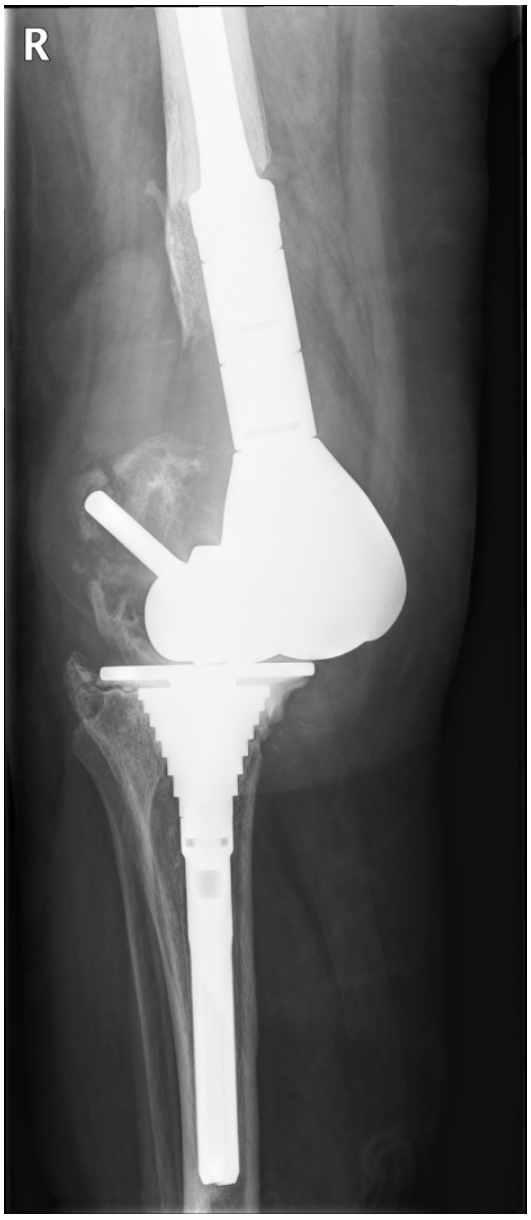

EVALUATION OF STABILITY OF ROTATING HINGE KNEE PROSTHESES

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Diplomarbeit

EVALUATION OF STABILITY OF ROTATING HINGE KNEE PROSTHESES

eingereicht von

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unter der Anleitung von

ao.Univ. Prof. Dr. Andreas Leithner

Graz, Datum …….. (Unterschrift)

Eidesstattliche Erklärung

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TABLE OF CONTENTS

ABBREVIATIONS

0	Cured
ACL	Anterior cruciate ligament
ANOVA	Analysis of variance
AORI	Anderson Orthopaedic Research Institutes
APSTAB	Anteroposterior Stability
APSTAB	Anteroposterior Stability
BMI	Body Mass Index
CCK	Constrained Condylar Knee
CI	Confidence interval
cirr.	Cirrcumference
cm	Centimeter
CM	Custom made
CT	Computertomography
CTx	Chemotherapy
deg.	Degree
DOD	Death of disease
DOOC	Death of other cause
e.g.	For example
EBB	Extracortical bone bridging
et al.	Et alii
ext.	Extension
flex.	Flexion
FU	Follow-up
GMRS™	Global Modular Replacement System
HMRS	Howmedica Modular Resection System/ Howmedica Modular Replacement System
IBG	Impaction bone grafting
IJD	Inflammatory joint disease
KMFTR	Kotz Modular Femur and Tibia Reconstruction System
KRH	Kinematic Rotating Hinge
KSS	Knee Society Score

lat.	Lateral
LCL	Lateral collateral ligament
LEAP	Lewis Expandable Adjustable Prosthesis
LPS™	Limb Preservation System
M.B.T.	Mobile-bearing Tibial Revision Tray
MCL	Medial collateral ligament
med.	Medial
MHz	Megahertz
MLSTAB	Mediolateral Stability
MLSTAB	Mediolateral Stability
mm	Millimeter
MRH	Modular Rotating Hinge
MRI	Magnetic resonance imaging
MRS	Modular Replacement System
MSTS	Musculoskeletal Tumor Society
n/a	Not applicable
NED	No evidence of disease
NIDJD	Noninflammatory degenerative joint disease
OSS™	Orthopedic Salvage System
PCL	Posterior cruciate ligament
PE	Polyethylene
RHK	Rotating Hinge Knee
ROM	Range of motion
TKA	Total knee arthroplasty
UHMWPE	Ultra-high molecular weight polyethylene
UICC	Union Internationale Contre le Cancer
vs.	Versus
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
yrs.	Years

1. ABSTRACT

1.1 English

Introduction: Rotating hinge knee prostheses are fully constrained with three degrees of motional freedom (flexion-extension, internal-external rotation and distraction). They are used for reconstruction of the knee in cases of severe articular compromise and major bone loss. The main indications are revision surgeries and reconstructions following distal femoral or proximal tibial tumor resections. The aim of this study was to examine the stability of various rotating hinge knee prostheses.

Materials and Methods: We performed a biomechanical analysis of three different prosthesis designs (Limb Preservation System-LPS^{TM}/M.B.T. (DePuy), S-ROM Noiles (DePuy) and Global Modular Resection System-GMRS^{TM} (Stryker)) to establish the association between the design of the central rotational stem (length and taper) and the implant´s stability “in vitro”. Therefore we used a self-constructed biomechanical apparatus on a test bench in the laboratory. Additionally, we retrospectively evaluated short- and mid-term results of LPS^{TM}/M.B.T. and S-ROM Noiles rotating hinge knee replacement after primary implantation, wide resection of malignancies or revision total knee arthroplasty, including three questionnaires, clinical examination, ultrasound and plain radiographs.

