. This choice is based on the experience gained in our hospital centre (Azienda Ospedaliera Universitaria Pisana- U.O. di Ortopedia e Traumatologia II).

## Materials and Methods

Rehabilitation, in recent years, has become an integral part of the therapeutic path for the patient with MP and it is important to plan it from the beginning of the disease to play a crucial role in the patient's process, following him/her in the different therapeutic phases. Functional rehabilitation is a fundamental aspect to guarantee the achievement of a suitable overall psychophysical well-being, if it is carried out in a correct and professional way. At our O.U. Orthopaedics and Traumatology II, 122 patients underwent MP implantation and composite lower limb prosthesis from July 2016 to January 2020. Of these, 57 are proximal femur, 41 are distal femur and 24 are proximal tibia.

Our rehabilitation protocol was created specifically to support these patients from the onset of the disease, with a preoperative rehabilitation program whenever possible and then after the first postoperative day. The principles of the rehabilitative treatment are primarily differentiated according to the resectioned segment. Subsequently, the basic pathology must be taken into account, since the functional problems of the oncological patient may depend on the disease itself or on medical, surgical (like removal of important muscle portions) and radiant treatments. On the one hand, there may be general problems common to all tumors such as chemotherapy damage, radiation damage, disuse syndromes, asthenia and psychological problems; on the other hand, local, organ-specific problems due to the direct involvement of vascular, nervous, bone and muscle structures [2]. In the same way it is necessary to consider how a non-oncological patient often undergoes several prosthetic revision procedures with subversion of the normal anatomy, and as extensive scars with formation of numerous adhesions on the soft tissues, marked muscular hypotrophy [11].

This differentiation is necessary to personalize the rehabilitation path as much as possible in order to offer the most appropriate therapeutic procedure to each patient, allowing him/her to reach the highest possible level of functioning and participation. Obviously, the functional results after MP implantation in cancer patients cannot be compared to the functional results of an initial prosthetic implantation in election. It is therefore essential to take into account the underlying pathology and the psychophysical state of the patient before and after surgery. For this reason, for the evaluation of functional results, we have applied a scheme that uses two questionnaires in combination. To a pathology-specific score (WOMAC) we added a generic score that analyzes the quality of life, studying the physical and mental state (SF-36)26. These questionnaires were proposed to patients at the third and sixth postoperative month in order to assess physical and mental progress during the rehabilitation treatment.

## Results

Several studies on rehabilitation in hip and knee prosthetics have highlighted the importance of rehabilitation treatment in the first two post-operative weeks in order to enhance functional recovery in the medium/long term. The degree of functional recovery of the patient after prosthesis surgery from large resections is essentially linked to the regression of painful symptoms and the recovery of joint and muscle tonetrophism, which result in a restoration of autonomy in the common activities of daily life.

Composite prostheses, thanks to bone saving and better muscle anchoring, have better functional results than MPs but is reserved

for young patients with good bone quality and long life expectancy. In general, as far as the proximal femur is concerned, the saving of the gluteal and ileopsoas muscles allows an effective rehabilitation, comparable to a first implant hip prosthesis. If these muscles are dissected and reinserted on the prosthesis, it will be necessary to wear a blocked hip brace for 30 days.

As far as the distal femur is concerned, the protocol is generally similar to standard knee prosthesis, unless a portion of the quadriceps muscle has to be removed. Among these, the worst functional results are shown in the proximal tibia MPs where the reinsertion of the extensor apparatus is difficult. In these cases it is also necessary to perform an overturning of the medial gastrocnemius to ensure adequate prosthetic coverage, with a consequent increase in the rate of complications. In general, these patients never recover 100% of muscle strength while remaining able to perform normal daily activities (Table 1).

In the evaluation of functional results after MP implantation in cancer patients, the most relevant problem is the presence of "comorbidity", i.e. the role played by the underlying pathology. One can easily imagine how the associated pathologies produce a continuous decline in functional indices, which influences the result independently from the prosthetic implant.

In fact, it can be seen that a Womac score that is not always optimal is often associated with a good SF-36 score. This shows how patients are generally satisfied with the results obtained, not so much in relation to the complete functional recovery but especially in relation to the underlying pathology and the possibility of performing normal daily activities in total autonomy. The functional outcomes resulting from the application of these protocols are very satisfactory as well as the long-term survival of the prosthetic implant. The use of the customized-on-patient protocols, has allowed obtaining a fair functional recovery guaranteeing an early return to normal daily activities.

