Diplomarbeit

Comparative Outcome of the ATTUNE® versus the Press fit Condylar® Total Knee Arthroplasty System

eingereicht von

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zur Erlangung des akademischen Grades

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an der

Medizinischen Universität Graz

ausgeführt an der

Universitätsklinik für Orthopädie und Orthopädische Chirurgie

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Graz, 30.01.2017

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Graz, am 30.01.2017 ....

Florian Hofer eh

Danksagungen

Zu allererst möchte ich mich bei Herrn Assoz. Prof. PD Dr. Patrick Sadoghi für die hervorragende, geduldige und unkomplizierte Betreuung bedanken. In der Folge möchte ich mich bei meinen beiden Mitbetreuerinnen, Frau Dr. Ines Vielgut und Frau Dr. Daniela Hirzberger bedanken. Des Weiteren danke ich Herrn Prof. Dr. Andreas Leithner und seinem Team, der Abteilung für Orthopädie und Orthopädischen Chirurgie, die mir die Grundlagen des wissenschaftlichen Arbeitens vermittelten.

Dieses Studium und damit diese Arbeit wären nicht möglich gewesen ohne vier ganz besondere Menschen in meinem Leben:

Meine Eltern, Irene und Alfred, haben mir nicht nur ermöglicht, meinen Traum zu verwirklichen, sondern waren stets eine riesige Unterstützung in den letzten sechs Jahren.
Mein Großvater, Alfred sen., der mich bei der Finanzierung dieses Studiums unterstützt hat und mit dem ich stets angeregt über neu gewonnene Erkenntnisse reden konnte.
Meine Freundin, Johanna, die seit über acht Jahren, auch in schwierigen Zeiten, nicht von meiner Seite weicht und sich nun endlich auch ihren Traum erfüllen kann.

Vielen Dank, ohne Euch wäre dieses Studium niemals möglich gewesen!

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List of Abbreviations

A.	artery
ACL	anterior cruciate ligament
AORI	Anderson Orthopedic Research Institute
BMI	body mass index
KSS	Knee Society Score
M.	muscle
N.	nerve
NSAIDs	nonsteroidal anti-inflammatory drugs
OA	osteoarthritis
OR	operating room
P.F.C.	Press Fit Condylar
PCL	posterior cruciate ligament
RA	rheumatoid arthritis
ROM	range of motion
TKA	total knee arthroplasty
TXA	tranexamic acid
VAS	Visual Analog Scale
VTE	venous thromboembolism
WOMAC	Western Ontario & McMaster Universities Osteoarthritis Index

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Abstract (English)

Background

Severe osteoarthritis of the knee joint is a common disease that causes not only patient suffering but also high costs for the health care system. Although total knee arthroplasty (TKA) has proven to be a highly effective treatment, the rate of complications and resultant patient dissatisfaction are issues that still need to be addressed. Therefore the ATTUNE system was designed to improve the implantation and lead to better clinical results. In the lights of these facts, this study was intended to examine, if the ATTUNE system has a better surgical outcome and leads to higher patient satisfaction than the Press-Fit-Condylar Sigma system.

Patients and Methods

This study prospectively analyzed 200 patients who had to receive total knee arthroplasty in the Department of Orthopedic Surgery at the Medical University of Graz. The patients in the study were divided into two groups: one of which received the ATTUNE prosthesis system, while the other received the P.F.C. Sigma knee arthroplasty, which has been used as a matter of routine in the last few years. The patients were evaluated preoperatively, then at intervals of seven days, six weeks, and six months after surgery. This evaluation was made using the Visual Analog Scale (VAS), the active Range of Motion (ROM), the Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC), and the Knee Society Score (KSS).

Results

At no time during the evaluation did the mean VAS, ROM, and KSS scores show marked differences between the two groups. However, patients who had received the ATTUNE total knee arthroplasty had significantly better WOMAC values six weeks after surgery. However, this difference was clinically not relevant.

Conclusion

The study revealed that there is no significant difference between the two patient groups (and thus methods) in the short-term post-operative period. Therefore we conclude that the ATTUNE system is equally good as the established P.F.C. Sigma system.

Abstract (German)

Hintergrund

Die fortgeschrittene Gonarthrose ist eine häufige Krankheit, die nicht nur zu großem Leid der Patienten führt, sondern auch mit hohen Kosten für das Gesundheitssystem verbunden ist. Die Knietotalendoprothese (KTEP) hat sich als hochgradig effektive Behandlung etabliert, die jedoch, aufgrund von relevanten Komplikationsraten verbunden mit unzufriedenen Patienten, noch Raum für Verbesserungen bietet. Das ATTUNE System wurde entwickelt um die Implantation der Prothese zu vereinfachen und somit zu besseren klinischen Resultaten zu führen. Auf Basis dieser Fakten, soll diese Studie zeigen ob das ATTUNE System zu einem besseren chirurgischen Ergebnis und zu höherer Patientenzufriedenheit führt als das Press-Fit-Condylar Sigma System.

Methodik

Die vorliegende Studie analysierte prospektiv 200 Patienten, die an der Abteilung für Orthopädie und Orthopädische Chirurgie der Medizinischen Universität Graz, eine KTEP erhielten. Die eingeschlossenen Patienten wurden zufällig in zwei Gruppen geteilt, eine Gruppe erhielt das ATTUNE System, die andere die P.F.C. Sigma Prothese, die bereits seit Jahren regulär in Verwendung ist. Die Patienten wurden präoperativ, sowie sieben Tage, sechs Wochen und sechs Monate nach der Operation evaluiert. Zu diesem Zweck wurden die Visual Analog Scale (VAS), der aktive Bewegungsumfang (ROM), der Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) und der Knee Society Score (KSS) herangezogen.

Ergebnisse

Zu keiner Zeit während unserer Evaluation zeigten die mittleren VAS, ROM und KSS Werte signifikante Unterschiede zwischen den beiden Gruppen. Patienten die das ATTUNE System erhielten hatten zeigten signifikant bessere WOMAC Werte sechs Wochen nach der Operation, jedoch ohne klinischer Relevanz.

Schlussfolgerung

Die Studie zeigte, dass es in der kurzfristigen postoperativen Betrachtungszeit keinen signifikanten Unterschied zwischen den beiden Patientengruppen gibt. Wir kommen daher zum Schluss, dass das ATTUNE System gleich gut ist wie das etablierte P.F.C. Sigma System.

1. Section one: The Knee and Knee Replacement

1.1. Introduction

Osteoarthritis (OA) is the most common joint disease in older patients. The pain and physical impairment caused by OA are the main reasons for joint replacement surgery. Any joint can be affected, but the knee and hip joints are the most common.[1] In less severe forms of osteoarthritis, non-surgical treatments or minor surgery should be considered. However, in cases of severe osteoarthritis of the knee joint, total knee arthroplasty (TKA) has proven to be the most effective treatment and should be considered if the symptoms prevent the patient from sleeping, working, or carrying out everyday activities. [1]

The number of procedures carried out each year since the 1970s and 1980s has increased, although TKA is a highly effective procedure, up to 20% of patients continue to suffer from pain after the joint replacement. Aseptic loosening, infection, pain, instability, and stiffness account for up to 90% of revision surgeries following the primary knee arthroplasty. [2] Many factors, such as the age of the patient, preoperative diagnosis, surgical experience and implant design affect the outcome of the procedure. Several of these issues cannot be influenced, which is why orthopedic manufacturers continue to introduce new designs to improve the results. [2]

The ATTUNE Total Knee Arthroplasty System (DePuy Synthes, Warsaw, IN) was designed to simplify the measurement of the femoral shield size and the balancing of the flexion gap. Using one instrument for both steps should prevent the TKA from failing due to problems regarding placement and balancing, and should result in better surgical outcome and higher patient satisfaction. [3,4]

The aim of this thesis is to determine if the ATTUNE system has a better surgical outcome with ensuent higher patient satisfaction than the Press-Fit-Condylar Sigma system (DePuy Synthes, Warsaw, IN), which has been routinely used at the Department of Orthopedic Surgery at the Medical University of Graz in recent years.

1.2. Anatomy of the Knee Joint

1.2.1. General aspects

The knee joint is a composite joint consisting of the tibiofemoral joint and the patellofemoral joint. [5,6] Furthermore, it is a condylar joint, which allows flexion and extension of the leg as well as internal and external rotation. [5]

1.2.2. Bone structures

The knee joint consists of three bones, the femur, the tibia and the patella. [5]

The distal femur widens to form the medial and lateral condyles, which are separated by the intercondylar fossa (posterior). [5,6] The anterior articular surface forms an asymmetrical saddle-like groove, which holds the patella. The radius of curvature of the condyles decreases from the anterior to the posterior, which needs to be considered for prosthesis design. The epicondyles, which are protuberances proximal to the condyles, serve as muscular and ligamentous insertions. [5]

The proximal part of the tibia, which carries the weight transferred by the femur, is the third component of the knee joint. [5,6] It consists of a lateral and a medial condyle, which hold the articular face to the femur. Between the two lies the intercondyloid eminence with two tubercles. On the anterior side of the tibia lies the tibial tuberosity where the patellar ligament inserts to the tibia. [5]

The patella, the body's biggest sesamoid bone, is a flat cuneiform bone, which is inserted in the tendon of the quadriceps muscle. [5,6] It consists of a flat base on the proximal end of the bone, and the apex on the distal end of the bone. The backside consists of cartilage and forms the articular face with the femur. [5] This posterior surface is separated by a ridge, which fits into the intercondylar fossa of the femur, into a medial and lateral portion. [6]

1.2.3. Ligaments

Figure 1 and Figure 2 show the bony structures as well as the ligaments of the knee joint, with the exception of the patella and its ligament. The patellar ligament arises from the quadriceps muscle. It reaches from the patella's tip to the tibial tuberosity. [5]

The tibial collateral ligament arises from the medial femoral epicondyle, runs to the front and inserts at the medial surface of the proximal tibia. The ligament stabilizes the medial part of the knee joint. The fibular collateral ligament arises from the lateral femoral epicondyle and attaches at the head of the fibula. This ligament stabilizes the knee joint in extension. [5]

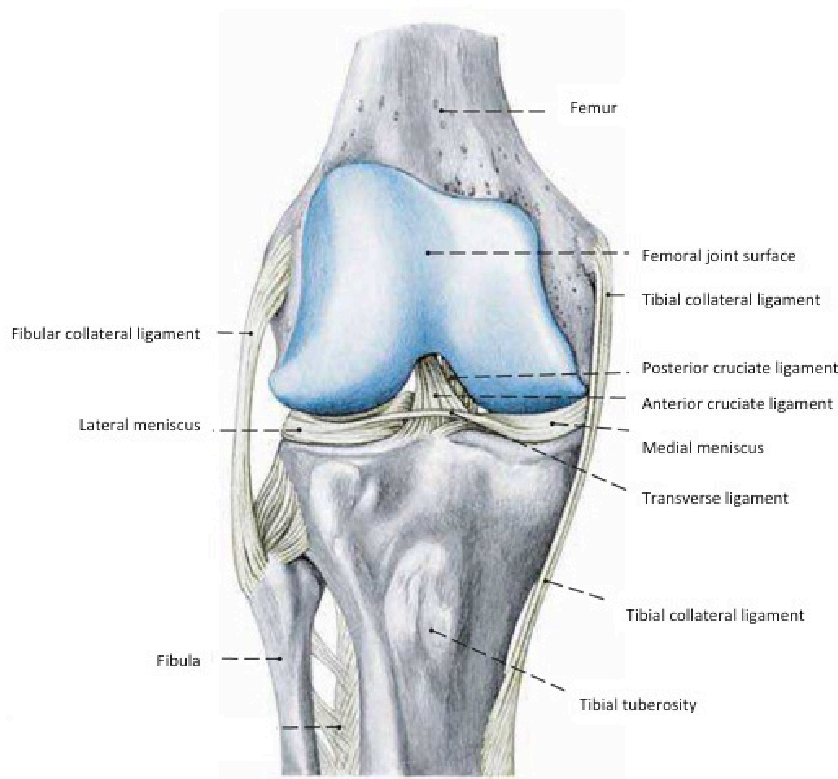

Figure 1: The knee joint and ligaments (anterior view) [5]

The cruciate ligaments are very strong structures, which cross each other slightly posterior to the articulate centre of the knee joint. [6] The anterior cruciate ligament (ACL) runs from the anterior intercondylary area of the tibia to the inner posterior

side of the lateral condyles of the femur. It divides into three bundles of fibre: the anteromedial, the intermediate and the posterolateral. [5] The posterior cruciate ligament (PCL), which is stronger than the ACL, extends from the posterior intercondylary area of the tibia and the posterior edge of the tibia to the inside of the medial femoral condylus. It consists of an anterolateral and a posteromedial bundle. [5] The anterior and posterior meniscofemoral ligaments run from the posterior horn of the lateral meniscus to the PCL and also insert at the medial femoral condylus. [5] The cruciate ligaments ensure the stability in the knee joint, especially in the sagittal plane. The posterolateral bundle of the ACL tightens, when the leg is extended, while the anteromedial tightens in flexion. Furthermore, the ACL tightens during inside rotation, and is loose when the leg is rotated outwards in the knee joint. The major parts of the PCL tighten during flexion of the knee joint. [5]