Results: The measurements with the biomechanical apparatus resulted that the GMRS^{TM} device was superior to the LPS^{TM}/M.B.T. and S-ROM Noiles implant design concerning stability and maximum amount of distraction before implant’s dislocation (38 mm vs. 27 mm vs. 26 mm). Clinical and radiographic evaluation showed that the S-ROM Noiles knee had better results for medial and lateral lift-off than the LPS^{TM} /M.B.T. design, although the more tapered central rotational stem. Only the distraction was higher in patients with the S-ROM Noiles rotating hinge knee. Overall, statistical analysis revealed that there were no significant differences in clinical and functional outcome between the tested devices. Differences in implant survival were also insignificant, neither between the groups nor between the implants.

Discussion: Rotating hinge knee prostheses with a short and markedly tapered central rotational stem seem to have the highest instability/angular laxity at any given amount of distraction. On the other hand, testing the stability of the LPS^{TM}/M.B.T. and S-ROM Noiles in vivo showed no significant differences between the implants. Despite the assimilable results, we recommend prosthetic designs with a long, cylindrical central rotational stem, especially in patients with severe compromised knees.

1.2 German

Einleitung: Rotating Hinge Knietotalendoprothesen sind achsgeführte Prothesen mit einer Bewegungsmöglichkeit in drei Ebenen (Flexion-Extension, Innen- und Außenrotation und Distraktion). Dieser Prothesentyp wird zur Rekonstruktion stark destruierter Kniegelenke oder nach großem Knochenverlust eingesetzt. Die häufigsten Indikationen sind Revisionsoperationen des Kniegelenks, sowie Tumorresektionen des distalen Femurs oder der proximalen Tibia. Das Ziel der Studie war die Stabilitätstestung ausgewählter Rotating Hinge Prothesen, welche an unserer Abteilung verwendet wurden.

Material und Methoden: Wir führten mit drei verschiedenen Prothesendesigns (LPS^{TM}/M.B.T. (DePuy), S-ROM Noiles (DePuy) und GMRS^{TM} (Stryker)) eine biomechanische Analyse „in vitro“ durch, um den Zusammenhang zwischen der Form des zentralen Rotationszapfens (Länge und Verjüngung) und der Stabilität der Prothesen zu demonstrieren. Zu diesem Zwecke verwendeten wir einen selbstkonstruierten biomechanischen Apparat. Zusätzlich wurde eine retrospektive Analyse der kurzzeitigen und der mittelfristigen Ergebnisse des endoprothetischen Gelenkersatzes mittels LPS^{TM}/M.B.T. und S-ROM Noiles rotating hinge Knietotalendoprothesen durchgeführt. Diese Prothesen wurden für Primärimplantation, zur Rekonstruktion nach weiter Resektion maligner Tumore und für Revisionsoperationen verwendet. Mittels klinischer Untersuchung, verschiedener bildgebender Verfahren (Röntgen und Ultraschall) und dreier Fragebögen wurden die entsprechenden Daten erhoben.

Ergebnisse: Die Messungen mit dem biomechanischen Apparat ergaben, dass das GMRS^{TM} System dem LPS^{TM} /M.B.T. und dem S-ROM Noiles Implantat bezüglich Stabilität und maximaler Distraktion bis hin zur Dislokation (38 mm vs. 27 mm vs. 26 mm) überlegen ist. Die klinischen und die radiologischen Untersuchungen, bei denen die mediale und laterale Aufklappbarkeit des Gelenks getestet wurden, ergaben im Vergleich zu dem LPS^{TM} /M.B.T. Knie bessere Resultate für das S-ROM Noiles Implantat, trotz des sich verjüngenden zentralen Rotationszapfens. Dennoch war die gemessene Distraktion in den Patienten mit einer S-ROM Noiles Knieprothese höher. Die statistische Auswertung zeigte keine

signifikanten Unterschiede zwischen den beiden Knieprothesen, weder für die klinischen noch für die funktionellen Ergebnisse. Ebenfalls nicht signifikant waren die Differenzen im ereignisfreien Überleben der Implantate, einerseits zwischen den Gruppen und andererseits zwischen den Implantaten.

Diskussion: Rotating Hinge Knieprothesen mit einem kurzen und sich deutlich verjüngenden zentralen Rotationszapfen scheinen die geringste Stabilität bei jeglicher Distraktion an den Tag zu legen. Andererseits zeigte die Stabilitätstestung am Patienten, dass es keine nennenswerten Unterschiede zwischen den beiden getesteten Implantaten gibt. Trotz der vergleichbaren Ergebnisse, empfehlen wir die Verwendung von Prothesendesigns mit einem langen und sich nicht verjüngenden zentralen Rotationszapfen, speziell in Fällen stark destruierter Kniegelenke.

2. GENERAL PART

2.1 Introduction

The knee joint consists of two articulations, tibio-femoral and patella-femoral, which provide motion in the sagittal plane (flexion and extension), internal and external rotation along a vertical axis and varus-valgus angulation in the frontal plane (Fig.1). The articular cartilage, the menisci, ligaments and muscles around the knee are subjected to dissipate substantial stresses, which occur during daily activities. Thus, appropriate coordination of joint laxity and stability is essential for the function of the knee. Stability and well balanced laxity are even the basic requirements for any total knee arthroplasty.

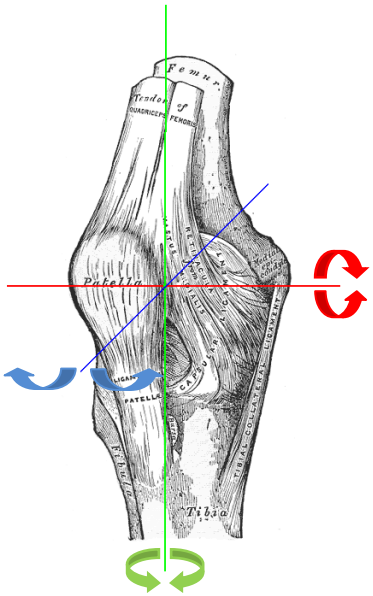


Fig.1: Knee joint and axis of movement (red: horizontal axis, green: vertical axis, blue: sagittal axis) [from www.athletic-preparation.com].