## Discussion

### Hip and knee megaprosthesis

The development of prostheses for large resections has therefore offered orthopaedic, oncological and degenerative surgery unhoped-for therapeutic opportunities until 30 years ago. However, it is a complex and risky surgery, to be reserved for selected clinical cases that, otherwise, would lead to the loss of joint function or the complete loss of the limb. For these reasons, the mentioned operations should be reserved for highly specialized centers where the surgeon's experience, combined with meticulous surgical technique and attention to soft tissue reconstruction can reduce the frequency of complications.

In fact, it is necessary to carry out a careful clinical-functional evaluation of the patient throughout the entire course of the disease, paying particular attention to the patient's personality, his/her motivations and expectations, his social and working role, the degree of compliance and the potential to be used for the development of alternative strategies in case of permanent functional deficit. Especially in the oncological field, in fact, patients are often very young, with often demolitive interventions, responsible for skeletal alterations and functional limitations. For these patients it is necessary to take care of them at an early and comprehensive stage, which includes not only functional physical recovery but also psychological and motivational facts, aimed to their reintegration into school or work activities, in order to guarantee them the best quality of life [2-12]. Depending on the type of surgical treatment used and the main pathology, the limb salvage technique can sacrifice different anatomical structures, causing a large number of sequelae. Early complications include infection, necrosis or dehiscence of the surgical wound, damage to nerve structures, muscle damage, thromboembolic complications and joint instability. Late complications include aseptic mobilization of the prosthesis, especially in reconstructions the proximal tibia or distal femur, infection of the prosthesis and joint instability. Infections are a serious complication associated with limb salvage procedures: the cases have decreased with the use of vascularized rotational flaps covering the prosthesis, especially for the proximal tibia. Joint instability is a relevant problem especially in hip reconstructions, although nowadays the reconstruction of the abductor mechanism and the use of bipolar components have improved the stability and function of the prosthesis [13].

In particular in oncological surgery, due to the frequent need to remove large portions of muscle tissue, MPs provide the opportunity to give the patient a function, to improve the quality of life even if not ad integrum. On the other hand, when muscle mass is preserved, the possibility of limb control and balance is optimised in the gait and static phases, improving joint function and consequently reducing the risk of mechanical complications of the implant. Moreover, the frequent concomitance with an adjuvant chemotherapeutic therapy must be kept in mind during the rehabilitation process. This leads to the possibility of "Fatigue Syndrome", which is a consequence of cytostatic treatment and manifests itself with psychophysical asthenia, muscle weakness, nausea and increased perception of pain [12-14]. The rehabilitation path should also be differentiated according to the articular head affected by the resection.

### Hip megaprosthesis

Proximal femoral MP often behaves like a normal first-implant hip replacement because it has a head that articulates with the prosthetic cup. In megaprostheses, both according to the existing literature and our experience, there is a greater instability of the implant (19% dislocation and 16% mobilization) if the acetabular component is also replaced. For this reason, if the acetabular cavity is disease-free, it is preferable not to implant a cup component but to use an endoprosthesis with a biarticular dome [9]. This will allow an early loading and a rapid functional recovery compared to

**Table 1:** Functional results after MP implantation in cancer patients.

| | Proximal Femur | | Distal Femur | | Proximal Tibia | |
|---|---|---|---|---|---|---|
| | Third Month | Sixth Month | Third Month | Sixth Month | Third Month | Sixth Month |
| Womac* | 47,1 | 34,5 | 44,6 | 29,4 | 50,5 | 35,2 |
| | (12,3) | (13,4) | (13,0) | (15,5) | (10,7) | (10,6) |
| | 29-70 | 22555 | 30-73 | 23986 | 32-62 | 13-54 |
| SF-36* | 41,7 | 51,0 | 43,3 | 53,2 | 40,7 | 52,7 |
| | (8,6) | (11,9) | (10,2) | (12,3) | (6,8) | (8,8) |
| | 23-53 | 18.69 | 19-58 | 18-66 | 28-53 | 37-68 |

*The values are given as the mean, (standard deviation), range.

cases where the acetabular component is also reconstructed. If the acetabulum is to be reconstructed because it is affected by neoplasia or altered by other pathologies, it is necessary to use measures aimed at increasing primary stability, such as using prosthetic heads with large diameters, using double motility cups or positioning cups with coverage greater than 45° and a lower antiversion of the femoral neck. In cases of extreme instability such as extra-articular resection and reconstruction with massive pelvic grafts, total retention cups may be used [15,16].