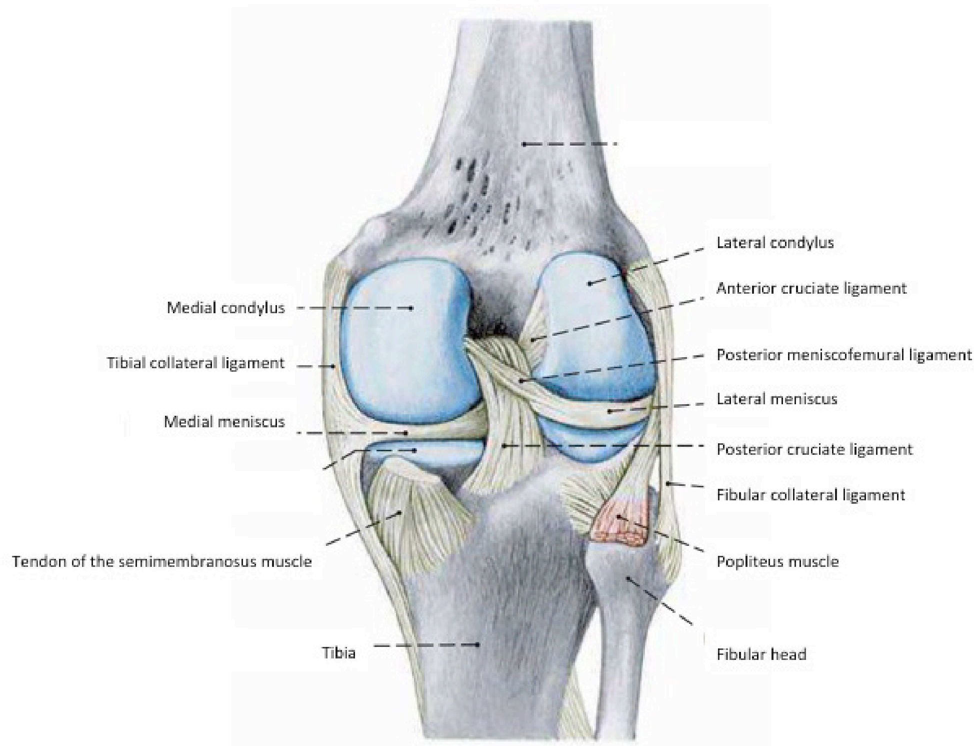

Figure 2: The knee joint and ligaments (posterior view) [5]

The arcuate popliteal ligament strengthens the dorsal capsule of the knee joint laterally. This ligament runs to the head of the fibula. [5]

The capsule of the knee joint consists of bundles of fibre. The patellar ligament replaces the capsule on the anterior side. [6] Transverse and longitudinal retinacular ligaments strengthen the capsule. The longitudinal retinacular extends from the quadriceps muscle of the femur and is used for extending the leg in the knee joint. The transverse retinacular runs from the lateral side of the patella to the iliotibial tractus. [5]

1.2.4. Menisci

The two menisci, which are shown in Figure 3, consist of crescent-shaped fibrous cartilage which is thicker on the outside. The purpose of the menisci is to increase the joint surface of the tibia and hold the femoral condyles. [5,6] The outer edge is connected to the joint capsule, whereas the anterior and posterior horns are connected by short tight ligaments to the intercondylary area of the tibia. The medial meniscus is also connected to the tibial collateral ligament. [5] Because of these ligamentous attachments the medial meniscus is less flexible than the lateral meniscus. The lateral meniscus shields a larger area of the tibial joint surface. [6]

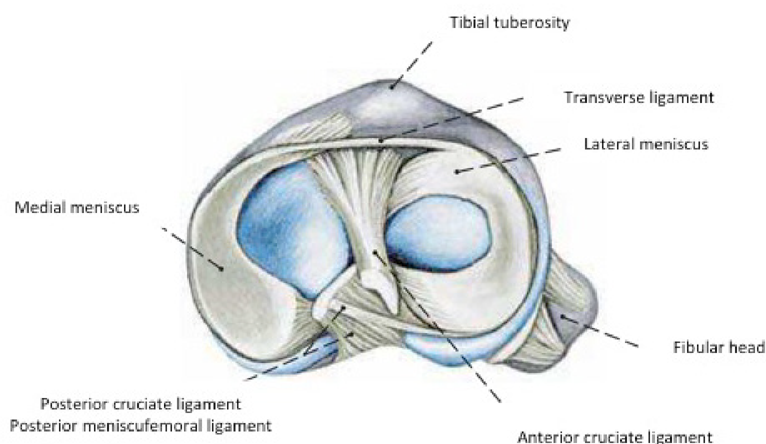

Figure 3: The menisci and cruciate ligaments[5]

The centre of the menisci does not contain any blood vessels and is nourished by the synovial fluid. The outer edge contains small blood vessels which run from the medial knee artery (a branch of the popliteal artery). Peripheral tears have a better chance of healing, due to the better vascular supply. [5,6] The connective tissue

contains numerous sensitive nerve fibres that can therefore cause pain when the menisci are torn. [5]

The menisci equalize the unevenness between the trochlea femoris and the tibial plateau and enlarge the joint surface to reduce pressure. Neither meniscus is fixed in its position. When the knee joint is flexed, both are pushed backwards. They also move during inside and outside rotation. The lateral meniscus is more mobile and is not connected to the lateral collateral ligament. [5]

1.2.5. Muscles

Figure 4 shows a medial view of the muscles of the knee joint and Figure 5 the lateral view. The muscles of the lower extremity not only enable the movement in the knee joint, they also stabilize it. According to their function and locations they are divided into Extensors and Flexors. Table 1 gives an overview of the muscles and their classification, as well as their neural innervation and blood supply. [5]

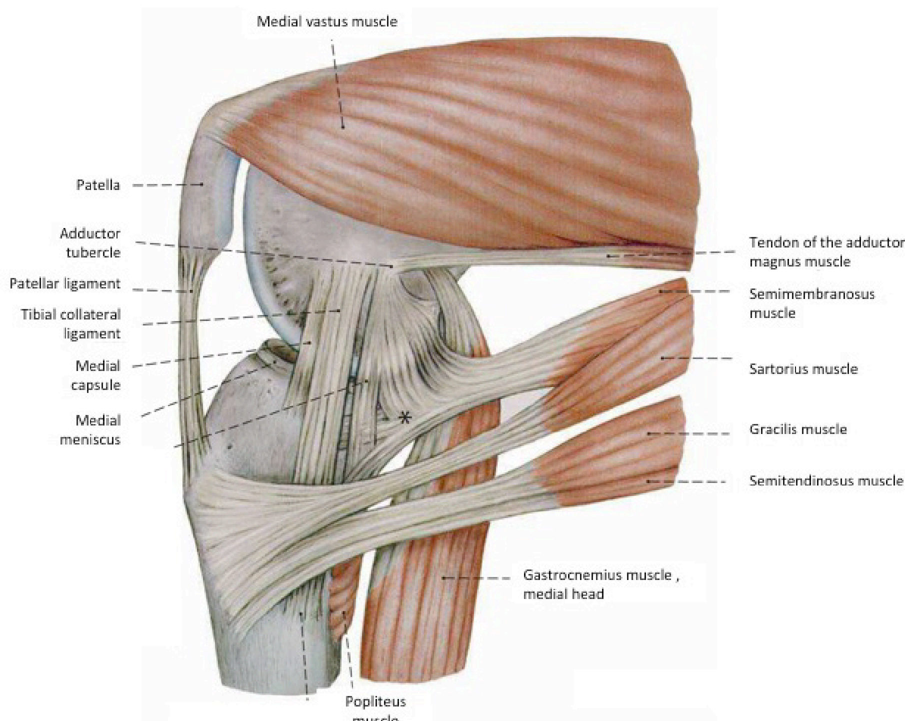

Figure 4: The muscles and ligaments of the knee joint (medial view) [5]

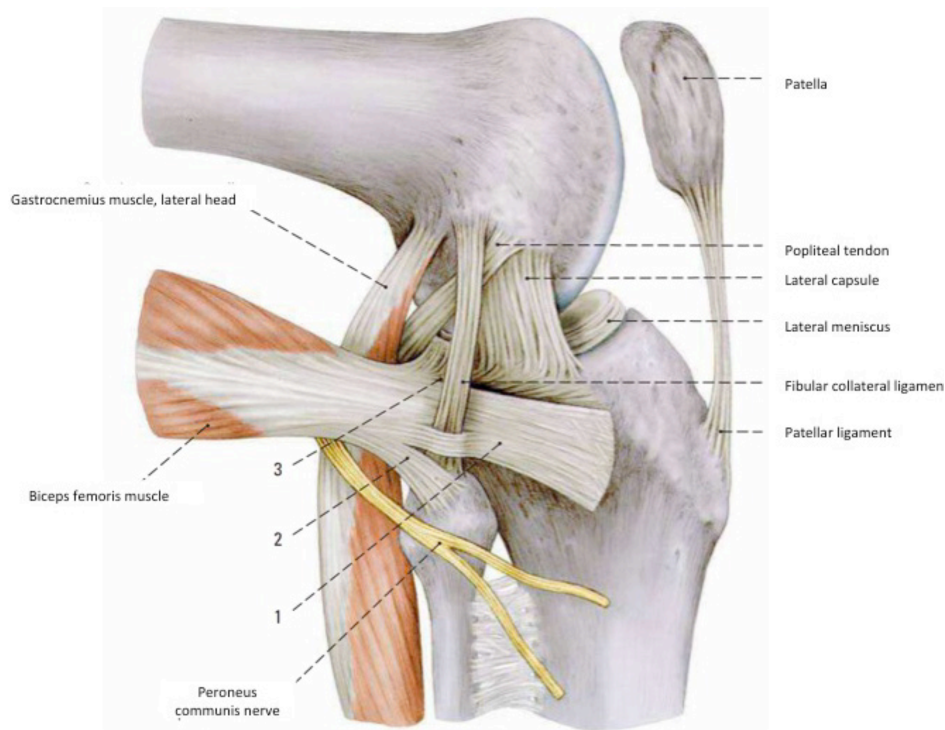

Figure 5: The muscles and ligaments of the knee joint (lateral view) [5]

1.2.6. Functional anatomy

The knee joint is the largest joint of the human body, and it allows two types of movement: flexion and extension as well as internal and external rotation when the knee is bent. [7]

When the knee joint is extended, both collateral ligaments, as well as the front section of the anterior cruciate ligament are tense. Just before reaching maximum extension, the free leg does an outside rotation of the tibia and the support leg an inside rotation of the femur, which is called final rotation. [7]

The normal range of passive extension is 0°-0°-160° but especially in children and young adults, a pronounced extension of 5° is possible. [6,7]

Table 1: Overview of the stabilizing and moving muscles of the knee joint [5]

Region	Function	Muscle	Neural Innervation	Blood Supply
Anterior Femoral	Flexion Internal rotation	M. sartorius	N. femoralis (L2-L3)	A. femoralis
	Extension Stabilization in walking and standing Internal rotation (M. vastus med.) External rotation (M. vastus lat.)	M. quadriceps femoris	N. femoralis (L2-L4)	A. circumflexa femoris lateralis A. profunda femoris
Posterior Femoral	Flexion Internal Rotation	M. semimembranosus	N. tibialis (L5-S2)	A. profunda femoris
	Flexion Internal Rotation	M. semintendinosus	N. tibialis (L5-S2)	A. profunda femoris
	Flexion External Rotation	M. biceps femoris	N. tibialis (L5-S2) (Caput longum) N. fibularis communis (Caput breve)	A. circumflexa femoris medialis A. profunda femoris A. poplitea
Medial Femoral	Flexion Internal Rotation	M. gracilis	N. obturatorius (L1-L2)	A. obturatoria
Posterior Tibial	Internal Rotation Stabilization	M. popliteus	N. tibialis (L5-S1)	A. poplitea
	Flexion (M. gastrocnemius)	M. triceps surae	N. tibialis (S1-S2)	A. poplitea A. tibialis posterior A. peronea
	prevents posterior tibial vessels from getting boxed in during flexion	M. plantaris	N. tibialis (S1-S2)	A. poplitea A. tibialis posterior

When the knee is bent, the fibular collateral ligament is fully relaxed, while the tibial collateral ligament is only partly so. On the other hand, both, the anterior, and the posterior cruciate ligaments are tensed. [7]

During the flexion of the knee joint, rotational movement is possible. In healthy knees the range of outside rotation is bigger, than the degree of internal rotation, due to the path of the cruciate ligaments, which block a pronounced internal rotation. Furthermore, the posterior fibres of the tibial collateral ligament are tensed in the final degrees of internal rotation. [7] The external rotation is limited by the tibial collateral ligament and less by the fibular collateral ligament. The maximum amount of rotation ranges from 45° to 60° in healthy knees. Due to their oblique position, a part of the cruciate ligaments is tense in every possible movement of the knee joint and can take over the guidance if the collateral ligaments are insufficient. [7] During flexion, the femur slides forward whilst rolling posteriorly, otherwise the femur would roll off the tibia. [6]

The correct shape of the knee joint has a big impact on the form of the leg. A malpositioned leg leads to unequal pressure on the knee joint and to faster wear of the joint surface. The mechanical leg axis in a healthy knee should run from the femoral head through the middle of the knee joint to the middle of the calcaneus, which is called a genu rectum. [7]

A genu valgum exists if the mechanical leg axis differs from the normal course and runs through the lateral femoral condylus. The tibial collateral ligament is overstretched and the lateral meniscus as well as the joint surface of the lateral femoral and tibial condylus is excessively worn. Furthermore, the joint gap is wider on the medial side than on the lateral side and the final rotation is more pronounced in the genu valgum. [7]

If the mechanical axis runs through the medial femoral condylus, it is called a genu varum. This leads to an overstretched fibular collateral ligament, excessive wear of the medial meniscus and the medial joint surface of the femur and tibia. A full extension is not possible, with the result that a final rotation cannot be achieved. [7]

1.3. Total Knee Arthroplasty

Operations of the knee joint are upon the most frequently performed surgical orthopedic procedures in Austria (Figure 6). The arthroscopy of the knee joint ranks in fourth place of the most commonly documented surgical procedures in Austria; the total knee arthroplasty is in the eighth place. [8] Amongst female patients the number of TKA procedures even overtook the number of total hip arthroplasties (Figure 6). [8]