During extension, distraction is resisted by the hamstrings, the neurovascular structures and the skin while throughout flexion, distraction is only prevented by the extensor mechanism. If the intrinsic soft tissue stability of the knee got lost as a result of multiple revision procedures or in cases of major bone loss with sacrifice of all joint ligaments, laxity in flexion and extension increases and may result in a flexion gap imbalance. Therefore, instability can only be prevented by using constrained, semi-constrained or hinged prostheses. Large bone defects can be managed with modular prostheses, metal augments, structural allograft and megaprostheses.

2.1.1 History of hinged prosthesis

The first totally constrained knee prostheses, including WALLDIUS (introduced in 1951; also known as MARK I-IV after several modifications), SHIERS (first implanted in 1953), STANMORE and GUEPAR (both introduced in 1969), were truly fixed hinge prostheses with a metal-on-metal articulation (Fig.2) [1-5]. This first generation of hinged prostheses allowed movement only in the sagittal plane (flexion and extension). There was no possibility of axial rotation, varus-valgus angulation or distraction, resulting in excessive forces transmitted to the bone-cement-prosthesis interface. As a result, high rates of complications occurred [6-12]. Indications for this kind of prostheses were reconstruction after minimal bone loss, osteoarthritis, severely deformed and unstable knees or cases of rheumatoid arthritis. The reported short term results (1-3 years) were good regarding pain, stability and range of motion (ROM) [4, 7, 13-15], on the other hand the mid- and long-term results of these devices were unsatisfactory because of high rates of component loosening, deep prosthetic infection, femoral shaft fracture, particulate wear debris, subsidence and stem fracture [2, 5, 7, 12, 15-29].

Conversely, Böhm and Holy reported their satisfying results with the BLAUTH hinged total knee replacement (introduced in 1972, modified in 1984; Fig.2) over a 20-year period [21]. Four-hundred-twenty-two arthroplasties were performed in 330 patients. The long term survival of the prosthesis showed excellent results with a cumulative rate of infection of 6,4%. Aseptic loosening occurred in three patients 16, 119 and 150 months after implantation [21].

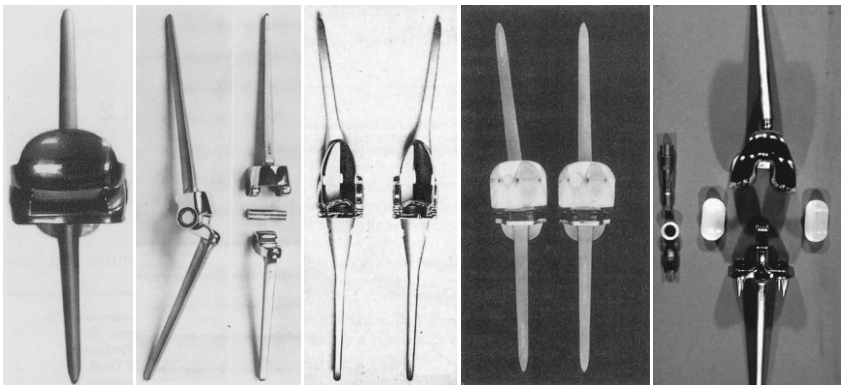


Fig.2: First generation of hinged prostheses: MARK IV, SHIERS, STANMORE, GUEPAR and BLAUTH (from Manning et al.; Revision Total Knee Arthroplasty, 219-236).

In the early 1970s the poor results of the first-generation hinged prostheses became apparent and the prostheses designers attempted to combine the

concepts of hinged and unconnected surface prostheses [7, 30]. These less constrained second generation implants, including the SHEEHAN (introduced in 1971), HERBERT (first described in 1973) and ATTENBOROUGH prostheses (introduced in 1974, modified 1977), should decrease the stresses transferred to the bone-cement-prosthesis interface (Fig.3). Furthermore the longevity should be improved. Therefore some modifications at the design were made, including varus-valgus motion and modest axial rotation of the hinge [7, 31].

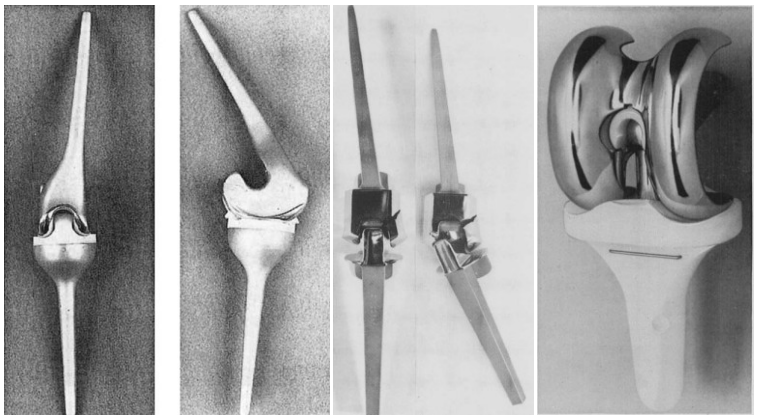


Fig.3: The SHEEHAN, HERBERT and ATTENBOROUGH prostheses (from Manning et al.; Revision Total Knee Arthroplasty, 219-236).

The SPHEROCENTRIC prosthesis (introduced in 1973) grounded the basic principles for modern linked prostheses designs. This prosthesis had an intrinsically stable non hinged ball-in-socket design and therefore the prosthesis allowed tri-axial rotation [7, 31]. Translation and following dislocation were not possible in any direction [6, 20]. The latest second generation designs were the NOILES knee (introduced in the late 1970s) and the KINEMATIC rotating hinge device (introduced in 1979, since 1988 available as modular prosthesis) (Fig.4). Although the short term results of all designs were promising (relating pain, range of motion and function) [5-7, 20, 24, 27, 30, 32], the mid- and long-term results deteriorated [7, 24, 27, 31, 33]. Infection, component fatigue failure and loosening were the most common complications. Rand et al. concluded that the results with the KINEMATIC RHK “were not better than those with non-rotating hinge implants” [24, 31, 34]. Overall the second generation was a clinical improvement over the first generation of hinged implants, nevertheless high failure rates and numerous complications continued.