Functional results after reconstructive surgery of the proximal femur are conditioned not only by a good stability of the implant but also by a good anchoring of the muscles. The reinsertion of the gluteal muscles guarantees the restoration of a valid active abduction, while the reinsertion of the ileopsoas improves hip flexion. The implant is also given good stability with a clear reduction in the percentage of dislocations. Various methods for muscle anchoring are described in the megaprostheses. For the reinsertion of the abductor apparatus, it is possible to perform a tension band by suturing the gluteal muscles to the vast lateral quadriceps and then fixing them to the prosthetic body with non-absorbable points, so as to improve the stability of the implant. When megaprostheses with only proximal anchorage holes are used, the gluteal muscles are sutured to the prosthetic body with non-absorbable threads.

With this method, the tightness is often insufficient, both because the gluteal muscles sometimes have to be dissected at a distance from the myotendinous junction due to oncological problems, with consequent difficulty in reinserting them, and also because the muscle fibres, arranged longitudinally, are separated from the suture threads without obtaining a valid tightness [9]. The new prosthetic designs, with an increased offset obtained by rising and lateralising the trochanter, allow the gluteal muscles to be brought closer to the prosthetic body, making their reinsertion easier and increasing the leverage arm. These prosthetic designs have also introduced devices to ensure good muscle anchoring, allowing mechanic stable reinsertion on the prosthetic body. During a period of 30 days after surgery, articulated hip brace, blocked at 0°-60° of flexural extension, is necessary in order to protect the joint and to allow adequate healing of the muscle components detached from the resected bone portion and reinserted on the megaprosthesis (Table 2) [17].

### Knee megaprosthesis

In the case of knee MPs, a distinction must be made between resection of the distal femur and the proximal tibia.

- In the distal femur, thanks to the frequent preservation of the extensor apparatus, the current megaprostheses allow an almost immediate start of functional recovery, similar to the protocol used in knee prostheses; on the other hand, if it should be necessary to sacrifice a part of the quadriceps, which is frequent especially in cancer patients, a period of immobilization in an articulated brace will be necessary in order to allow a proper soft tissue repair [10].
- In proximal tibia resections a period (about 30-40 days) of protection of the knee joint is necessary in order to respect the biological healing time of the extensor apparatus, which is necessarily detached and reinserted to the prosthetic component. More and more often, the medial gastrocnemius is also performed in rotation flaps, which are transported in order to offer a valid prosthetic coverage by soft tissues, representing a critical phase of healing [18].

Analizing these data, it is easy to predict how the clinical and functional results of megaprostheses in large resections of the proximal tibia are generally less valid than those of megaprostheses used for the reconstruction of the proximal or distal femur. In fact, it should be noted that none of these patients can achieve a complete recovery of strength, although most of them show a satisfactory recovery of quadriceps tone, managing to perform an adequate knee extension movement. This does not generally result in any limitation in the performance of daily life activities, but it does have a limited impact on lifestyle and some limitations related to long-distance walking and sports activities [10-19]. In an attempt to overcome these difficulties, we are increasingly working on innovative prosthetic designs that allow a safe and durable anchoring of the extensor apparatus to the prosthesis.

Regardless of the anatomical district concerned, MPs can be implanted with or without cementing. Cementation is used in particular in elderly patient or whenever adjuvant radiotherapy or in co is existing of metastases and osteoporotic bone, allowing early loading. In young patients or patients with good bone quality, on the other hand, it is preferable to use an uncemented prosthesis, as it is not necessary to grant the full load immediately as in the elderly, also ensuring bone savings in case of subsequent revision (Tables 3 and 4).

Below we present in detail the standardized rehabilitation protocol that is used in our center. However, it is necessary to take into account the need to evaluate and adapt it case by case in order to personalize it to the characteristics and expectations of each individual patient.