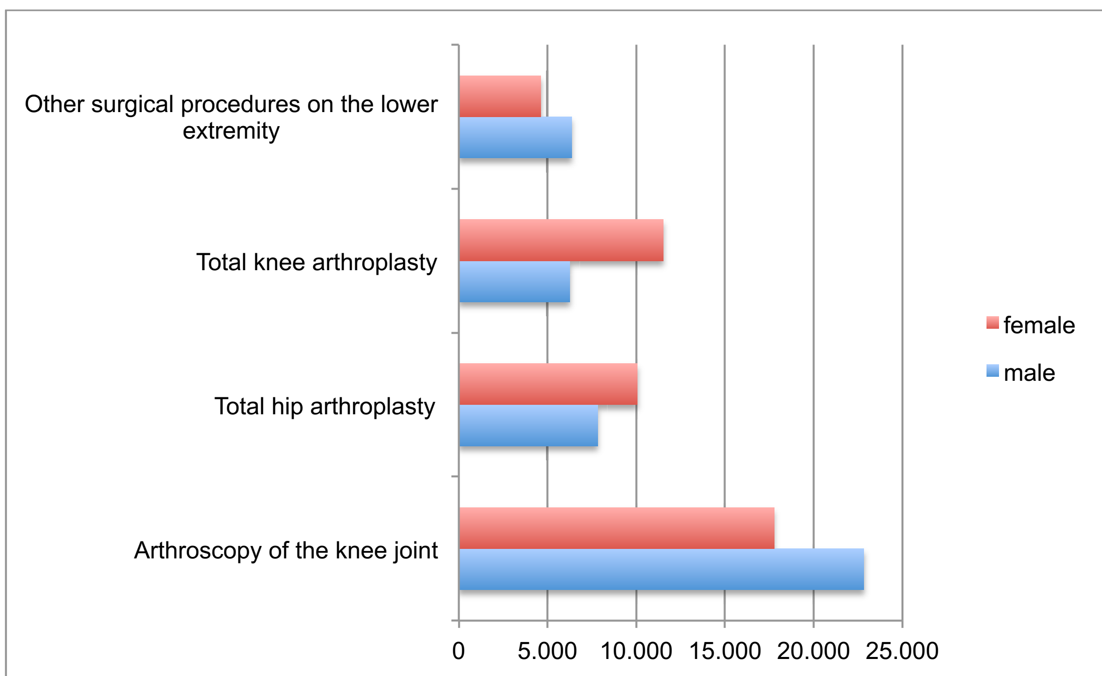

Figure 6: Orthopedic operations most frequently performed in Austria in 2014, Source: Statistik Austria[8]

As already mentioned, the number of total knee replacements has been increasing over the last decades. [2] This trend, slight but constant, has maintained in the last six years, as seen in Figure 7. At present, approximately 17,800 total knee arthroplasties are performed in Austria each year, with the larger number of these procedures, approximately 11,500, being done on female patients. [9] The main reason for the rising number may be an increase in the incidence of severe osteoarthritis. The rising life expectancy and obesity seem to be the main reasons behind the increasing number of total knee arthroplasties. [10]

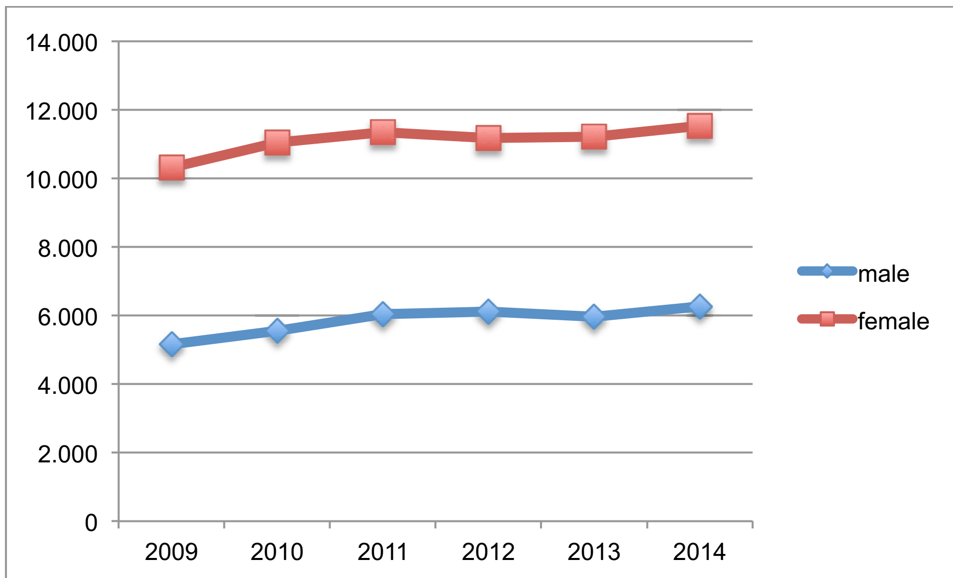

Figure 7: Number of TKA performed in Austria from 2009 to 2014, Source: Statistik Austria[9]

1.4. Indications for TKA

There are various indications for total knee arthroplasty, the main one being advanced symptomatic gonarthrosis. Further indications are post-traumatic joint destruction; joint destruction caused by disease, infection or tumour; irreparable joint instability and osteoporosis. [11]

According to the severity of the illness, a treatment plan should be implemented. Figure 8 shows such a plan for osteoarthritis. The aim is to avoid overtreatment, especially in patients with mild symptoms. Furthermore, treatment should not be based solely on radiographic imaging and the level of joint damage; the patient's symptoms and the level of physical impairment are factors not to be ignored. [1] As shown in Figure 8, the step-by-step progression starts with simple advice, which should empower the patients to help themselves. The medical professionals should provide information about the disease, and its course, and about how changes in the patient's lifestyle could possibly slow down this chronic disorder. [1] In more advanced levels of osteoarthritis, non-surgical treatments, like non-steroidal anti-inflammatory drugs, or infiltrations using local anesthesia and cortisone, may be administered. In patients with moderate to severe osteoarthritis minor or major surgery may be indicated. [1]

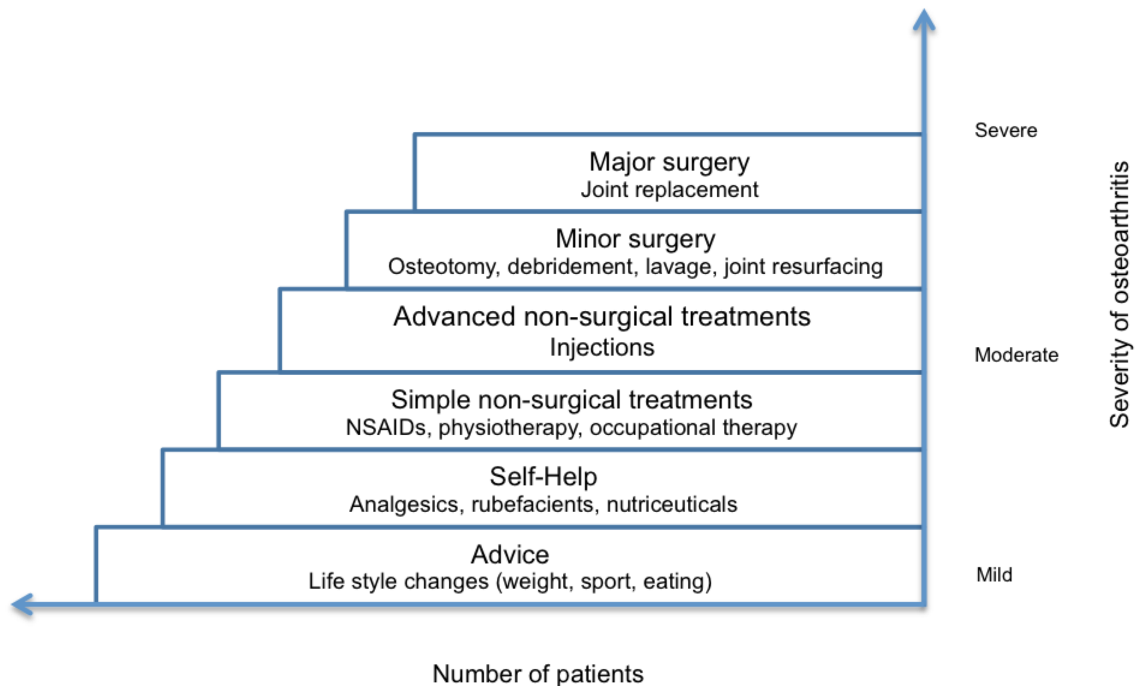

Figure 8: Treatment protocol for patients with osteoarthritis[1]

Before a joint replacement is performed, there are some absolute and relative contraindications which should be weighed up. TKA should not be performed if the condition of skin and muscles is not appropiate, for example, in patients with skin necrosis in the surgical area. Severe arterial circulation defects or the loss of function of the quadriceps muscle are also absolute contraindications for this surgery. [11] Furthermore, severe neurological diseases of the knee joint, such as neuropathic arthropathy or poliomyelitis, prohibit the implantation of a knee prosthesis, as does severe bone destruction, which makes the anchoring of the prosthesis impossible. The indications for the operation should be critically examined if the patient has to do hard manual labour, or if he suffers from epilepsy or another severe cerebral seizure condition. [11]

1.4.1. Osteoarthritis

Definition and Classification

Osteoarthritis is a degenerative joint disease, which affects primarily the cartilage of the joint surface and, secondly, the bone structure. It leads to cartilage degeneration, bone lesions and inflammatory shrinking of the joint capsule and is

therefore associated with pain and functional impairment. [12,13] Osteoarthritis of the knee can occur in the medial or lateral tibiofemoral corpartment as well as in the patellofemoral compartment. An affliction of two or more compartments is common. [13]

Osteoarthritis can be classified in many different ways. The Outerbridge and the Kellgren-Lawrence Classification are two of the most frequently used graduations. The Outerbridge Classification evaluates the quality of the joint cartilage and its defects on a scale from 0 to 4, as seen in Table 2. [14]

Grade	Description
0	normal cartilage
1	swelling and softening of the cartilage
2	partial fissures
3	defects reach the subchondral bone
4	complete loss of the cartilage, the subchondral bone is exposed

Table 2: Outerbridge Classification of Cartilage Defects[14]

The Kellgren-Lawrence Classification, shown in Table 3, uses a graduation based on X-rays of the affected joint. Grade 2 and higher is indicative of the presence of osteoarthritis.[14]

Grade	Description
0	normal joint gap
1	doubtful narrowing of the joint gap, possible osteophytic lipping
2	definite osteophytes , possible narrowing oft he joint gap
3	multiple medium sized osteophytes, definite joint gap narrowing, mild sclerosis, possible dislocation
4	big osteophytes, significant joint gap narrowing, pronounced subchondral sclerosis, joint dislocation

Table 3: Kellgren-Lawrence Classification[14]

Etiology and Risk Factors

Osteoarthritis develops due to an imbalance between load on the knee and the resistance of the joint. Furthermore, other factors such as immobilization can favour the development of OA, because of a reduction of the metabolism of the joint. We differentiate between primary and secondary osteoarthritis. [12] The reason why the primary form develops is still not fully understood, but it seems to be multifactorial. Cartilage destruction is the ultimate result. [12,15] There are many causes for secondary osteoarthritis: trauma, metabolic diseases, infections or simply advanced age. [12]

Risk factors for the development of osteoarthritis in the knee joint include a genetic predisposition, joint trauma, age and obesity. Vascular diseases, over-exercise and metabolic diseases may also play a role. Female patients over the age of 50 also have a higher risk of developing osteoarthritis, especially of the knee. Men under the age of 50 are more affected by osteoarthritis than women of the same age. [1,15]

Epidemiology

Due to the frequency of osteoarthritis in elderly patients and the rising age of the human population, this disease is of great importance. By the age of 40, about 50% of the population show signs of osteoarthritis. Nearly every person suffers from degenerative changes by the age of 65, although only 25% show symptoms such as pain or functional impairment. The knee joint is the localization most affected, followed by the shoulder and the hip joint. [12]

Pathogenesis

Osteoarthritis starts with the loss of flexibility of the cartilage and changes in the collagen matrix and, like every degenerative joint disease, progresses slowly. Chondrocytes act as mediators for osteoarthritis and have therefore been a focus of research. Because of their low regenerative potential, damage to cartilage is irreversible until the progression is interrupted. [12,15] The first sign of OA, which can be seen in x-rays, is a reduction of the joint gap, due to the loss of cartilage. A subchondral sclerosis of the surface of the joint and fissures in the cartilage may also appear in early stages of osteoarthritis. [12] Osteophytes result from the shearing of the outer edge of the joint, due to the loss of cartilage. This leads progressively to the deformation of the joint. Due to its constant pressure on an increasingly smaller surface, the bone is destroyed and cysts are formed. Many patients do not have symptoms at this stage because of the body's counter reactions, e.g. creating more osteophytes. [12] If the balance between joint destruction and reparative processes is interrupted, osteoarthritis can be triggered. Inflammatory reactions to the wear on the joint and osteonecrosis can also trigger osteoarthritis and its accompanying symptoms of pain and swelling. [12]

1.4.2. Rheumatoid Arthritis

Definition and Classification

Rheumatoid arthritis (RA) is a chronic systemic disease that affects several joints in a symmetrical fashion. Furthermore it is the most common inflammatory joint disease, affecting tendons, blood vessels and organs. [12,16]

The American College of Rheumatology defined seven types of criteria for the classification of rheumatoid arthritis. The patient has to suffer from at least four of the criteria listed in Table 4 to be diagnosed with rheumatoid arthritis. In addition, criteria one to four have to be present for a minimum of six weeks. [12]

Criteria	Definition
Morning stiffness	Morning stiffness in the joint for at least 1 hour
Arthritis of at least 3 joint regions	A minimum of 3 joint regions must have had a swelling of the soft tissue or effusion of the joint capsule.
Arthritis of the hand joints	At least one joint region is swollen
Symmetric arthritis	The same regions are affected at the same time in both sides of the body
Rheumatic nodes	Subcutaneous nodes over the joint
Rheumatoid factors	Abnormal titres of the rheumatoid factors
Radiologic pathologies	Typical changes in radiologic imaging of the hand

Table 4: Criteria for classification of rheumatoid arthritis[12]

Etiology and Risk Factors

The etiology of RA, as in other inflammatory rheumatoid joint diseases, is mostly unknown, but it seems to have multifactorial causes. In some of these diseases, a genetic predisposition plays a role. [12,16] Changes of the immune system are likely to be responsible for the development of rheumatoid arthritis in addition to the influence of genetics and other unknown factors. [16] Bacterial infections can be the cause for other arthritic diseases, but no pathogens have been linked to rheumatoid arthritis yet. [12]

Epidemiology

In central Europe about 1% of the population suffers from rheumatoid arthritis, the majority, about three times more often, being female patients who are afflicted. [12]

Pathogenesis

The pathogenesis has not yet been identified, but the current hypothesis is that rheumatoid arthritis is an autoimmune disease. The combination of genetic predisposition and environmental influences leads to the outbreak of this disease. [12,17] Pathogens, nutrition and stress are some of the factors that possibly trigger RA or exacerbate it. The immune system sets off an inflammatory process: synovitis, destroys cartilage and, ultimately, the whole joint. [12]

1.4.3. Other Indications

Osteoarthritis and rheumatoid arthritis are the leading causes of total knee arthroplasty. [1,2,12] There are, however, other diseases or defects that can be indications for TKA. Osteonecrosis may cause defects which cannot be treated in an other way than by implantation of prostheses. Risk factors are known to be high dose cortisone therapy, infections, exposure to radiation and smoking. [11,12,17]

1.5. Contraindications for Total Knee Arthroplasty

In order to avoid preventable complications, the patient should be critically evaluated for possible contraindications.