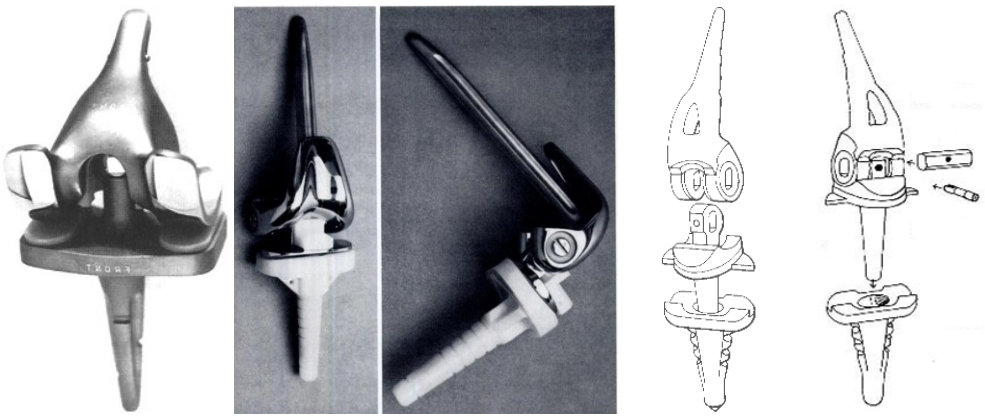


Fig.4: SPHEROCENTRIC prosthesis, KINEMATIC rotating hinge and the schemas of the NOILES total knee device (from Manning et al.; Revision Total Knee Arthroplasty, 219-236).

The third generation of modular rotating hinge knee devices underwent several modifications in comparison to the first and second generation implants. The first designs were the FINN RHK (introduced in 1989) and the S-ROM Noiles RHK (developed from its precursor the Noiles hinged knee, introduced in 1992). The latest modern hinge devices are the NEXGEN RHK (introduced in 2002) and the Howmedica Modular Resection System (HMRS; first implanted in 1990; development of the Kotz Modular Femur and Tibia Reconstruction System [KMFTR]; Fig.5).

Fig.5: FINN Knee, S-ROM Noiles, NEXGEN and HMRS (from www.depuy.de, www.zimmergermany.de).

The introduction of modular, anatomical sized “off the shelf” components allows intraoperative customization of osseous resection lengths and easier revision of failed prostheses [34, 35]. The incorporated rotating hinge mechanism addresses complications like loosening or particular wear debris [28, 36, 37]. The bearing surface between the congruent femoral and tibial components consists of ultra-high molecular weight polyethylene (UHMWPE), to avoid metal-on-metal articulation and particular wear debris [25, 27, 28, 31, 38, 39]. Furthermore, there is surface contact throughout total range of motion which leads to the distribution of weight bearing forces through the femoral condyles (Fig.6a&b) [7, 8, 25, 27, 31,

38-44]. Restoration of the original joint line prevents problems like low-riding or high-riding patella with consecutive limited total range of motion [45]. Therefore several sizes of the femoral component, distal augments and a variation of thickness of the polyethylene inlays can be used [5]. A deepened patellar tracking groove prevents dislocation but patellar tendon reconstruction is often very difficult, especially when the proximal tibia device is used [44, 46]. In such cases the patellar tendon is usually tied to the prosthetic component and sewn to the medial gastrocnemius flap, which is in continuity with the tibial periosteum (Fig.6c) [29, 39, 46-52]. Rotational alignment is also important for proper patellar tracking, to avoid any gait disturbance and aseptic loosening [31, 35, 53]. Rotating hinge knee prostheses do not tolerate malaligment, leading to early complications like loosening due to high forces transmitted to the fixation interface [5, 31, 35]. The manufacture and utilization of “super-alloys”, for example cobalt-chrome-molybdenum or titanium, resulted in better durability of the implants. Intramedullary stem fixation can be carried out with cement or with press-fit fixation (porous coating surfaces) [31]. The third generation modular, mobile bearing prostheses produced good results in the short-term and mid-term [5, 8, 25, 27, 31, 37, 38, 41-43, 53-55]. Additional follow-ups are necessary to evaluate the long-term success of these implants. Survivorship experiences following megaprosthetic implantation were reported in tumor patients but there is a lack of outcome regarding megaprosthetic reconstruction for non-neoplastic-related etiologies [5, 37, 41].