### Hip and knee allograft-prosthesis composites

The treatment of composite prostheses of the femur and proximal tibia deserves a separate chapter. These, in selected cases, offer an excellent functional recovery and guarantee an adequate bone stock in case of further surgical revisions. Composite prostheses are indicated in bone tumors where the tendon insertion section is close to

The bone surface and where it is possible to directly reinsert the residual tendon to that present on the mass graft. This method allows obtaining a fusion of the two tendons with great mechanical efficiency and consequent improvement of functional results. The technique also allows the reconstruct not only of the buttocks (in hip prostheses) and patellar tendons (in the knee), but also other tendons usually neglected in metal prostheses (for example, the ileopsoas and large gluteus tendon or the medial and lateral flexor tendons of the knee). The most anatomical and extensive repair has a favorable effect on the pitch biomechanics, but also on joint stability (decreased dislocation). Compared to megaprostheses there is therefore a better functional result, while the durability and mobilizations are comparable [20].

Therefore, while the functional result is better in composite prostheses than in megaprostheses, also the rate of complications and surgical difficulty are higher in the use of composite prostheses. In particular these implants have high rates of infection, pseudoarthrosis, allograft resorption and periprosthetic fracture. In addition, healing times at the bone-transplant interface require longer immobilization times and more demanding rehab therapies. For these reasons, these interventions are reserved for young patients, who need high functional results and are expected to live longer than the reconstruction, thus requiring an adequate bone stock for further revision. On the other hand, patients with metastases or patients who

**Table 2:** Rehabilitation Stages: Proximal femoral replacement with Megaprosthesis.

| |
|---|
| It is important to start early rehabilitation treatment in the post-operative phase. The rehabilitation treatment remains extremely customizable for each patient. |
| **1st week after surgery** |
| Pain management through drug therapy, cryotherapy, manual therapy, correct positioning and physical therapy. |
| Correct positioning of the operated limb to avoid complications and edemas. |
| Prevention of thromboembolic complications through mainly drug therapy, but also manual therapy, correct positioning of the operated leg in discharge, active, active-assisted mobilization of the tibiotarsal joint. |
| Postural passages avoiding displacement movements or movements that excessively engage the joint. |
| Education about the hygienic and behavioural rules. |
| Active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Cautious passive mobilization exercises on the operated leg for an initial restoration of the joint motion. |
| Cautious active, active-assisted mobilization exercises on the operated leg for an initial restoration of muscle tone and trophism. |
| Position a full-time hip brace with a range of movement at 0°-60° (up to 0°-90° in selected cases) with the opportunity to transfer for bed to a chair and to reach an upright position with toe-touch weight-bearing on operated leg (for 35 days from the surgical operation) teaching how to use mobility assistive device such as crutches or walker, or based on the indications of the surgeon, the patient requires bed and chair rest for 30 days in the most demolition surgery (wearing the full-time hip brace). |
| **2nd week after surgery** |
| Continue postural passages avoiding displacement movements or movements that excessively engage the joint. |
| Continue active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Continue passive mobilization exercises on the operated leg for the restoration of the joint motion. |
| Continue active, active-assisted mobilization exercises on the operated leg for the restoration of muscle tone and trophism. |
| **3rd-4th week after surgery** |
| Continue postural passages avoiding displacement movements or movements that excessively engage the joint. |
| Continue active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Increase passive mobilization exercises on the operated leg for the restoration and maintenance of the joint motion. |
| Increase active, active-assisted mobilization exercises on the operated leg for the restoration and maintenance of muscle tone and trophism. |
| **After the 1st month after surgery** |
| Walking with partial weight-bearing on operated leg with mobility assistive device such as crutches or walker. |
| Progressive removal of hip brace. |
| Increase active mobilization exercises on the operated leg for the restoration and maintenance of muscle tone and trophism. |
| Increase passive mobilization exercises on the operated leg for the restoration and maintenance of the joint motion. |
| Gain re-education. |
| Stair climbing re-education. |
| Proprioceptive exercises. |
| Education about the progressive recovery of normal daily life activities. |
| Start of an advanced rehabilitation program to be customized on the individual patient. |