1.5.1. Absolute Contraindications

Absolute contraindications should be identified preoperatively, because these disorders can lead to prosthesis failure or life threatening situations.

Sepsis

Active infections, ranging from localized knee inflammation to systemic sepsis are absolute contraindications for total knee arthroplasty. If ignored, the results may be implant failure or life threatening infections. Exact preoperative examinations, including anamnesis, clinical examination, and blood tests are therefore mandatory to avoid these complications. [11,18]

Extensor Mechanism Dysfunction

Extensor mechanism dysfunction is one example of non-reconstructible instabilities of the knee joint; these count as absolute contraindications. [11,18,19] Extensor mechanism failure after total knee arthroplasty is the most frequent complication that leads to revision surgeries. [19] Although these problems have been reduced due to improvements in surgical technique and prosthesis design, many patients still suffer from complications.[11,18,19]

Peripheral Vascular Disease

An existing severe vascular disease may lead to devastating complications. These range from mildly impaired wound healing to severe infections resulting in amputation or possible death. [20] Vascular evaluation should therefore be part of the preoperative examination of high-risk patients. Arthroplasty must not be performed before revascularization, so that these severe complications can be prevented or at least reduced. [11,18,20]

1.5.2. Relative Contraindications

If a patient suffers from relative contraindications, the pros and cons should be critically evaluated. The implantation should only be performed if the benefits outweigh the risks.

Physical Constitution

The individual patient's preoperative physical constitution has a big impact on the postoperative outcome. Gait distance, weak muscles and a severely reduced range of motion are predictors of a poor clinical outcome. Furthermore, neurologic diseases like Alzheimer's Disease, which result in a reduced compliance, should be critically evaluated. [11,21]

Body Mass Index

Many studies suggest that patients with a high BMI have higher rates of complications. [22,23] Especially in the short- and mid-term postoperative period, the number of complications is significantly higher in patients suffering from adipositas. The risks, for example, a higher rate for misalignment, dislocation and early revision, rise with increasing BMI. [22] Furthermore, the procedure itself is challenging in obese patients. Due to difficulties in positioning and gaining access to the surgical field, intraoperative complications are more common in adipose patients. [22]

Skin Conditions

Skin conditions, like psoriatic lesions, in the surgical area, should be thoroughly evaluated. If possible, cutting through the lesions should be avoided, to prevent wound healing disorders or exacerbations of the skin. In the case of psoriasis vulgaris, there is no evidence that patients suffering from this disease have an increased risk of deep infections after undergoing total knee arthroplasty. It seems that a routine administration of antibiotics and antiseptic skin preparation are sufficient to prevent infections in psoriatic patients. [18,24]

1.6. Alternatives to Total Knee Arthroplasty

Total joint replacement is the most effective treatment for severe osteoarthritis, as well as for other diseases that lead to joint destruction with accompanying physical impairment and pain. Nevertheless, TKA may not be indicated for all patients suffering from OA, especially in mild cases or when contraindications exist for this procedure. In these cases, alternative types of therapy are required until such time as the total knee replacement is necessary. [1]

1.6.1. Physiotherapy

Physiotherapy and exercise in general lead to muscle strengthening and reduced levels of pain. [1] Furthermore, the flexibility of the joint can be preserved or even improved. Physiotherapy uses active and passive techniques to improve the patient's status. Active methods, which are used by the patients under the supervision of a professional physiotherapist, are indicated for restoring the joint mobility and for muscle strengthening. Passive physiotherapy, on the other hand, uses different techniques, like massage and heat application to reduce the patient's level of pain. Continual exercise requires a high level of compliance, which might prove demanding, especially in the long term. [1,12]

1.6.2. Technical Orthopedic Support

Different aids can help the patient by reducing pain and increasing mobility. Walking sticks and joint braces have been in use for a long time and have shown significant positive results in several trials. These and other devices like shoe wedges or inlays and taping methods can help the patient to bridge the period of time until a definitive treatment is indicated and possible. [1]

1.6.3. Physical Therapy

Cryotherapy has analgesic effects and is primarily indicated in acute inflammatory diseases. Heat therapy, on the other hand, should improve muscular trophism in chronic diseases of the musculoskeletal system. Electrotherapy can reduce pain and may also help in building up atrophic muscles. [12]

1.6.4. Drug Therapy

The main goal of pharmacological treatment is to reduce pain and physical impairment. Some of these drugs are intended to influence pro-inflammatory cytokines whilst others are supposed to improve healing processes. [13]
Non-steroidal anti-inflammatory (NSAIDs) have been in use for pain relief for a long time. Their efficiency has been shown in many trials, but they do also have many adverse effects, such as on the gastrointestinal and coagulation systems. Analgesics, which directly influence the central nervous system, are less common in the treatment of chronic diseases like osteoarthritis, but they are used for fighting postoperative pain. Other drugs, like antidepressants or sedatives, are also used for pain management in chronic diseases of the musculoskeletal system. [1,12]

Steroids should only be used in phases of pain exacerbation, due to their adverse effects, such as triggering or aggravating osteoporosis. In most cases an intra-articular injection leads to short-term pain relief and may help in bridging phases of increased pain. [1,12]

Chondroprotective substances like hyaluronic acid, other polysaccharides or glycosamines should be integrated in the cartilaginous metabolic processes and should aid in repairing the destroyed joint cartilage. The drugs introduced by intra-articular injection are removed from the joint in a few days, but their effects, are meant to last longer. These substances have analgesic effects, and hyaluronic acid is also meant to have lubricating effects in the joint in question. [1,12]

1.6.5. Surgical Alternatives

In the early stages of osteoarthritis, arthroscopic surgery is a common intervention to reduce pain, to slow down disease progression and modify the damaged joint cartilage. The interventions range from simple joint lavage, to debridement, and to cartilage transplantation. Furthermore, arthroscopies are also used for detailed diagnosis, for example, to assess the level of the destruction of the joint. However,

evidence has shown, that arthroscopy of the knee joint in the elderly with osteoarthritis is only indicated in case of locking and catching due to a meniscal tear or free body in the knee joint [1,11]

An osteotomy can be performed, especially on young patients, with varus or valgus deformity of the leg. These procedures are supposed to reduce the level of pain and delay or even prevent the formation of a severe joint destruction, Therefore, an osteotomy to correct misalignment is not only a way to bridge the time until TKA is indicated; in younger patients it can be seen as an alternative procedure to knee replacement. [1,11,25]

In severe cases, especially in recurring, untreatable infections of the knee joint, or in other cases of massive bone destruction, arthrodesis might be required. In cases of severe trauma or large malignant tumours, a wide resection and possibly an exarticulation are indicated, if there is no possibility of reconstruction using other methods. [11]

1.6.6. Prophylaxis

Many degenerative diseases of the musculoskeletal system are the result of unequal load distribution on the joints. In central Europe, work place guidelines, which should be overseen by occupational physicians, are common. These rules are to protect employees from diseases and injuries caused by their work environment. [12]

Leisure accidents, on the other hand, may also lead to chronic disorders of the musculoskeletal system. Consequently, measures for accident prevention are necessary. [12]

1.7. Preparing for Surgery

1.7.1. Preoperative Examination

Total knee arthroplasty is a planable, elective intervention and therefore, a detailed preoperative review of patient indications, contraindications and possible complications is not only possible, but also necessary. Ideally known pre-existing illnesses should be treated effectively and medication should be adjusted to prevent further risks during and after surgery. Furthermore, the patient should have a realistic understanding about the chances of success and the possible complications. [26]

To assess the preoperative status, the intraoperative risks and the patient's expectations, a thorough anamnesis is necessary. This conversation should also serve as an opportunity to reduce the patient's anxiety and to resolve pending issues. [26]

The preoperative physical examination is used to identify further contraindications, or risk factors. It also assesses the preoperative condition of the joint, including the range of motion. In addition to the knee joint, the skin, peripheral pulses and the neurologic status should also be examined. [26]

Furthermore, a blood test including the most important parameters should be done before every surgery. The most vital tests are the assessment of blood type, haemoglobin and haematocrit, electrolytes and proteins. If the patient suffers from certain diseases, additional tests such as to determine glucose levels or the T3, T4 and TSH levels are necessary. Tests identifying liver and kidney function, as well as blood clotting function and inflammation markers are required to assess the intraoperative risk. [26]

1.7.2. Imaging

Preoperative X-rays are necessary for planning the procedure. They may help to determine bone quality, pre-existing misalignments and the level of joint

destruction. The imaging of the leg should be performed in two planes, anterior-posterior and lateral views. To assess the position of the patella and its degree of osteoarthritis, a tangential X-ray should be carried out. The evaluation of misalignments is only possible in X-rays of the whole leg, and so these should be part of every preoperative examination. [26]

1.7.3. Anaesthesia

The work of the anaesthetist does not start in the operating theatre, but at least one day prior to the operation, during the preoperative examination. This should not only reveal unknown diseases, which can be the cause of intra- or postoperative complications, but should also help in deciding on the type of anaesthesia. Functional testing and apparative diagnostics to determine the risk of anaesthesia complement the physical examination. [27]

Total knee arthroplasty can be performed in general or regional anaesthesia. Both procedures have certain benefits and risks. General anaesthesia can be given to every patient and results in complete analgesia in every patient. A great advantage of the regional anesthesia is the continuation of the patient's spontaneous breathing, but analgesia is not as reliable as the general anaesthetic. [27]

A meta-analysis of the outcomes of total hip arthroplasty and total knee arthroplasty using regional or general anesthesia showed some significant differences. They found a decrease in the operating time using regional anesthesia in the entire group, but there was no significant difference between the two groups for total knee arthroplasty. There was also no significant difference in the need for transfusion and the amount of blood loss for TKA. Furthermore, the meta-analysis showed no substantial differences in thrombo-embolic diseases and post-operative nausea for total knee replacement. [28]

1.8. Surgery

The goal of total knee arthroplasty is to remove the destroyed cartilage and replace the joint surface of the tibia and the femur with metal and polyethylene. If the surface of the patella is replaced as well, it is called a tricompartimental system. During this procedure, preexisting misalignments of the axis of the leg should be corrected. The anterior cruciate ligament has to be removed to make the implantation possible in most designs. In the case of an unstable knee joint, caused by loose ligaments, a hinged prosthesis should be implanted. [29]

Preoperative X-rays should be done to make the planning of the implantation possible. Furthermore, detailed clinical examinations should be performed to assess the range of motion and the stability of the knee joint. The decision on a type of prosthesis should be made based on these findings. [29]

The most frequently used surgical approach is medial parapatellar. After removing adhesions and parts of the Hoffa fat pad, the anterior cruciament ligament, as well as the menisci, are removed. The infrapatellar bursa is opened up and the patella ligament is mobilized up to the upper edge of the tibial tuberositas. This enables the surgeon to luxate the patella to the side, so that the joint surface is accessible. [29] Depending on the preoperative plan and according to the TKA systems, the cutting blocks are fixed and the femur and tibia are cut to hold the prosthesis components. An intramedullary rod in the femur and an extramedullar rod parallel to the tibia, from the ankle to the knee joint, are used for alignment. In most TKA systems there have to be five cuts on the femur and one on the tibia and patella. It is very important to spare the collateral ligaments and the posterior cruciate ligament, using retractors, when cutting the femur and tibia. [29]

One of the most difficult steps in this procedure is the rotation alignment of the femoral component. Furthermore, it has been shown that the alignment deviation of the femoral and tibial components in rotation in patients with early mechanical failures (under 10 years) differs significantly from patients with expected mechanical failure (after 10 years). This has not only been one of the only two

statistically significant findings of a study by Sikorski, but also the most marked mismatch in patients with premature mechanical failure. [30]

Anatomical landmarks and lines are used for proper alignment. The transepicondylar axis, defined as the connection of the femoral epicondyles, is used to measure the rotation of the femoral part of the prosthesis. [30] Whiteside's-Line should be rectangular to the transepicondylar axis and connects the deepest point of the femoral trochlea with the middle of the intercondylary fossa. [29] Whiteside's line is the most consistent anatomical landmark, whereas other references vary to a certain degree. [30] The plane of the posterior part of the femoral condyles has to be considered during femoral resection. The cutting block should be aligned parallel to the transepicondylar line, which should result in a three-degree angle to the plane of the posterior part of the femoral condyles. [29] The alignment of the tibial component is also very important, especially considering the interaction with the patella. The tibial component has to be large enough to sit on the cortical surface of the bone and must not be over-rotated to centralize the patella into the trochlea. [29]