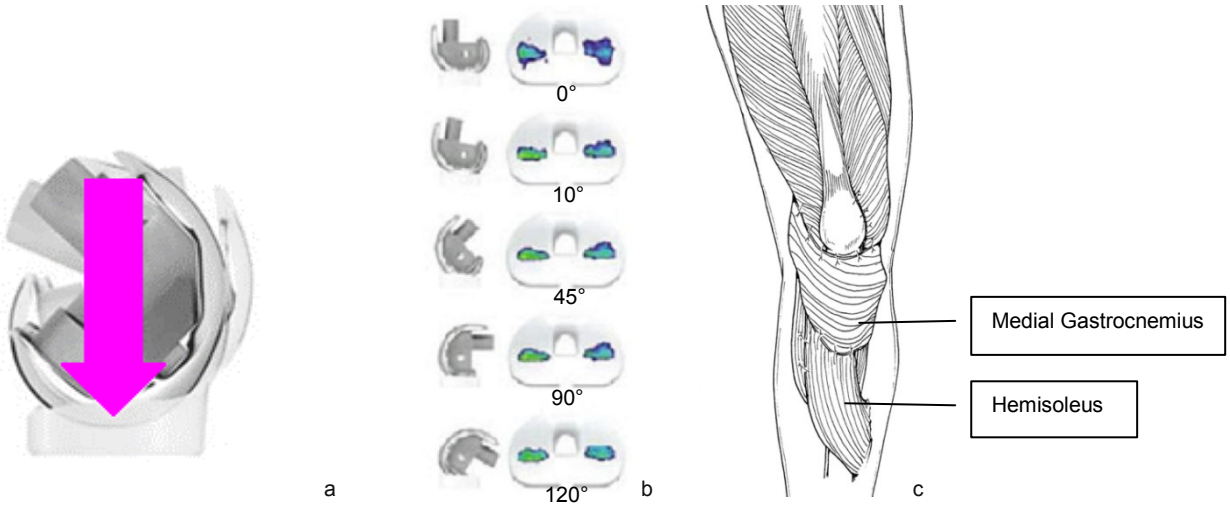


Fig.6a&b: Weight-bearing forces transferred through the femoral condyles throughout total range of motion (from www.zimmergermany.de). Fig.6c shows a technique for soft tissue coverage of the prosthesis with a medial gastrocnemius and a hemisoleus flap. The reattached patella tendon is presented additionally (from Chim et al.; Ann Plast Surg 2007;59:398-403).

2.1.2 Indications for Rotating Hinge Knee prostheses today

The surgical goals of limb salvage surgery for tumoral and non-neoplastic indications are a stable fixation of the prostheses to the host bone and joint line restoration to achieve a stable range of motion consistent with the patient's daily activities. To accomplish these goals prostheses with least degree of constraint should be used because the soft tissues should participate in load transfer. Increased prosthetic constraint, decreases the load sharing properties of soft tissues and therefore increased stress is transferred to the bone-cement-prosthesis interface with the facility of implant loosening [28, 34, 42, 53-57].
The implant selection should be based on the massiveness of bone loss, the status of ligaments and the soft-tissue stabilizing structures [5, 7, 35, 53, 58]. In cases of global insufficiency or complete loss of all joint ligaments (medial collateral ligament-MCL, lateral collateral ligament-LCL, anterior cruciate ligament-ACL, posterior cruciate ligament-PCL), the increasing constraint from a posterior stabilized prosthesis to a non-linked constrained, hinged or rotating hinge device is required [5, 12, 27, 35, 47, 55]. In cases of gross segmental bone loss, modular prostheses or allograft-prosthesis composites are used for reconstruction [47, 59].

Today the indications for rotating hinge knee prostheses are diversified [5, 7, 31, 41, 45, 47, 53, 56, 60]:

- tumor resection in the distal femur and/or the proximal tibia
- multiple revision procedures of the knee after failed previous TKA
- ligamentous incompetence (clinical absence of all major ligaments)
- inflammatory (IJD) or non-inflammatory degenerative joint disease (NIDJD)
- extreme varus or valgus deformity combined with serve flexion contracture
- cases in which less-constrained devices failed
- uncorrectable flexion-extension gap imbalance resulting in cam dislocation of an unlinked design
- periprothetic fracture of the distal femur or nonunion after bone fracture
- serve trauma with extensive bone loss
- possibility of rapid rehabilitation (treatment option for the elderly, low-demand patient with limited life expectancy)

Example: The Usage of RHKs for treatment of periprothetic fractures

Open reduction and internal fixation using screw plates or blade-plate devices, femoral locking plates or retrograde intramedullary nails have been described as an appropriate treatment for distal femoral fractures [61]. Nevertheless complications like infection, fixation failure or nonunion are more likely to occur using these techniques. If it's not possible to preserve fractured fragments with their attached collateral ligaments, hinged or rotating hinge knee prostheses seem to be an alternative treatment because these devices allow restoration of a stable limb and early mobilization [61, 62].
Keenan et al. reported about the treatment of supracondylar femoral fractures above total knee prostheses with custom made rotating hinge prosthesis. At an average follow up of twelve months, six of seven patients had good or excellent results measured by the Bristol Knee Score [63]. Davila et al. also reported their satisfying results in treatment of persistent supracondylar femoral nonunions in two patients treated with megaprostheses (Kinematic RHK) [64]. Berend et al. reviewed 37 patients with distal femoral reconstruction using the Biomet Orthopedic Salvage System (OSS^{TM}) for non-tumor cases. Thirteen knees were reconstructed due to periprosthetic fracture and one due to distal femoral nonunion [41]. Park et al. concluded that endoprosthetic replacement is a reliable method of reconstruction for pathological fractured isolated bone metastases [62]. All authors recommend prosthetic replacement because it allows immediate full weight bearing, early mobilization and shows a good functional outcome [41, 42, 61-65].

Disadvantages of rotating hinge knee prostheses are limited revision options and a difficult reattachment of the patellar tendon, especially when proximal tibia replacement components are used. If rotating hinge prostheses fail, revision surgeries are challenging procedures, because the only possibilities are the reinsertion of another rotating hinge knee, an allograft-prosthesis composite, arthrodesis or amputation.

2.1.2.1 Anderson Orthopaedic Research Institutes classification (AORI)

In revision arthroplasty the loss of bone is graded intraoperatively after removal of prior implanted components and debridement of all necrotic and osteolytic areas. In these cases the Anderson Orthopaedic Research Institutes classification (AORI) is used [7]. The bone loss is graded for the femur and the tibia separately. It is a progressive scale reaching from one up to three (Tab.1, Fig.7).

Each grade describes the bone deficit and the status of the collateral ligaments. For each AORI grade, several methods for bone reconstruction are recommended. Type I defects have an intact metaphyseal bone and can be reconstructed with autologous bone graft, particulate graft, cement and primary knee implants. Type II defects have moderately deficient metaphyseal bone and need to be reconstructed with revision knee implants and augments, wedges or structural grafts. Type III defects have severely deficient metaphyseal bone and are often associated with compromised collateral ligaments. Therefore, allografts and long-stemmed revision implants, custom implants or modular tumor prostheses are required for reconstruction [7, 38, 66].