**Table 3:** Rehabilitation Stages: Distal femoral replacement with Megaprosthesis.

| |
|---|
| It is important to start early rehabilitation treatment in the post-operative phase. The rehabilitation treatment remains extremely customizable for each patient. In the case of Oncological surgery that involve the sacrifice of a part of the quadriceps muscle, using a knee brace locked in extension for 35 days is necessary to promote healing of soft tissues (protocol similar to the proximal tibia replacement). |
| **1st week after surgery** |
| Pain management through drug therapy, cryotherapy, manual therapy, correct positioning and physical therapy. |
| Correct positioning of the operated limb to avoid complications and edemas. |
| Prevention of thromboembolic complications through mainly drug therapy, but also manual therapy, correct positioning of the operated leg in discharge, active, active-assisted mobilization of the tibiotarsal joint. |
| Postural passages avoiding displacement movements or movements that excessively engage the joint. |
| Education about the hygienic and behavioural rules. |
| Active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| **From the 1st post-operative day as far as compatible with pain symptoms:** |
| Cautious passive mobilization exercises on the operated leg for an initial restoration of the joint motion (it is possible to use devices for passive mobilization). |
| Cautious active, active-assisted mobilization exercises on the operated leg for an initial restoration of muscle tone and trophism. |
| Walking with partial weight-bearing on operated leg with mobility assistive device such as crutches or walker. |
| Gain re-education. |
| Stair climbing re-education. |
| Proprioceptive exercises, especially with operated leg placed on the ground. |
| **2nd-3rd-4th week after surgery** |
| Continue active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Continue passive mobilization exercises on the operated leg for the restoration of the joint motion. |
| Continue active, active-assisted mobilization exercises on the operated leg for the restoration of muscle tone and trophism. |
| Walking with progressive partial weight-bearing on operated leg with mobility assistive device such as crutches or walker with the improvement of balance, distance, coordination and endurance. |
| Increase proprioceptive exercises. |
| **After the 1st month after surgery** |
| Walking with full weight-bearing on operated leg with progressive removal of mobility assistive device. |
| Increase active mobilization exercises on the operated leg for the restoration and maintenance of muscle tone and trophism. |
| Increase passive mobilization exercises on the operated leg for the restoration and maintenance of the joint motion. |
| Education about the progressive recovery of normal daily life activities. |
| Start of an advanced rehabilitation program to be customized on the individual patient. |

**Table 4:** Rehabilitation Stages: Proximal tibial replacement with Megaprosthesis.

| |
|---|
| It is important to start early rehabilitation treatment in the post-operative phase. The rehabilitation treatment remains extremely customizable for each patient. |
| **1st week after surgery** |
| Pain management through drug therapy, cryotherapy, manual therapy, correct positioning and physical therapy. |
| Correct positioning of the operated limb to avoid complications and edemas. |
| Prevention of thromboembolic complications through mainly drug therapy, but also manual therapy, correct positioning of the operated leg in discharge, active, active-assisted mobilization of the tibiotarsal joint. |
| Postural passages avoiding the activation of the leg extensor muscles. |
| Education about the hygienic and behavioural rules. |
| Active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Position a full-time knee brace locked in extension (for 35 days from the surgical operation) to promote healing of the insertion of the patellar tendon on the megaprosthesis. |
| Cautious passive, active, active-assisted mobilization exercises on the hip joint of the operated leg to maintain joint motion and muscle tone and trophism, avoiding the activation of the leg extensor muscles. |
| Bed rest and transfer to chair. |
| **2nd-3rd-4th-5th week after surgery** |
| Continue postural passages avoiding the activation of the leg extensor muscles. |
| Continue active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Cautious passive, active, active-assisted mobilization exercises on the hip joint of the operated leg to maintain joint motion and muscle tone and trophism, avoiding the activation of the leg extensor muscles. |
| Based on the indications of the surgeon, reaching an upright position with toe-touch weight- bearing on operated leg (for 35 days from the surgical operation) teaching how to use mobility assistive device such as crutches or walker (wearing the full-time knee brace), compatibly with the patient's clinical conditions. |
| **6th-7th week after surgery** |
| Low intensity isometric leg extensor muscles contractions. |
| Cautious passive mobilization exercises on the operated leg for an initial restoration of the flexion with a full-time knee brace with a range of movement at 0°-30° for 7 days and then at 0°-60° for other 7 days. |
| Walking with partial weight-bearing on operated leg with mobility assistive device such as crutches or walker, avoiding the activation of the leg extensor muscles. |
| **After the 7th week after surgery** |
| Continue passive mobilization exercises on the operated leg for the restoration of the joint motion. |
| Continue active, active-assisted mobilization exercises on the operated leg for the restoration of muscle tone and trophism. |
| Walking with progressive partial weight-bearing on operated leg with mobility assistive device such as crutches or walker with a knee brace unlocked. |
| Gain re-education. |
| Stair climbing re-education. |
| Proprioceptive exercises. |
| Education about the progressive recovery of normal daily life activities. |
| Start of an advanced rehabilitation program to be customized on the individual patient. |

are undergoing numerous prosthetic revisions and complex fractures in the elderly are indications for megaprosthesis implantation due to low demand and limited life expectancy with reduced likelihood of revision [21,22].