After removing the cartilage and bone according to the cutting blocks, the flexion and extension gaps should be checked. An irregular gap has to be adressed by making a soft tissue release. [29] Although there is no sufficient data on how much tension should be achieved, it is believed that it should be the same around the perimeter of the knee. Too little tension will result in luxation of the knee, whereas too much tension will result in too rapid wear and tear on the components. [30]

Before implantation of the prosthesis, there should always be a trial, using test components. The goal of this test run is to check the range of motion, the stability and the free movement of the kneecap. If the chosen components are sufficient, the prosthesis can be implanted, after scrupulous cleaning of the surface. Once the cement has hardened, the wound can be closed up. [29]

1.8.1. Unconstrained Prosthesis

Unconstrained prostheses replace the surface of the knee joint, without the components being connected. The stability depends on the native ligaments in the knee joint. This is the reason why not only a precise surgical technique is necessary; a prosthesis design that closely resembles human anatomy is indispensable. [26]

Unconstrained prostheses are indicated in cases of bicompartmental or tricompartmental gonarthrosis, when there is no way to maintain the integrity of the knee joint. The collateral ligaments, as well as the posterior cruciate ligament have to be stable to make the implantation of an unconstrained prosthesis possible. [27] A misalignment of the leg should not exceed a varus of 25° or a valgus of 20°. Further contraindications for this type of prosthesis are neuromuscular instability, a genu recurvatum as well as the above-mentioned contraindications for every total knee arthroplasty e.g. acute infections. [27]

In the case of a defect or non-existing PCL, there is the possibility of implanting a posterior-stabilized unconstrained prosthesis. These implants are more constrained and require the removal of the posterior cruciate ligament. A cam on the femoral component engages a tibial polyethylene post, during flexion and therefore stabilizes the posterior edge. Inflammatory arthritis, which can lead to a rupture of the PCL, as well as other PCL deficiencies, is an indication for the posterior-stabilized unconstrained prosthesis. [31]

1.8.2. Constrained Prosthesis

There are two types of constrained prostheses, non-hinged and hinged designs. The non-hinged constrained implants do not have an axle connecting the two components, but have got a large tibial post and a deep femoral box. This leads to a higher rotational and alignment stability. This prosthesis is indicated in cases of lax collateral ligaments or flexion gaps. [31]

Constrained hinged prostheses have a connection between the femoral and tibial components; these are therefore more constrained than the non-hinged designs

and are used for patients who suffer from global ligament deficiency, hyperextension instability, and after wide tumour resections. The great disadvantage of this type of prosthesis is the strain on the prosthesis joint and the interfaces between prosthesis, cement and bone. Furthermore, the requisite wide resection of the bone complicates future revisions. [27,31]

1.8.3. Unicompartmental Prosthesis

Patients who suffer from severe medial or lateral gonarthrosis, which means only half of the knee joint is affected, may benefit from unicompartmental prostheses. Studies have shown, that the failure rates of these implants are not higher than in total knee arthroplasty. Furthermore the range of motion seems to be better in patients who receive unicompartmental knee replacement. [12,32]

1.8.4. Use of Bone Cement

Since the 1970s, the use of polymethyl methacrylate bone cement has constantly increased. About ten years later, in the 1980s, the first non-cemented knee prosthesis were invented, in answer to the high rates of loosening of the cemented prostheses. These first generation cementless implants have shown poor long-term results, which can be traced back to different problems, like the loosening of the patella component or the migration of polyethylene particles. [26] The cemented prostheses seem to have an advantage over the cementless systems, because of the barrier function of cement and the more even force distribution on the tibial component. Although long-term studies showed no significant differences between the cemented and cementless total implants, the use of polymethyl methacrylate bone cement is still the gold standard practice in total knee arthroplasty. [26]

Cemented TKA is a more forgiving procedure than the cementless technique. The implants do not have to be pressed into the bone to provide the necessary stability. Furthermore, the cement compensates for uneven surfaces and its sealing effects lead to less blood loss and therefore, less need of blood transfusions. Despite these benefits, lots of studies have shown that it is possible to achieve excellent results using the cementless technique if a strict patient

selection is carried out, as well as the achievement of a high quality performance during surgery. [33]

1.8.5. Patella Resurfacing

There have been a lot of controversial discussions in the past regarding whether the patella should be replaced during total knee arthroplasty. Different trials have shown that this procedure has the potential for a better surgical outcome and less postoperative anterior knee pain, while on the other hand it is suspected that the resurfacing of the patella could be a possible cause of complications. [34] A major meta-analysis including 1,003 knees, showed no differences in anterior knee pain, with or without the resurfacing of the patella. Furthermore, the group that received a patellar implant showed a significantly better functional outcome, and lower rates of revision surgery. [34]

There are also different types of non-resurfacing techniques, like osteophyte excision, combined with patella denervation. Although single studies suggest that a combination of these two interventions leads to better functional outcome and less pain, a meta-analysis has shown no significant differences between these two groups. [35]

1.8.6. Outcome

Although total knee arthroplasty is a highly effective intervention, there are quite a few possible complications which can occur, either during surgery or postoperatively, which may possibly result in revision surgery. [1,2,36]

Sadoghi et al. performed a systematic review of national arthroplasty registers to determine the factors causing revision surgery after total ankle arthroplasty, total hip arthroplasty and total knee arthroplasty. In total knee arthroplasty, aseptic loosening, septic loosening and pain without other cause led to the majority of corrective interventions, as seen in Figure 4. [37]

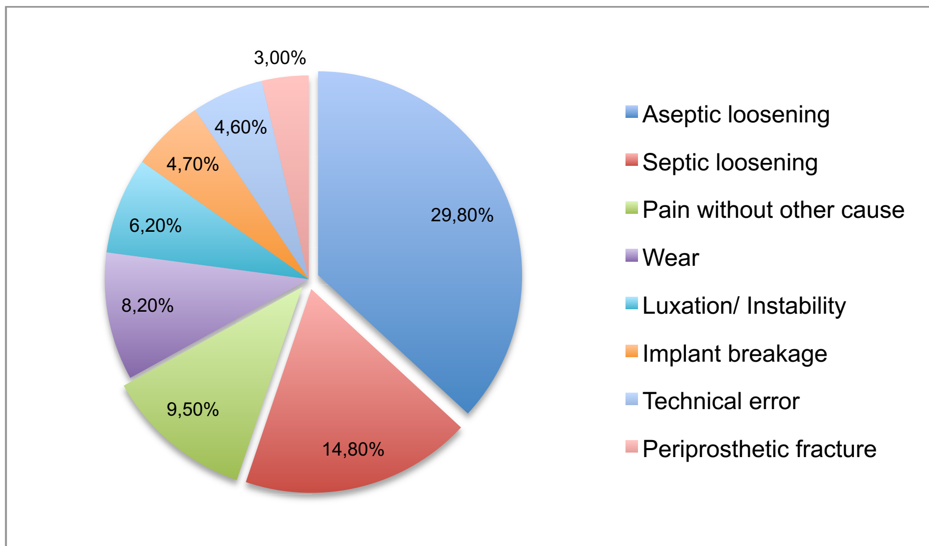

Figure 9: Causes for revision surgery in Total Knee Arthroplasty from 1979 to 2009 [37]

Although it is very convenient to regard revision, the last step for prosthesis survival, as the marker for complications, other factors should be considered. Patients might continue to suffer from pain or physical impairment, without undergoing revision surgery. Up to 20% of complications could be missed, if prosthesis survival were to be used as the only indicator for the postoperative outcome. Therefore, further tests should provide additional information to assess the clinical outcome and especially patient satisfaction. [2]

Furthermore, a procedure that is successful as far as the surgeon is concerned can still result in a dissatisfied patient. Harris et al screened 331 patients and their surgeons after total joint arthroplasty to determine if patients' satisfaction levels differ from that of surgeons. After six months, 94.3% of the surgeons and only 89.7% of the patients where happy with the postoperative outcome. At 12 months 95.3% of the surgeons and 90.3% of the patients were satisfied with the results. [38] The reasons for these differing results might be the patients' expectations on the one hand and the overestimation of satisfaction by the surgeons on the other hand. [36,38]
Even though there is a significant difference in the satisfaction levels of these two groups, overall patient satisfaction after total knee arthroplasty is very high, as shown in many trials. [38]

1.9. Prosthesis Systems

1.9.1. Press-Fit-Condylar Sigma Knee System

The original P.F.C. system was introduced in 1984, but was replaced in 1996 by the P.F.C. Sigma Knee System. This revised prosthesis has a deeper femoral trochlea and a raised lateral epicondylar ridge as well as a rounder femoral condyle. The tibial component was not changed. [39]

Literature

Due to having been on the market for a long time, the P.F.C. system has been the subject of several studies, which show the long-term results after the implantation of this prosthesis system. [39-42]

Schai and his team did a ten-year follow-up on 122 patients (155 knees), who had received the original P.F.C. system, and reported a survival rate of 90%. The majority of revisions had to be performed because of component failure. Schai's group reported no aseptic loosening, three metastatic joint infections, and two revisions for synovectomy. The entire group had mean Knee Society Scores (KSS) of 95 points, functional scores of 84 points and a mean range of movement of 113° flexion and -0.3° extension. [42]

Patil performed a 14-year follow up, including seventy-seven patients who had received the P.F.C. sigma implant for primary total knee arthroplasty. They reported a 97% survivorship, with failure defined as revision due to any reason. The 37 living patients had a mean postoperative Knee Society Score of 84.4 ± 19.4 points and a mean postoperative KS function score of 87.0 ± 24.5 points. The mean range of motion was 115.8° ± 14.7 in flexion. [39]

A team of surgeons in the UK reported mid-term results for 145 patients (155 knees) who had received the P.F.C. Sigma Knee System. With failure defined as revision for any reason, they had a success rate of 99.4%. [41]

Dalury performed a multicentre study to determine the survival rate of the P.F.C. sigma knee arthroplasty, as well as the clinical and radiographic outcome. The minimum follow-up in this study, including 1,512 patients, was five years. They reported a failure rate of 2%, which was defined as the number of patients who needed revision surgery, most of which was due to infections. Dalury estimated a ten-year survival rate of 95.6%. [40]

Technique

For the tibial resection a tibial alignment device is used, with the platform positioned on the condyles and the malleolar clamp directly proximal to the malleoli, while the knee is in maximal flexion. The tibial cutting block is fixed on the device and the tibial stylus is positioned to determine the exact level of resection. [43]

For distal femoral resection, the P.F.C. Sigma Knee System uses an intramedullary rod after entering the medullary canal with a drill. Afterwards a femoral locating device is implanted with the valgus angle and the appropriate left/right designation in place. The femoral alignment is done using an external alignment tower with a rod going from the femoral locating device to the femoral head. A calibrated outrigger is used for rotational correction, which is placed at the femoral trochlea in slight external rotation and fixed at the medial condyle. In the next step the cutting block is placed on the outrigger and fixed with pins to the anterior cortex. The locating device and intramedullary rod can be removed and the femoral condyles can be resected using an oscillating saw. A femoral sizing guide is used for size measurement and rotational alignment and the cutting blocks are positioned so that the anterior, posterior and chamfer cuts can be performed. [43]

In the next step, the trial components can be implanted; with these in place the knee can be extended and the stability is tested. If the chosen parts are satisfactory, they can be removed and the final components can be implanted, after first inserting a punch in the tibia and lug drills in the femur. [43]

1.9.2. ATTUNE

The ATTUNE total knee arthroplasty system was introduced only a few years ago, which is why there are currently no long-term studies, and only a few short- to mid-term studies available.

Literature

Pfitzner et al did a prospective trial in 2012, which included 55 patients under 70 years old, who had been suffering from primary osteoarthritis of the knee. Patients were examined one day before and six months after surgery. After the implantation of the ATTUNE prosthesis joint flexibility improved, by an average of 11.83 ± 0.2°. The mediolateral stability had also improved significantly six months after surgery. Sagittal instability could not be significantly improved by implanting the ATTUNE system. The group believed that these good early postoperative results could be traced back to improvements in the kinematics of this prosthesis and better conformity, especially in mid-flexion. Pfitzner also mentioned that, because inlays were available in gradiations of 1mm and because the instrumentation had been optimized, better stability could be achieved. [44]

Ranawat did a prospective trial, comparing 100 patients who had received the ATTUNE system to 100 patients who had had the P.F.C. total knee arthroplasty. They did follow-up examinations six weeks, one year and two years after surgery, with a mean follow-up of 1.9 years. After two years they reported no significant differences in pain or function scores between the ATTUNE and the P.F.C. groups. Patients in the ATTUNE group suffered from significant less anterior knee pain and less crepitation than those in the P.F.C. group. The postoperative range of motion showed no difference between the two groups. Patients in both groups had similar satisfaction scores, but significantly more people who had received the P.F.C. prosthesis felt emotionally affected by their implant. [45]

Technique

The ATTUNE knee system uses a tibial jig, (see Figure 10) for tibial alignment and resection; this enables the surgeon to adjust the tibial posterior slope using an

uprod. An ankle clamp is placed over the malleoli and the cutting block is positioned over the tibial condyles and the varus/ valgus adjustment is performed. A tibial stylus is attached to the cutting block to set the level of resection. [4]

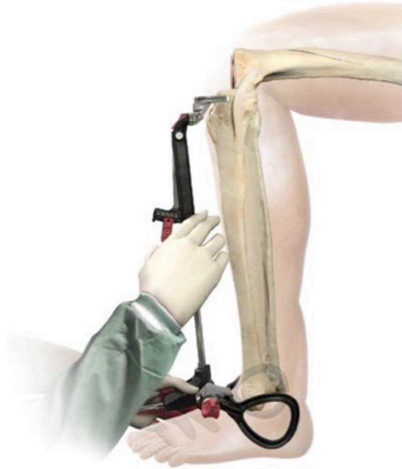

Figure 10: Use of the tibial jig (ATTUNE)[4]