AORI Femur Grade	Deficit	MCL/LCL	Bone Reconstruction
F 1	Intact Metaphyseal bone	Intact	Cement or Particulate Graft
F 2a	Metaphyseal Loss-**Single** Condyle	Intact	Cement or Metal Augment
F 2b	Metaphyseal Loss-**Both** Condyles	Intact	Cement, Metal Augment or Structural Graft
F3	Deficient Metaphysis	Compromised	Structural Allograft or Segmental Replacement

AORI Tibial Grade	Deficit	MCL/LCL	Bone Reconstruction
T 1	Intact metaphyseal bone	Intact	Cement or Particulate Graft
T 2a	Metaphyseal Loss-Med **or** Lat Plateau	Intact	Cement or Metal Augment
T 2b	Metaphyseal Loss-Med **and** Lat Plateau	Intact	Cement, Metal Augment or Structural Graft
T 3	Deficient Metaphysis	Compromised	Structural Allograft or Segmental Replacement

Tab.1: Anderson Orthopaedic Research Institutes classification (AORI) for femoral and tibial bone loss, according to Manning et al..

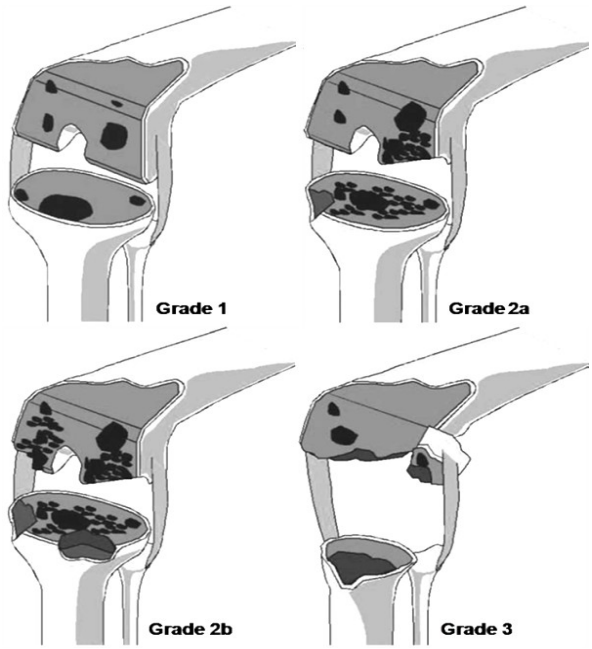


Fig.7: Anderson Orthopaedic Research Institute classification (AORI). Grade 1 deficit has intact metaphyseal bone, Grade 2a deficit involves metaphyseal bone of only one condyle or plateau, Grade 2b deficit involves metaphyseal bone of either condyles or plateaus. A Grade 3 deficit has massive cavitary defects with severe metaphyseal bone loss (from Baumann et al.; Clin Orthop Relat Res (2009) 467:818–824).

2.1.2.2 Enneking surgical staging system

In 1980, Enneking et al. described a staging system for musculoskeletal neoplasms (Tab.2) [67, 68]. This staging system contains three planes of tumor assessment: surgical grade (G), surgical site (T) and regional or distant metastases (M). For surgical planning, the neoplasms are divided into two grades- low grade and high grade. Low grade lesions can be managed conservatively, while high grade lesions require more aggressive treatment to achieve local control. The surgical grade describes the overall biologic aggressiveness of a tumor and indicates what kind of surgical margin is appropriate. The anatomic extent (T_1 or T_2) indicates how the surgical procedure/surgical margin can be achieved. Therefore the expansion of the neoplasm is divided into two stages- intracompartmental (A) or extracompartmental (B). The presence or absence of metastases (M_0 or M_1) indicates the failure of local control and the chances for prolonged survival.

Stage	Grade	Site
I A	Low	Intracompartmental (T_1)
I B	Low	Extracompartmental (T_2)
II A	High	Intracompartmental (T_1)
II B	High	Extracompartmental (T_2)
III A	Low or High, metastases	Intracompartmental (T_1)
III B	Low or High, metastases	Extracompartmental (T_2)

Tab.2: Enneking staging system for musculoskeletal neoplasms.

Assumptions for the use of the Enneking staging system are a total preoperative work-up containing several imaging procedures like MRI and CT scan, radioisotope scans and biopsy for histopathological diagnosis.

Enneking described four surgical margins with regard to the Surgical Staging System (SSS) and the intended surgical procedure additionally. An intralesional margin (e.g. incisional biopsy) describes the piecemeal excision of a neoplasm. Macroscopic and microscopic tumor tissue is left in the surgical area and there is contamination of all exposed tissue planes. If a neoplasm is removed in one piece, a marginal excision is achieved (e.g. excisional biopsy). The dissection plane runs along the peripheric tumor (pseudo)capsule or reactive tissue and has to be confirmed histologically. The removal of a malignant tumor with a continuous cover of healthy tissue is called wide resection [8, 69]. The dissection planes involve only one compartment. A radical procedure is achieved, if the whole compartment including tumor, capsule, reactive zone and involved muscles and/or bone is removed as one block (Fig.8).

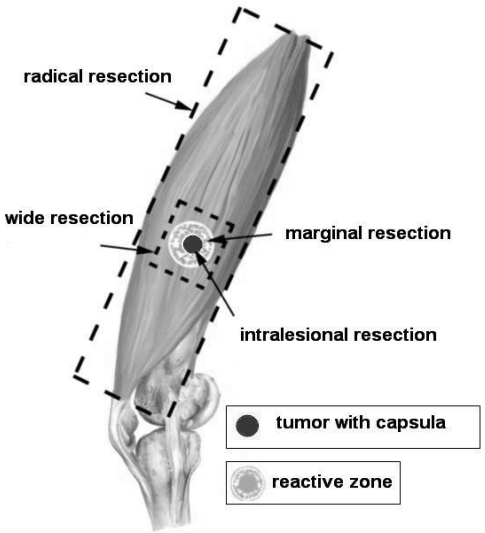


Fig.8: Surgical margins for benign (intralesional, marginal) and malignant (wide or radical) soft tissue neoplasms according to Enneking (from www.med.uni-marburg.de).