## Allograft-prosthesis composite for proximal femur

Long or short prosthetic stems may be used in proximal femoral composite prostheses. The short stem is rarely used and is always cemented in the transplant. Synthesis with the femur is then performed using plate and screws. The short stem prosthesis finds its indication in pediatric reconstructions to avoid the intense schielding stress caused by uncemented stems. In addition, the possibility of subsequent elongation is left open. The long prosthetic stem must pass through the osteotomy. It is always cemented shortly in the transplant (necrotic bone without the possibility of "bone ingrowth"), while at the host bone level it can be cemented or uncemented. Cementation is used in the elderly patient, in particular in the case of adjuvant radiotherapy, metastases and osteoporotic bone, allowing an early load. The fusion of the osteotomy area allows a uniform distribution of the loading forces, both proximally and distally, in a way comparable to a conventional prosthesis. However, in cemented long-stem prostheses, osteotomy is not a critical factor, as the stem transmits the loading forces distally to the femur as well as in megaprostheses. This makes the fusion of the osteotomy less important and solves the problem of pseudoarthrosis, a frequent complication in the use of this method.

When the distal part is left uncemented to achieve osteointegration with the host bone, the immediate stability is given by the step osteotomy in the host bone and the reciprocal osteotomy on the adjacent allograft. Permanent stability is achieved after the allograft is joined to the host bone [9]. Whether megaprosthesis or a composite prosthesis is used for the reconstruction of the proximal femur, one of the major problems, common to both methods, is the muscle reinsertion, especially for the abductor apparatus. With megaprostheses muscle reinsertion is more difficult, with less satisfactory functional results, while functional results are better with composite prostheses. This is due to the possibility of performing a more physiological, mechanically valid and stable muscle re-integration over time. In composite prostheses the re-integration of the abductor apparatus can take place through

different techniques. The osteotomy of the great trochanter is the most mechanically stable choice but it reserved for non oncological cases. In oncological surgery, if possible, it is preferable to use the termino-terminal suture between the tendons of the transplant and the tendons of the host, as the osteotomy of the great trochanter increases the risk of failing a safe surgical margin of resection.

However, the tensile forces exerted by these tendons are such that over time they cause the frequent fracture of the great trochanter. This complication is one of the most frequent reported in the literature, but it often remains asymptomatic, maintaining a satisfactory residual function of the abductor apparatus. This is due to the formation of a fibrous callus that functionally stabilizes the synthesis.

Finally, the reisection of the ileopsoas tendon of the host to

transplantation in composite prostheses improves both the stability of the implant and the muscle flexural strength, allowing a more physiological gait. Good muscle anchorage and the restoration of an almost normal anatomy (bone-stock, offset, length, etc.) have made it possible to considerably reduce postoperative dislocations in composite prostheses, a frequent complication in megaprostheses (Table 5) [23].

Allograft-prosthesis composite for proximal tibia patients with a proximal composite tibia prosthesis generally have better functional results than those with MP. An inherent difficulty in a proximal tibial implant is the reconstruction of the extensor mechanism. The attachment of the patellar tendon to the allograft tibial tubercle, which includes its patellar tendon in addition to the tendons of the knee flexor muscles, theoretically provides a more biological healing interface than the attachment of the tendon to the metal prosthesis [22]. In patients with proximal tibia resection, reconstruction of the extensor mechanism is performed by suturing the remaining native patellar tendon superimposed on the tendon provided by the allograft. In addition to this suture, the proximal tibia composite prosthesis allows the native tendons of the medial and lateral flexor muscles of the knee to be reinserted into those of the allograft with a termino-terminal suture. As with MPs, an overturning of the medial gastrocnemius muscle is necessary to ensure adequate coverage of the prosthetic component. This more accurate anatomical reconstruction, combined with a more stable and durable muscle anchorage, is the cause of the better functional recovery compared to the use of metal megaprostheses [24,25].