The ATTUNE knee system uses a femoral jig, (see Figure 11) for the distal femoral resection, combining an intramedullary rod, an outrigger and a distal femoral cutting block. Before the rod can be inserted, the desired resection depth and valgus angle has to be set. After insertion, the cutting block should be fixed using non-headed pins. In the next step, the distal femoral jig can be removed and the distal femur can be resected. [4]

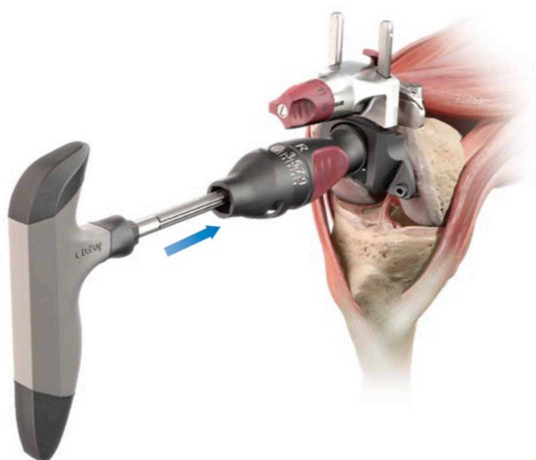

Figure 11: Distal femoral jig (ATTUNE)[4]

After resecting the femur, a spacer block is used for assessing the extension and flexion gap as well as balancing. Depending on the surgeon’s preference, the femoral rotation can be set in two different ways. It can be done using anatomical landmarks and the measured sizer, or by soft tissue balancing using the balanced sizer, both illustrated in Figure 12. [4]

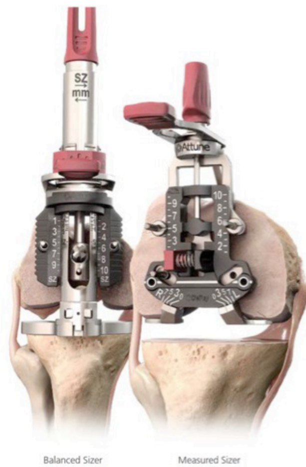

Figure 12: Measured and balanced sizers[4]

The A/P and chamfer cuts are done using cutting blocks and an oscillating saw. In the next step the trial components are placed and the tibial surface is prepared with a keel punch and femoral lug holes are drilled, so that the final components can be implanted. [4]

1.10. Complications in TKA

1.10.1. Venous Thromboembolism

Postoperative venous thromboembolism (VTE) not only causes longer hospital stays, but also hospital costs that are ten times higher than for patients without VTE. Furthermore, pulmonary embolism, as a result of VTE, still has mortality rates of 19.49%. Identifying the risk factors is an important part of prevention. Age, malignant tumours, cardiac insufficiency, adipositas, immobilization or smoking are some of the most important risk factors causing VTE. [14,46]

Different studies have identified demographic factors, like age, gender and the BMI as risk factors for VTE after total knee arthroplasty. In patients aged seventy and older, the risk rises significantly. Two papers reported that females are at greater risk than males after total knee replacement. [46] The patient’s BMI has been identified as a risk factor in TKA and THA, with patients who have a BMI of over 30 being at greater risk of getting VTE. Furthermore, one study identified that Caucasians have a lower risk than people of negroid descent. [46]

Whether the risk of VTE associated with the underlying diagnosis is not clear. Whilst one paper identified rheumatoid arthritis as a risk factor, others described RA as a protective factor for venous thromboembolic diseases. [46] Furthermore, cardiovascular, respiratory and neurological diseases were not linked to a higher likelihood of suffering from VTE after TKA. Metabolic syndrome, on the other hand, has been identified in two papers as a risk factor for venous thromboembolic diseases. [46] Although malignant tumors have been examined as a potential risk factor, no one has been able to establish a link between malignancy and VTE after total knee replacement. [46]

Bilateral surgery, cemented fixation and a surgery duration longer than two hours have all been proven as risk factors for VTE after total knee replacement. Table 5 gives an overview of the risk factors mentioned, as well as of the controversial and protective factors, as identified in a meta-analysis by Zhang. They stated that if a minimum of three papers came to the same conclusions, the results could be

defined as definite risk or protective factors, otherwise they would be considered controversial. [46]

Risk factors	
	TKA (vs. THA)
	Older age
	Female sex
	Higher BMI
	Bilateral surgery
	Cemented fixation
	Surgery time > 2 hours
Controversial factors	
	Diabetes mellitus
	Malignancy
	General anesthesia
	VTE history
	Varicose vein
	Hypertension
	Hormone replacement
Protective factors	
	Chemoprophylaxis
	Enoxaparin (vs. other LMWH)
	Direct F-Xa inhibitor (vs. LMWH)
	Earlier mobilization

Table 5: Risk factors, controversial factors and protective factors for VTE after TKA[46]

1.10.2. Infections

Periprosthetic joint infections are feared complications of total knee arthroplasties. They can result in further complications that lead to prolonged suffering, long hospital stays, high costs and even death. Consequently, primary prevention of

infections should play a major role in total knee arthroplasty. Any patient-related risk-factors which may be influenced should be first revealed and then reduced before surgery. Smoking, adipositas, a BMI of over 30, diabetes, depression, use of steroids and frailty are associated with joint infections. [47]

1.10.3. Aseptic Loosening

Aseptic loosening is the main reason for revision surgeries of total knee arthroplasties, accounting for 29.80% of prosthetic failures in TKA. [37] The cause of this complication has not yet been identified, but there are different theories. It is believed that a pro-inflammatory state is triggered by excess-wear particles, which leads to osteolysis and loosening of the prosthesis. [37,48]

Different factors seem to have an influence on the development of aseptic loosening. In addition to surgery- and prosthesis-related factors, there are patient-related risk factors, which may increase the possibility of developing prosthetic loosening. [48] In total hip arthroplasty, being male and having high activity levels have been identified as risk factors for aseptic loosening, whereas having a high BMI and smoking have not been confirmed. In TKA, no significant patient-related risk factors could be identified. [48]

1.10.4. Fat Embolism

Fat embolism, the intravasation of fat particles from the bone marrow, is a rather rare complication. It has been reported as a complication in fractures of the long bones and total joint replacement of the lower extremity. The increased intramedullary pressure during instrumentation, seems to be the cause for the intrusion of fat particles and blockage of the blood vessels. [49] Although serious systemic manifestations of fat embolism are quite rare, in up to 65% of TKA patients the intravasation of fat globules could be detected. As there is no specific test for fat embolism, a combination of criteria must be considered for diagnosis, as detailed in Table 6. [49]

Major criteria	
	Petechia
	Respiratory insufficiency
	Cerebral signs
Minor criteria	
	Tachycardia (>120 bpm)
	Fever
	Retinal signs
	Jaundice
	Renal insufficiency
Laboratory findings	
	Thrombocytopenia
	Anemia
	High erythrocyte sedimentation rate
	Fat macroglobulinemia

Table 6: Gurd's criteria for the diagnosis of Fat Embolism Syndrome [49]

Although the severity of the Fat Embolism Syndrome can vary, the combination of three major criteria is highly suspect in relation to the existence of a serious systemic fat embolism. Upper body petechia, respiratory insufficiency and pathological neurological signs are the major diagnostic criteria, which can be combined with further symptoms. Laboratory findings like thrombocytopenia and a high erythrocyte sedimentation rate can help in confirming the diagnosis. [49]

1.10.5. Blood Loss

Orthopedic surgery accounts for up to 10% of all transfused red blood cell units; it is thus the surgical field with the most frequent need for transfusions. The average blood loss in primary total knee arthroplasty is about 1,500 ml, which can lead to a haemoglobin drop of 3g/dl. [50]

There are several strategies to reduce the need for transfusions and the number of associated adverse events. Tranexamic acid (TXA), which can be administered orally, intravenously or topically, has shown its potential for reducing blood loss and blood transfusions in many trials. [50] The use of a tourniquet is a widespread treatment for reducing blood loss. Nevertheless, multiple studies have shown that tourniquets do not reduce this complication at all, but lead instead to an increase in blood loss and a rise in postoperative pain. In the early post-operative stage, even the flexion is reduced in patients who have undergone surgery in which a tourniquet was used. [50]

Another method for reducing blood loss is a fibrin sealant, which achieves local hemostasis. Although some studies show other results, fibrin sealants seem to be an effective and safe method to reduce blood loss. [50] Nevertheless, the effects of tranexamic acid exceed those of fibrin sealants. Because of the comparatively reduced effectiveness and their high costs, fibrin should not be used for hemostasis in total joint replacement and should be replaced by tranexamic acid. [50]

1.10.6. Other Complications

Nerve damage during total knee arthroplasty can be a result of direct or indirect injury. Peroneal nerve palsy is a rare complication, which can result in devastating problems. A complication rate of up to 1.3% has been described in broad studies; the frequency might in fact be greater because of the existence of subclinical nerve damage. [51] Deformities, contractures and rheumatoid arthritis are patient-related risk factors that can contribute to the development of peroneal nerve palsy. Constrictive dressings and haematoma are surgery-related risk factors which can lead to nerve damage. Although only 50% of the patients with peroneal nerve palsy enjoy a complete recovery, patients generally have a good functional outcome. [51]

The frequency of patellofemoral instabilities varies significantly in different trials. Excessive wear, loosening of the retropatellar component, patella fractures and maltracking cause patellofemoral problems after total knee arthroplasty. Balancing

and soft-tissue release are highly important in preventing maltracking of the patella. Further risk factors include misalignments, prosthesis design and mispositioning of the prosthesis. Because the isolated patella revision has a bad clinical outcome, a correction of the components or distal reorienting surgeries, such as the transposition of the tibial tuberosity, should be preferred. [52]

Vascular damage is a rare complication, however, with possibly devastating consequences. It can lead to neurologic problems, compartment syndrome and infections which can lead to further complications, such as amputation or even death. [53] Several mechanisms have been described as a cause of vascular injuries. Indirect trauma, thrombosis, thermal injury, mechanical stretching and compression are the most common sources of vascular damage during total knee arthroplasty. A high BMI, pre-existing diseases and vascular calcifications could not be identified as risk factors, but females seem to have a greater risk of vascular complications. Although, vascular injuries have the potential for devastating consequences, most patients experience only postoperative stiffness, if treated in time. [53]

Due to longer life expectancies, the higher frequency of total knee arthroplasties and the rise in pre-existing diseases, the frequency of periprosthetic fractures has also increased in recent years. [54] Osteoporosis, rheumatic diseases, old age and being female are general risk factors for periprosthetic fractures. Intrinsic local factors, such as femoral notching, flexion deficit of over 90°, or misalignments could also increase the probability of fractures after total knee arthroplasty. [54] The aim of treating periprosthetic fractures should be the achievement of osseous stability, early mobilization and pain release. Depending on the stability of the prosthesis, the treatment can be performed either by repositioning and osteosynthesis, or by changing the prosthesis or components. [54]

Misalignment after total knee arthroplasty is another factor contributing to patient dissatisfaction. Coronal alignment is regarded as being very important in securing a good clinical outcome. [55] Nevertheless, in 64% of the studies reviewed by Hadi et al, there was no link between misalignment and a bad outcome. In sagittal alignment, no study has shown a significant correlation between misalignment and

the postoperative outcome. Half of the studies examined showed that a worse axial alignment led to worse outcome parameters. [55]

1.11. Postoperative Care

The postoperative phase should lead to early mobilization and reduction of patient's stay in hospital. Therefore, an interdisciplinary and comprehensive aftercare system should be installed. Physiotherapy is an important part of post-surgery care and should start on post-operative day 0. Studies have shown that early postoperative treatment and mobilization leads to shorter hospital stays and better pain scores. [56]

Wound infections lead to further complications, which in turn cause patient suffering and necessitate additional treatments and interventions. [56] Wound care starts as early as the beginning of the surgery, because a shorter period of tourniquet application, a periarticular local anesthesia and the subvastus approach lead to less wound oozing. [56] There are many different types of wound dressings available, but studies have shown that the use of modern and traditional wound dressings has any significant influence on the length of hospital stay. [56]

An effective post-operative pain management system is also important, as severe pain not only makes for dissatisfied patients, but also leads to longer recovery times and delays in mobility and thus hospital discharge. [57] Local infiltrations during surgery help to reduce pain, especially in the acute postoperative period, and therefore help to achieve early mobilization and hospital discharge. Studies have shown that periarticular injections lead to lower pain scores, a decrease in narcotic use and therefore fewer adverse effects. [57] The main advantage of regional anaesthesia is the continuous administration of anaesthetics, especially after surgery. The combination of a sensory and a motor blockade does have some disadvantages, such as a higher risk of falling. New methods of pain control, e.g. cryoneurolysis, are continually being introduced. [57]

2. Section 2: Clinical Study

2.1. Hypothesis

Although total knee arthroplasty is a highly effective treatment for severe osteoarthritis and other degenerative joint diseases, up to 20% of patients continue to be dissatisfied with the results. Persistent pain or functional limitations after surgery indicate the necessity for ongoing research in order to develop improvements in total knee replacement. [1,2]

The ATTUNE system was designed to improve the implantation of the prostheses by simplifying the balancing of the flexion gap and the size measurements. This has been accomplished by inventing a single instrument to carry out both steps simultaneousley. [3,4]

The hypothesis of this prospective controlled trial was that the biomechanical modifications in the ATTUNE total knee arthroplasty system lead to a better clinical outcome in patients.

2.2. Methods

2.2.1. Trial

We performed a prospective controlled randomized clinical trial to determine advantages of the ATTUNE Total Knee Arthroplasty over the Press Fit Condylar System. All procedures were performed at the Department of Orthopedic Surgery at the Medical University of Graz, carried out or assisted by Patrick Sadoghi, MD PhD. The implantations were performed identically in both groups. The tibia first method and the balancing of the flexion gap were carried out using the medial approach. Each prosthesis was implanted using cement and a rotating platform inlay.

2.2.2. Patients

Two hundred patients took part in the trial; they were assigned to two groups of equal size, i.e. 100 patients in the P.F.C. group and 100 patients in the ATTUNE group. All the patients had been suffering from severe osteoarthritis of the knee confirmed by X-ray, high levels of pain in at least two knee compartments and, finally, reduced joint function. All patients participated voluntarily in this trial. Patients under 60 were not included in the study, nor were patients suffering from varus- or valgus- misalignments of more than 15°.