2.1.2.3 Loss of ligaments (non-linked constrained vs. rotating hinge devices)

Non-linked constraint devices are modificated total condylar-III knee prostheses. The UHMWPE with an intercondylar post allows some degrees of rotation, smooth medial-lateral translation and limited varus-valgus angulation [47, 58]. Constrained prostheses are used in patients with varus-valgus instability or flexion gap imbalance (risk of posterior dislocation) [45, 47, 58]. If a posterior stabilized

prosthesis does not provide enough stability, non-linked constrained devices or rotating hinge prostheses are options for treatment, but there are still dissensions about the indications of each design [41, 47, 53, 56, 70].

Non-linked constrained knee designs have a changing center of rotation during flexion and thereby less tangential anterior-posterior stress is transferred across the prosthetic interface. Such devices are more rotationally constrained than RHK and therefore greater rotational forces are transferred to the fixation interface. If non-linked constrained knee designs are insufficient to provide enough stability in cases of varus-valgus instability or flexion-extension gap imbalance, soft tissue reconstruction combined with implantation of a posterior stabilized- or a non-linked constrained prosthesis are options for treatment. Furthermore rotating hinge knee designs are used for complex arthroplasty or revision surgery in cases of global ligamentous insufficiency combined with massive bone loss [5, 42, 45, 47, 55, 70].

Walker and Manktelow performed a mechanical testing of constrained condylar knees (CCK) and rotating hinge devices [58]. Cyclic loads were applied to the prostheses and at the end of the test the angulation of the femoral component on the tibial component was measured. After 10 million cycles of loading, which produced combined forces and moments, there was minimal varus-valgus laxity for the rotating hinge devices, while the CCKs reached higher varus laxity. One tested rotating hinge device (Commercial B) showed small deformations on the bearing surfaces while the plastic posts of the CCKs showed permanent bending and deformation. The authors concluded that deformation of the polyethylene increases by time and that CCKs do not provide complete stability during certain function [31, 58].

There are no prospective randomized studies comparing non-linked constrained designs with rotating hinge devices. Goldberg et al. reviewed their experiences with 64 revision TKA using posterior stabilized-, non-linked constrained- and rotating hinge designs. Better survival and functional scores were found for the non-linked constrained designs than for the rotating hinge devices [47, 71].

The early hinged prostheses, e.g. WALLDIUS and SHIERS, were routinely used for complex primary arthroplasty [1, 5, 27, 47, 72]. Suboptimal surgical technique, patients with severe compromised knees and wrong implant selection resulted in poor outcome. Particulate debris due to metal-on-metal articulation, aseptic

loosening due to fixed hinge and large prosthetic size requiring excessive bone resection were the most frequent reason for complications [2, 5, 7, 9, 12, 15-24, 31, 32, 34, 56, 60, 73, 74]. The recent generation of hinged knee devices incorporates many design features of less constrained revision prostheses like improved femoro-patellar articulation, metal baked tibial baseplates, porous coatings for fixation, modular augments, sleeves and stems. Nowadays, load is transmitted across the hinge and the tibial bearing surface and not worn by the axle alone [44]. Theoretically these changes should result in improved mechanics of the extensor mechanism, decreased stress at the hinge and the implant's interface, less particulate debris and less aseptic loosening [44, 47].

There are only a few studies including long-term follow-up of current rotating hinge devices. Westrich et al. (24 FINN rotating hinge knee prosthesis, mean follow up: 33 months) and Jones et al. (30 S-ROM Noiles rotating hinge knee prosthesis, mean follow up: 49 months) reported about good short term results, because of the design improvements in comparison to earlier designs [27, 42, 47].

2.1.2.4 Segmental bone loss (Modular Segmental Replacement Prostheses "Megaprostheses" vs. Allograft-Prosthesis Composite)

Implant selection in case of segmental bone loss is based on the ligamentous status and the dimension of bone loss. Small segmental bone defects could be reconstructed using standard prostheses and metal augments, cement, allograft or bone graft [47, 53, 59, 75].

As a result of massive bone loss, the ligament attachments, which are required for stability, are absent or of insufficient strength. For this reason, patients with massive osseous defects and severe compromised soft tissues are candidates for semi-constrained or constrained prosthesis, rotating hinge prosthesis or an allograft-prosthesis composite [36, 45, 47, 70, 71, 76].

The use of allograft-prosthesis composites was often described as an alternative for joint reconstruction following distal femoral or proximal tibial bone tumor resection or for complex revision total knee arthroplasty, but the decision whether a megaprosthesis or an allograft-prosthesis composite is used for reconstruction is disputed, because both techniques have the same indication → segmental bone loss [5, 37, 47, 50, 53, 59, 65, 66, 73, 77-89].

Clatworthy et al., Engh and Parks and several other authors described the technical recommendations for allograft-prosthesis composite reconstruction [47, 53, 59, 66, 84, 90-93]:

- obtainment of an accurate sized allograft
- use of long stemmed components which extend into the host bone diaphysis for fixation (at least two cortical diameters)
- cemented fixation of the stem to the allograft
- osteotomy of the epicondyles and fixation to the allograft for collateral ligament stability
- adapted step cuts in allograft and host bone to enhance rotational stability (fixation with two cerclage cables)
- strut grafts can be used to enhance stability, plates and screws should be avoided to decrease the danger of allograft fracture due to drill holes
- fixation to the host bone with cemented or press-fit stems
- avoidance of cement extrusion at the host-allograft junction to ensure healing between allograft and host bone
- morselized auto- or allograft at the host-allograft junction to facilitate union

Several authors related advantages of allograft reconstruction, such as better soft tissue attachment, extra stability of the healed allograft against bending forces and therefore the use of a less constrained knee design and easier revision procedures because of restored bone stock [44, 46, 49, 59, 65, 78, 84, 93-96].
Disadvantages and most common complications of allograft-prosthesis composite reconstruction include difficulties in getting an equal sized allograft, higher technical difficulties compared with endoprosthetic reconstruction, a tendency to pathologic fracture or to collapse, resorption, nonunion (0-20%) and infection (0-10%) [37, 44, 49, 50, 59, 88, 89, 96]. Some factors associated with an increased risk of allograft failure are infection, adjuvant chemotherapy and irradiation [43, 84]. Bauman et al. concluded that the mechanism of failure is additionally influenced by the type of allograft. Smaller grafts prone to resorption while large bulk grafts tend to infection or non-union [59].