In cases of oncological knee surgery, composite prosthesis offer unhoped-for opportunities until a few years ago even in cases where the tumor involves the joint. The distal femur and the proximal tibia are in fact among the bone sites with the highest incidence of tumor localization with frequent involvement of joint structures. Traditional surgical options include thigh amputation or extraarticular resection of the knee, which also involves complete loss of the extensor apparatus and subsequent reconstruction of the knee in arthrodesis [26]. In order to allow an adequate reconstruction of the extensor apparatus, the surgical innovation has permitted the resection of the distal femur, the proximal tibia, the entire extensor apparatus and the entire inviolated articular capsule, replacing them with distal femur resection megaprosthesis combined with a composite prosthesis of the proximal tibia. In this case, the composite tibia prosthesis includes not only the proximal tibial bone graft, but also the entire extensor apparatus of the donor, including patellar and quadricepital tendon. This allows an adequate reconstruction of the extensor mechanism thanks to the suture between the quadricipital tendon of the graft and the one of the recipient. Firstly this allows performing a complete excision and reconstruction of the extensor apparatus, but it also eliminates the problem of patellar tendon's reinsertion on the tibia,

**Table 5:** Rehabilitation Stages: Proximal femoral replacement with Composite Prosthesis.

| |
|---|
| It is important to start early rehabilitation treatment in the post-operative phase. The rehabilitation treatment remains extremely customizable for each patient. |
| **To 10th day after surgery** |
| Pain management through drug therapy, cryotherapy, manual therapy, correct positioning and physical therapy. |
| Correct positioning of the operated limb to avoid complications and edemas. |
| Prevention of thromboembolic complications through mainly drug therapy, but also manual therapy, correct positioning of the operated leg in discharge, active, active-assisted mobilization of the tibiotarsal joint. |
| Postural passages avoiding displacement movements or movements that excessively engage the joint. |
| Education about the hygienic and behavioural rules. |
| Active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Low intensity isometric leg extensor and gluteal muscles contractions. |
| Position a full-time hip brace locked at 0°. |
| Bed rest and transfer to chair. |
| **From 11th day to 20th day after surgery** |
| Continue postural passages avoiding displacement movements or movements that excessively engage the joint. |
| Continue active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Continue passive mobilization exercises on the operated leg for the restoration of the joint motion (wearing the full-time knee brace with a range of movement at 0°-30°). |
| Continue active, active-assisted mobilization exercises on the operated leg for the restoration of muscle tone and trophism. |
| Position a full-time hip brace with a range of movement at 0°-30° with the opportunity to walk with partial weight-bearing on operated leg with mobility assistive device such as crutches or walker. |
| **From 21st day to 30th day after surgery** |
| Continue postural passages avoiding displacement movements or movements that excessively engage the joint. |
| Continue active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Increase passive mobilization exercises on the operated leg for the restoration and maintenance of the joint motion (wearing the full-time knee brace with a range of movement at 0°-60°) |
| Increase active, active-assisted mobilization exercises on the operated leg for the restoration and maintenance of muscle tone and trophism. |
| Position a full-time hip brace with a range of movement at 0°-60° with the opportunity to walk with partial weight-bearing on operated leg with mobility assistive device such as crutches or walker. |
| Gain re-education. |
| Proprioceptive exercises. |
| **After the 1st month after surgery** |
| Initially keep the hip brace unlocked and then progressive removal of hip brace. |
| Walking with progressive partial weight-bearing on operated leg with mobility assistive device such as crutches or walker. |
| Increase active mobilization exercises on the operated leg for the restoration and maintenance of muscle tone and trophism. |
| Increase passive mobilization exercises on the operated leg for the restoration and maintenance of the joint motion. |
| Stair climbing re-education. |
| Increase proprioceptive exercises. |
| Education about the progressive recovery of normal daily life activities. |
| Start of an advanced rehabilitation program to be customized on the individual patient. |

which usually is the most critical step in the reconstruction of the extensor apparatus (Table 6) [20].

Those are the standardized rehabilitation protocols used in our center for patients with proximal femoral and proximal tibia composite prostheses.