2.2.3. Methods

We performed several examinations of our patients at different intervals. A range of scoring systems was used, all of which have long been in use in clinical studies. First of all we determined the preoperative status. Seven days after surgery we performed our first postoperative examination, with further follow-up testing after six weeks and again after six months. Testing will be continued one, two and five years after surgery.

To determine the level of pain a Visual Analog Scale (zero meant no pain, while ten represented the worst imaginable pain) was used.

The active Range of Motion was determined to quantify the patients' physical impairment. Together with pain, a loss of mobility is one of the main reasons patients seek help when suffering from osteoarthritis.

We used the Western Ontario and McMaster Universities Osteoarthritis Index to assess pain, disability and joint stiffness in our patients. We created a questionnaire, divided into four sections. Patients were asked about symptoms such as swelling, blockage, and mobility and how often these had occurred in the previous week, with the scope being from "never" to "always".
Secondly, joint stiffness was evaluated, both in the morning and during the course of the day. Furthermore, patients were asked how often and during which activities they had experienced pain in the previous week. Lastly, patients were asked if they were experiencing difficulties in their daily routine, e.g. using stairs, walking

and getting in or out of a car. The values of the WOMAC score range from 0 (worst case), to 100 (best case).

The Knee Society Score is divided into two sections, pain and function, which are in turn further subdivided. The evaluation of pain, range of motion and stability is part of the KSS pain score, which is reduced by the presence of flexion contractures. The KSS function score consists of two criteria, walking and climbing stairs, and is reduced if the patients need walking aids.

2.3. Results

2.3.1. Biometric data

The biometric data from the ATTUNE and P.F.C. patients was compared (Table 7), to ensure an equal starting position in both groups and prevent a distortion of the results. The mean age of patients in the ATTUNE group was 71.2 years with a standard deviation of 7.8 years. In the P.F.C. group patients were slightly younger, with a mean age of 69.3 years (± 8.7 years). The further analysis of these two groups showed no significant difference. Both groups consisted of 100 patients, 63 in each group being female. The mean BMI in the ATTUNE group was 28.8 (± 4.7) and 29.4 (± 4.8) in the P.F.C. group, again showing no significant difference.

	ATTUNE (n=100)	**P.F.C.** (n=100)	p-Value
Sex (m/w)	37/63	37/63	not significant
Age (mean score ± SD)	71.2 ± 7.8	69.3 ± 8.7	not significant
BMI (mean score ± SD)	28.8 ± 4.7	29.4 ± 4.8	not significant

Table 7: Biometric data in the ATTUNE and P.F.C. group

2.3.2. Level of pain

The preoperative levels of pain, as shown in Table 8, were nearly identical. The mean value was 6.7 (± 2.1) in patients who had received the ATTUNE arthroplasty and 6.8 (± 1.9) in the P.F.C. group. Seven days after surgery, there was a very significant drop in the pain level, with 3.8 points on the visual analog scale. Over the next weeks and months the values dropped constantly (see Figure 13). At six weeks after surgery, patients in the ATTUNE group had slightly lower VAS scores (2.2 ± 1.6) than patients who had received the P.F.C. sigma prosthesis. Nevertheless, the difference in mean pain levels between both groups of patients was not significant six weeks after surgery, or at any other time that the patients were screened. After six months, patients' mean pain scores stood at 1.7 points, with a standard deviation of ± 1.0 in the ATTUNE and ± 1.3 in the P.F.C. group.

	ATTUNE (n=100)	**P.F.C.** (n=100)	p-Value
preop (mean score ± SD)	6.7 ± 2.1	6.8 ± 1.9	not significant
7 d po (mean score ± SD)	3.8 ± 2.2	3.8 ± 2.1	not significant
6 w po (mean score ± SD)	2.2 ± 1.6	2.5 ± 1.5	not significant
6 m po (mean score ± SD)	1.7 ± 1.0	1.7 ± 1.3	not significant

Table 8: Level of pain in ATTUNE and P.F.C. groups, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

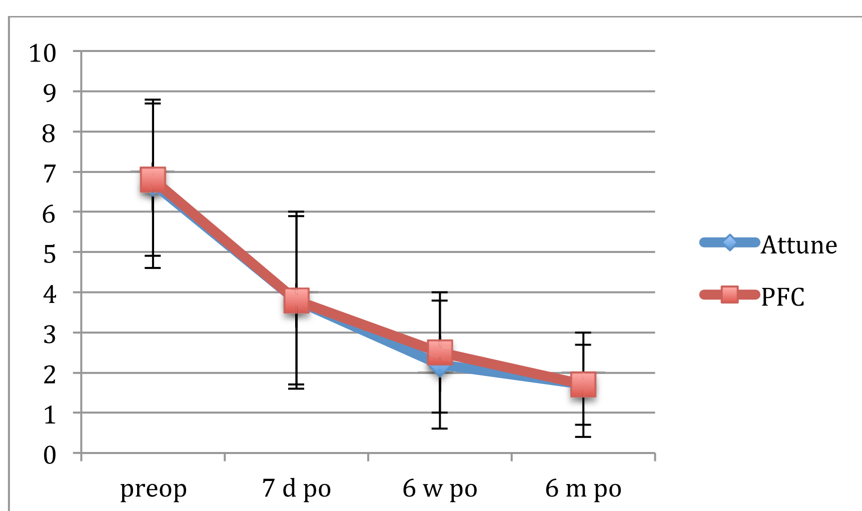

Figure 13: The course of pain levels in the ATTUNE and P.F.C. group, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

2.3.3. Active Range of Motion

The preoperative active range of motion, as listed in Table 9, was better in patients who received the P.F.C. sigma knee prosthesis, but the difference between the groups was not significant. In the short-term, i.e. seven days after surgery, the scores in both patient groups worsened. Figure 14 shows that after this initial drop in the range of motion, the values improve significantly over the next weeks. After six weeks, the mean value in the ATTUNE group was 107.7° (± 16.9°), and 106.5° (± 12.7°) in the P.F.C. group, which meant an improvement in both groups, as compared to their initial preoperative situation. The mean values improved continuously and reached 114.4° (± 13.4°) (ATTUNE patients) and 115.8° (±

14.3°) (P.F.C. patients), after six months. Although the mean range of motion is higher at different times in different groups, a significant difference between the ATTUNE and the P.F.C. system could not be determined.

	ATTUNE (n=100)	**P.F.C.** (n=100)	p-Value
preop (mean score ± SD)	94.9 ± 21.4	96.1 ± 17.3	not significant
7 d po (mean score ± SD)	84.3 ± 13.1	84.1 ± 11.5	not significant
6 w po (mean score ± SD)	107.7 ± 16.9	106.5 ± 12.7	not significant
6 m po (mean score ± SD)	114.4 ± 13.4	115.8 ± 14.3	not significant

Table 9: Active range of motion in ATTUNE and P.F.C. groups, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

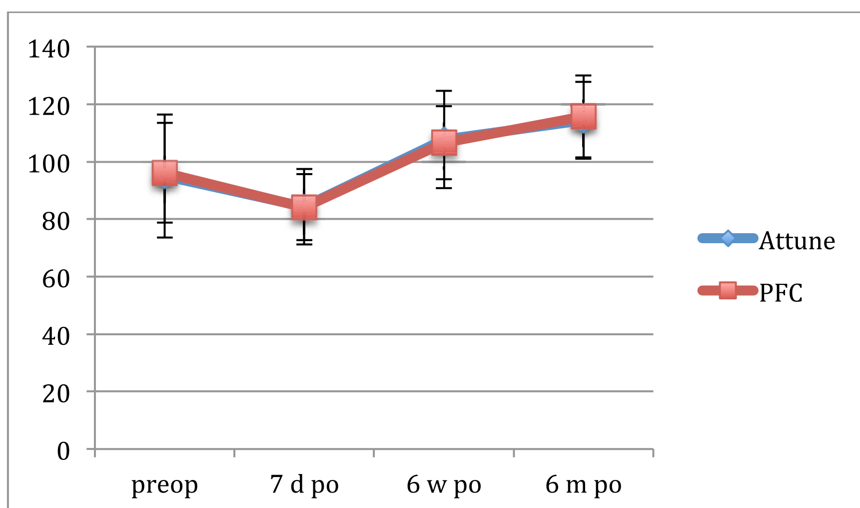

Figure 14: The course of active range of motion in the ATTUNE and P.F.C. group, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

2.3.4. Western Ontario and McMaster Universities Osteoarthritis Index

The WOMAC score values for both groups (see Table 10) showed no significant differences in the preoperative phase. Seven days after surgery, the mean score had already improved, with higher values in patients who had received the ATTUNE knee arthroplasty, although not significantly better than in the P.F.C. group. Figure 15 shows the continual improvement in the WOMAC score after surgery. The ATTUNE group continues to have slightly better results over the

period of 6 months, with a significantly better score, 83.1 (± 13.0) after six weeks compared to the P.F.C. group, 78.1 (± 12.1).

	ATTUNE (n=100)	**P.F.C.** (n=100)	p-Value
preop (mean score ± SD)	53.3 ± 14.8	53.6 ± 15.2	not significant
7 d po (mean score ± SD)	68.7 ± 13.9	65.2 ± 12.5	not significant
6 w po (mean score ± SD)	83.1 ± 13.0	78.1 ± 12.1	p=0.02
6 m po (mean score ± SD)	89.5 ± 13.0	84.9 ± 12.1	not significant

Table 10: Mean WOMAC scores in ATTUNE and P.F.C. groups, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

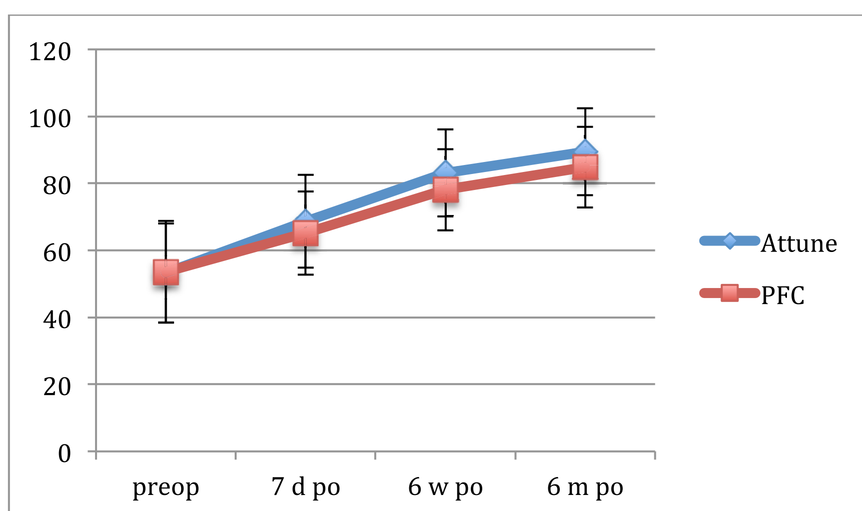

Figure 15: The course of WOMAC scores in the ATTUNE and P.F.C. group, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

2.3.5. Knee Society Score - Pain Section

The KSS preoperative pain section showed no significant differences between patients who had received the P.F.C. arthroplasty and those who had received the ATTUNE system. The mean values in both groups improved in the early postoperative phase. Patients in the ATTUNE group had mean scores of 66.2 (± 15.8) after seven days and 81.1 (±15.9) six weeks after surgery. This upward trend, (see Figure 16) was also present in the P.F.C. group, but not as pronounced. Patients with the P.F.C. prosthesis had a mean KSS pain score of

64.4 (± 15.2) after seven days and 79.6 (± 14.8) after six weeks. Nevertheless, the differences between the groups were not significant and were nearly identical six months after surgery.

	ATTUNE (n=100)	**P.F.C.** (n=100)	p-Value
preop (mean score ± SD)	52.8 ± 15.1	52.0 ± 13.2	not significant
7 d po (mean score ± SD)	66.2 ± 15.8	64.4 ± 15.2	not significant
6 w po (mean score ± SD)	81.1 ± 15.9	79.6 ± 14.8	not significant
6 m po (mean score ± SD)	85.9 ± 15.7	85.5 ± 17.5	not significant

Table 11: KSS pain scores in ATTUNE and P.F.C. groups, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

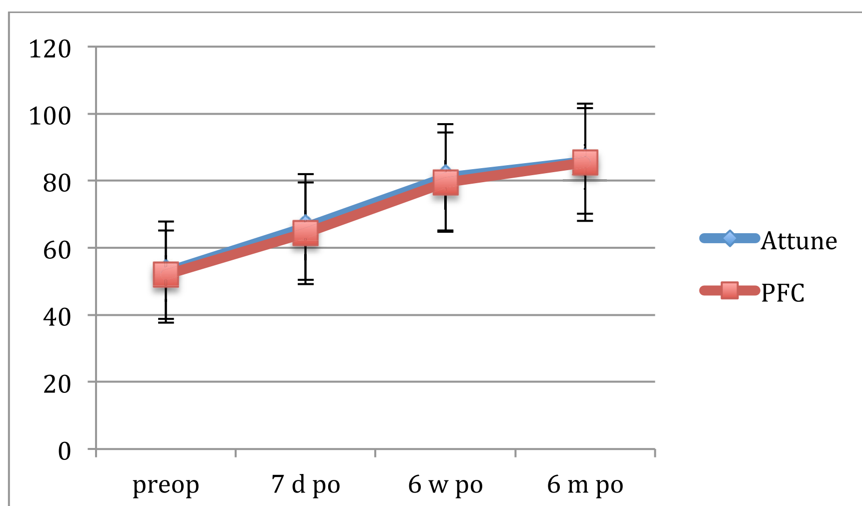

Figure 16: The course of KSS pain scores in the ATTUNE and P.F.C. group, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

2.3.6. Knee Society Score - Functional Section

Patients in the P.F.C. group had a mean preoperative KSS function score of 41.9 (± 14.1), whereas patients who had received the ATTUNE arthroplasty achieved mean scores of 42.9 (± 13.8). Seven days after surgery, the values dropped, followed by an improvement after six weeks, which is shown in Figure 17. Although patients in the P.F.C. group had better score values both after six weeks (52.6 ± 22.9) and after six months (86.7 ± 15.1), as compared to patients in the

ATTUNE group (50.2 ± 19.4 and 74.0 ± 18.3), the findings reveal no significant difference.

	ATTUNE (n=100)	**P.F.C.** (n=100)	p-Value
preop (mean score ± SD)	42.9 ± 13.8	41.9 ± 14.1	not significant
7 d po (mean score ± SD)	24.5 ± 9.3	24.3 ± 7.4	not significant
6 w po (mean score ± SD)	50.2 ± 19.4	52.6 ± 22.9	not significant
6 m po (mean score ± SD)	74.0 ± 18.3	86.7 ± 15.1	not significant

Table 12: KSS function score in ATTUNE and P.F.C. groups, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

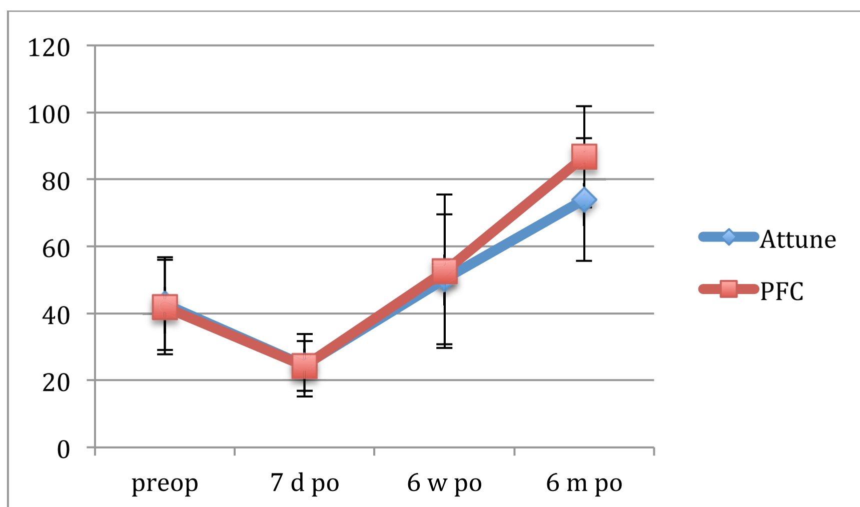

Figure 17: The course of KSS function scores in the ATTUNE and P.F.C. group, preoperative (preop), 7 days postoperative (7 d po), 6 weeks postoperative (6 w po), 6 months postoperative (6 m po)

2.4. Discussion

The aim of this study was to analyze differences in surgical outcome between the Press Fit Condylar Sigma total knee arthroplasty and the ATTUNE system. The hypothesis was that biomedical changes in the ATTUNE prosthesis lead to a better clinical outcome.

The biometric data in both groups was very similar. The majority of the patients was female, which also matches the gender distribution in cases of osteoarthritis of the knee. The age distribution, as well as the mean BMI score, concurs with the distributions in similar trials. [39,45,58]

The preoperative levels of pain were very similar in both patient groups, with a mean value of 6.7 ± 2.1 (ATTUNE) and 6.8 ± 1.9 (P.F.C.). Seven days after surgery we reported an immediate and significant improvement in both groups with a mean level of pain of 3.8 (± 2.2/ ± 2.1). These values continued to improve, so that patients reported very low levels of pain after 6 months. The active ROM was lower one week after surgery, but improved in the course of our follow-up. The mean improvement in both groups, from the preoperative active Range of Motion to the six month survey, was over 19°, which makes the performance of daily tasks significantly easier for the patients.

Ranawat et al performed a trial over two years, comparing 200 patients who had received the P.F.C. or ATTUNE system. Their patients had similar preoperative KS pain scores. They reported a mean value of 52.4 ± 15.1 in the ATTUNE group and 50.2 ± 15.0 in the P.F.C. Sigma group. A follow-up after two years showed that those mean scores had improved to 92.4 ± 9.5 in the ATTUNE group and 92.8 ± 7.8 in the P.F.C. group. [45] At this point in time, we can only report the data of our 6-month follow-up, but we already have excellent results in both groups: mean scores of 85.9 ± 15.7 for ATTUNE patients and 85.5 ± 17.5 for P.F.C. patients.

Patients in Ranawat's trial had better preoperative Knee Society function scores than those in our trial. Ranawat reported a mean score of 52.3 ± 15.9 in the ATTUNE group and 49.9 ± 14.8 in the P.F.C. group. Two years postoperatively

they reported a mean value of 89.3 ± 14.8 (ATTUNE) and 89.4 ± 11.4 (P.F.C.), which is an excellent result. [45] After six months we reported Knee Society function scores of 74.0 ± 18.3 for patients in the ATTUNE group and 86.7 ± 15.1 for patients in the P.F.C. group. These results can be considered good to excellent.

With regard to the postoperative level of pain, active range of motion and KSS, we found no significant differences between the ATTUNE and the P.F.C. arthroplasty after six months of follow-up. Ranawat et al also came to the conclusion that there were no significant differences between the two groups. [45] We did find a significant difference in the WOMAC scores six weeks after surgery. Patients in the ATTUNE group had constantly better WOMAC values over the postoperative period of six months, although we only found significantly different results from six weeks after surgery. This difference seems to be only of statistical significance and is therefore not clinically relevant.

New prostheses are introduced on the market every year, but there is still a lack of randomized controlled trials comparing different brands of prosthesis. [58] Most trials compare different types of arthroplasty systems. [59] Because of the large number of new inventions and the lack of studies, it is difficult to place our findings in perspective to other new introduced total knee arthroplasty systems.

Pennington et al. did an analysis of the five most frequently used brands of prostheses in the United Kingdom in 2012. They compared the costs, clinical outcomes and revision rates of the P.F.C. Sigma, AGC Biomet, Nexgen, Genesis 2 and Triathlon prosthesis systems. The Nexgen and P.F.C. Sigma total knee arthroplasties reported the lowest revision rates and the AGC Biomet system was the least costly brand. [58]

In 2012 the P.F.C. Sigma system accounted for 36% (27,613 in total) of the performed total knee arthroplasties in the UK, whereas in less than 1% (92 in total) of the procedures the ATTUNE cruciate retaining system and in only four cases the ATTUNE posterior stabilized system were used. [60] In 2015 the ATTUNE cruciate retaining system already accounted for 2% (1,767 in total) and the

ATTUNE posterior stabilized system for 1% (881 in total) of the total knee arthroplasties performed in the UK. The P.F.C. Sigma total knee arthroplasty was used for 27,797 (32%) total knee replacements in 2015. [61]

We will continue to assess our patients over the following years, in order to evaluate mid- and long- term results of the ATTUNE total knee arthroplasty. A PubMed search, using the term “total knee arthroplasty AND attune” reveals the lack of studies regarding this new knee prosthesis system, with only three findings (24.11.2016). One biomechanical study examined the tibial revision knee arthroplasty using the ATTUNE revision implant in AORI type 2a defects. [62] Another study compared the trochlear compartment geometry of six recent TKA systems, including the ATTUNE prosthesis. [63] Only one clinical study reviewed the post-surgical outcome of the ATTUNE total knee arthroplasty over a period of two years. [45]

The main limitation of our study was the short observation time of six months after surgery. Therefore, we will continue our trial and encourage further studies to determine the long-term results of the ATTUNE total knee arthroplasty system. [9]

2.5. Conclusions

Based on the statistical analysis of our findings, we conclude that there are no significant differences between the ATTUNE and the P.F.C. arthroplasty system regarding postoperative pain and function scores. Only the WOMAC score showed a statistically significant difference after six weeks. Although we were not able to find significant advantages of one prosthesis system, we did accomplish good to excellent results with both systems. This leads us to the conclusion, that the ATTUNE system is as good as the P.F.C. Sigma system in the short-term period.

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Appendix

Informed Consent Form

Wir möchten Sie einladen, an oben benannter Studie teilzunehmen. Diese klinische Studie wurde von der zuständigen Ethikkommission der Medizinischen Universität Graz geprüft und befürwortet.

Klinische Studien sind notwendig, um verlässliche neue medizinische Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer klinischen Studie ist jedoch, dass Sie daran teilnehmen möchten und Ihr Einverständnis schriftlich erklären. Bitte lesen Sie den folgenden Text als Ergänzung zum Informationsgespräch mit Ihrem Arzt sorgfältig durch und zögern Sie nicht, Fragen zu stellen.

Worum geht es bei dieser klinischen Studie:

Arthrose ist eine der häufigsten Erkrankungen des mittleren und höheren Lebensalters. Arthrose verursacht Schmerz und Immobilität der Erkrankten sowie hohe Kosten durch teure und langwierige Behandlung, Krankenstände, Frühpensionen und Operationen.

Ziel dieser Studie ist es zu klären, wie zufrieden Sie als unser(e) PatientIn nach Implantation Ihrer Knietotalendoprothese sind. Die Zufriedenheit und die Genesung werden mittels eines Fragebogens erhoben (vor der Operation und am 7. Tag nach der Operation). Bei der ambulanten Routineuntersuchung erfolgt abschließend eine letzte Fragebogenerhebung über ihren Gesundheitszustand.

Die Weitergabe der Daten erfolgt ausschließlich zu statistischen Zwecken, wobei Sie ausnahmslos anonym bleiben. Auch in etwaigen Veröffentlichungen der Daten dieser klinischen Studie werden Sie nicht namentlich erwähnt.

Mit herzlichen Grüßen,

____________________________ ____________________________

OA Dr. Norbert Kastner PatientIn

In Vertretung: Sandra Eminovics, BSc

Patient Questionnaire

VAS

Wie würden Sie ihre Schmerzen im Moment einschätzen:

1	2	3	4	5	6	7	8	9	10

keine vorstellbare Schmerzen **stärkste Schmerz en**

WOMAC

Symptome

Diese Fragen beziehen sich auf Beschwerden von Seiten Ihres Kniegelenkes in der **vergangenen Woche**.

S1. Haben Sie Schwellungen an Ihrem Knie?

niemals	selten	manchmal	oft	immer
☐	☐	☐	☐	☐

S2. Fühlen Sie manchmal ein Mahlen, hören Sie manchmal ein Klicken oder irgendein Geräusch, wenn Sie Ihr Knie bewegen?

niemals	selten	manchmal	oft	immer
☐	☐	☐	☐	☐

S3. Bleibt Ihr Knie manchmal hängen, oder blockiert es, wenn Sie es bewegen?

niemals	selten	manchmal	oft	immer
☐	☐	☐	☐	☐

S4. Können Sie Ihr Knie ganz ausstrecken?

immer	oft	manchmal	selten	nie
☐	☐	☐	☐	☐

S5. Können Sie Ihr Knie ganz beugen?

immer	oft	manchmal	selten	nie
☐	☐	☐	☐	☐

Steifigkeit

Die nachfolgenden Fragen betreffen die Steifigkeit Ihres Kniegelenkes während der **letzten Woche**. Unter Steifigkeit versteht man ein Gefühl der Einschränkung oder Verlangsamung der Fähigkeit Ihr Kniegelenk zu bewegen.

Für jede der nachfolgenden Aktivitäten sollen Sie das Ausmaß der Schwierigkeiten angeben, welche Sie durch Ihr Kniegelenk innerhalb der letzten Woche erfahren haben.

S6. Wie stark ist Ihre Kniesteifigkeit morgens direkt nach dem Aufstehen?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

S7. Wie stark ist Ihre Kniesteifigkeit nach dem Sie saßen, lagen, oder sich ausruhten im **Verlauf des Tages**?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

Schmerzen

P1. Wie oft tut Ihnen Ihr Knie weh?

niemals	monatlich	wöchentlich	täglich	immer
☐	☐	☐	☐	☐

Wie ausgeprägt waren Ihre Schmerzen in der **vergangenen Woche** als Sie z.B:

P2. sich im Knie drehten?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

P3. Ihr Knie ganz ausstreckten?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

P4. Ihr Knie ganz beugten?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

P5. auf ebenem Boden gingen?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

P6. Treppen herauf oder heruntergingen?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

P7. nachts im Bett lagen?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

P8. saßen oder lagen, z.B. auf der Couch?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

P9. aufrecht standen?

keine	schwach	mäßig	stark	sehr stark
☐	☐	☐	☐	☐

Aktivitäten des täglichen Lebens

Die nachfolgenden Fragen beziehen sich auf Ihre körperliche Leistungsfähigkeit. Hierunter verstehen wir Ihre Fähigkeit sich selbständig zu bewegen bzw. sich selbst zu versorgen.
Für jede der nachfolgenden Aktivitäten sollen Sie das Ausmaß der Schwierigkeiten angeben, welche Sie durch Ihr Kniegelenk innerhalb der **letzten Woche** erfahren haben.

Welche Schwierigkeiten hatten Sie **letzte Woche** als Sie z.B.:

A1. Treppen herunterstiegen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A2. Treppen heraufstiegen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A3. vom Sitzen aufstanden?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A4. standen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A5. sich bückten um z.B. etwas vom Boden aufzuheben?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A6. auf ebenen Boden gingen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A7. ins Auto ein- oder ausstiegen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A8. einkaufen gingen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A9. Strümpfe/Socken anzogen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A10. vom Bett aufstanden?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A11. Strümpfe/Socken auszogen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A12. im Bett lagen und sich drehten, ohne das Knie dabei zu beugen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A13. in oder aus der Badewanne kamen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A14. saßen?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A15. sich auf die Toilette setzten oder aufstanden?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A16. schwere Hausarbeit verrichteten (schrubben, Garten umgraben, ...)?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐

A17. leichte Hausarbeit verrichteten (Staub wischen, kochen, ...)?

keine	wenig	einige	große	sehr große
☐	☐	☐	☐	☐