## Conclusion

Currently there is a gap in the literature about a standardized rehabilitation protocol for patients undergoing megaprosthesis implantation by lower limb resection. In recent years, however, there has been an increase in the use of MPs, both in osteo-oncological surgery, thanks to better medical and radiant therapies associated with better diagnostic and screening methods, and in traditional orthopaedics, where the progressive ageing of the population and the ever-increasing functional demand have led to a constant increase in hip and knee prosthetic revision surgery, with an increase in the so-called "difficult" cases. MPs are also becoming valid therapeutic alterative in complex periprosthetic fractures, severe post-traumatic joint subversions or in general in all those cases characterized by significant bone loss. This progressive increase in the number of cases makes it increasingly necessary to draw up standard guidelines for patient management. This is very important because it is a particularly demanding surgery and not without risks and complications, which for these reasons is recommended to be reserved only for a few centers hyper-specialized in surgery and rehabilitation of oncological and degenerative musculoskeletal tissue diseases. However, these centres are very few in proportion to recent epidemiological data on the incidence of the disease. It is therefore frequent that post-surgical rehabilitation pathways cannot be provided in the hyperspecialised centre, but they are delegated to territorial structures which are often several hundred kilometres away from the surgery centre.

The aim of creating standardised rehabilitation protocols is precisely to provide local structures with guidelines for the management of the ever-increasing number of these patients. This is in fact crucial in order to obtain therapeutic continuity, an indispensable factor for improving surgical efficacy in terms of functional relapses and for achieving and maintaining functional results adequate for a good quality of life for these patients.

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**Table 6:** Rehabilitation Stages: Proximal tibial replacement with Composite Prosthesis.

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| It is important to start early rehabilitation treatment in the post-operative phase. The rehabilitation treatment remains extremely customizable for each patient. |
| **1st week after surgery** |
| Pain management through drug therapy, cryotherapy, manual therapy, correct positioning and physical therapy. |
| Correct positioning of the operated limb to avoid complications and edemas. |
| Prevention of thromboembolic complications through mainly drug therapy, but also manual therapy, correct positioning of the operated leg in discharge, active, active-assisted mobilization of the tibiotarsal joint. |
| Postural passages avoiding displacement movements or movements that excessively engage the joint. |
| Education about the hygienic and behavioural rules. |
| Active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Position a full-time knee brace locked in extension (for 30 days from the surgical operation) to promote healing of the insertion of the patellar tendon. |
| Cautious passive, active, active-assisted mobilization exercises on the hip joint of the operated leg to maintain joint motion and muscle tone and trophism, avoiding the activation of the leg extensor muscles. |
| Bed rest and transfer to chair. |
| **2nd-3rd-4th week after surgery** |
| Continue postural passages avoiding the activation of the leg extensor muscles. |
| Continue active mobilization exercises on the non-operated leg to maintain joint motion and muscle tone and trophism. |
| Cautious passive, active, active-assisted mobilization exercises on the hip joint of the operated leg to maintain joint motion and muscle tone and trophism, avoiding the activation of the leg extensor muscles. |
| Based on the indications of the surgeon, reaching an upright position with toe-touch weight- bearing on operated leg teaching how to use mobility assistive device such as crutches or walker (wearing the full-time knee brace), compatibly with the patient's clinical conditions. |
| **5th-6th week after surgery** |
| Cautious active, active-assisted mobilization exercises on the operated leg for the restoration of muscle tone and trophism. |
| Cautious passive mobilization exercises on the operated leg for an initial restoration of the flexion with a full-time knee brace with a range of movement at 0°-30°. |
| Walking with partial weight-bearing on operated leg with mobility assistive device such as crutches or walker. |
| Gain re-education. |
| Proprioceptive exercises. |
| **After the 6th week after surgery** |
| Continue passive mobilization exercises on the operated leg for the restoration of the joint motion. |
| Continue active, active-assisted mobilization exercises on the operated leg for the restoration and maintenance of muscle tone and trophism. |
| Walking with progressive partial weight-bearing on operated leg with mobility assistive device such as crutches or walker. |
| Walking with complete weight-bearing on operated leg based on the indications of the surgeon when an adequate fusion between bone and graft can be highlighted radiologically. |
| Position a full-time knee brace with a range of movement at 0°-60° for 10 days, then at 0°-90° for other 10 days and then unlocked. |
| Stair climbing re-education. |
| Increase proprioceptive exercises. |
| Education about the progressive recovery of normal daily life activities. |
| Start of an advanced rehabilitation program to be customized on the individual patient. |

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