Structural bone grafting for segmental, large cavitary, and combined defects has shown promising short- and midterm results [88, 92]. Engh and Parks reviewed the histology and radiographs from seven allografts used for reconstruction of three knees. The grafts were used to treat F3/T3 lesions according to the AORI classification system and they were in place for a mean time of 41 months. None of the components loosened and all grafts healed at the graft-host junction [92, 97]. Engh et al. also related the mid-term results of structural allograft reconstruction of type III bone defects. At an average time of 50 months, 87% of the patients had good or excellent results [92, 98].

Ghazavi et al. reported on thirty knees with distal femoral or proximal tibia allografts. All components were cemented, with long cement-free stems. All in all, there were seven failures in this series. Four knees were revised for septic loosening, two of them failed for recurrent infection and one failure for infection occurred additionally. Component loosening occurred in two, graft fracture in one, and graft-host non-union in one [92, 99].

Clatworthy et al. reported a series of structural allografts used for reconstruction of large segmental defects in revision total knee arthroplasty. The study consisted of fifty-two knees requiring sixty-six grafts. Overall, thirteen knees failed. Five were revised for resorption and loosening, four knees failed for infection, including one of six revised for septic failure. There were two cases of non-union while only one required an additional revision procedure and two knees in one patient failed clinically. Overall, the success rate was 75%. The estimated graft survival was 92% and 79% at five and ten years [91, 92].

Wilkins and Kelly reported four revision cases changing rotating hinge knees to allograft-prosthetic composites. Revision was required due to aseptic loosening and fracture of the femoral prosthetic component. There were no postoperative complications or graft failures. The functional scores showed good results. The authors determined that in patients with distal femoral replacement who require revision, an allograft-prosthetic composite serves an excellent long-term replacement without significant loss of function [65].

Ogilvie et al. using two different scoring systems also found high functional scores following reconstruction for bone sarcoma [88]. These results were comparable to those of Malo et al. using the same scoring systems following tumor resection and endoprosthetic reconstruction [77, 88].

Wunder et al. and Mascard et al. concluded, that limb salvage surgery at the knee would have a better outcome using tumor prosthesis than with allograft-implant composite [22, 84, 85]. Hirn reviewed the study of Wunder et al. and showed some weak points, which were responsible for the worse outcome of allograft-prosthesis reconstruction. He pointed out, that the investigators did not use prosthetic components with long intramedullary stems, so there was no stabilization between the prosthesis and the host bone resulting in less stability [93].

Segmental bone defects should be reconstructed with an allograft-prosthesis composite in younger patients with longer life expectation. In contrast, older, infirm individuals with higher surgical risk should get a modular, segmental replacement prosthesis [31, 34, 47, 59, 60, 94, 100].
Overall, complication rates are comparable to those of endoprosthetic reconstructions, although Wilkins and Kelly and Shih et al. reported a longer durability of allograft composites [15, 25, 37, 50, 53, 59, 65, 73, 82, 84-88, 94, 101].

2.2 The Limb Preservation System (LPS^{TM}/M.B.T.)

The Orthogenesis Limb Preservation System (LPS^{TM}, introduced in 2001) is a comprehensive modular implant system, designed to facilitate limb sparing surgery. This procedure provides skeletal support for missing bone and the opportunity for mobility. The system's modularity allows different configurations of the components. LPS^{TM} permits the replacement of proximal tibia, proximal, distal or total femur. In addition, it is possible to reconstruct only femoral mid-shaft portion.

2.2.1 Distal femoral and proximal tibial replacement components

The LPS^{TM} femoral stems are available with a porous surface for better host bone integration or as cemented version. Four different lengths are obtainable (straight 100 mm and 125 mm stems and bowed 150 mm and 200 mm stems). The diameter of the distal stem extensions varies. As well, a cemented design is

available for 9-17 mm diameters (1 mm increments), the porous style is produced with 10,5 mm-18,5 mm diameters (1 mm increments).

The LPS™ femoral segmental components increase in 5 mm and 20 mm steps (25 mm-45 mm, 65 mm, 85 mm, 105 mm and 125 mm). The total femoral segmental component has a length of 55 mm.

The LPS™ Distal Femoral Component is intended to replace the missing femoral bone stock. It is designed to articulate with M.B.T. Revision Tray, LPS™ Proximal Tibial Replacement or S-ROM Noiles tibial tray component. All components are anatomic (left or right) to allow normal knee kinematics. Furthermore the femoral component has a fixed 5° degrees physiologic valgus position. The most common size is extra-small, but there is also an extra-extra-small component available. The LPS™ Distal Femoral Component has a deepened femoral trochlea groove for better femoro-patellar articulation.

The LPS™ Hinged Tibial Insert Bearing has a cylindrical designed central rotational stem with a length of 46 mm and a stem taper of 0° degrees. The polyethylene inlay allows hyperextension to reduce rocking and stress transferred to the tibial component. There is no built-in rotational stop to provide natural kinematics. Load sharing hinge insert designs do not concentrate stress through the hinge pin. Obtainable sizes are extra-extra small, extra-small, small and medium (all 12 mm-23 mm).

The M.B.T. Revision Tray is available in six different sizes (2, 2,5, 3-6), as cemented or as porous version. It can be modified with several sleeves (sizes 37, 45, 53 and 61), augments and stem extensions. The surface bearing area has been highly polished to improve the wear characteristics.

The LPS™ Proximal Tibial Replacement Component was designed for replacement of the proximal tibia in cases of extensive bone loss. It is only available in one size (extra-small). The surface bearing is also highly polished to reduce the polyethylene wear (Fig.9).

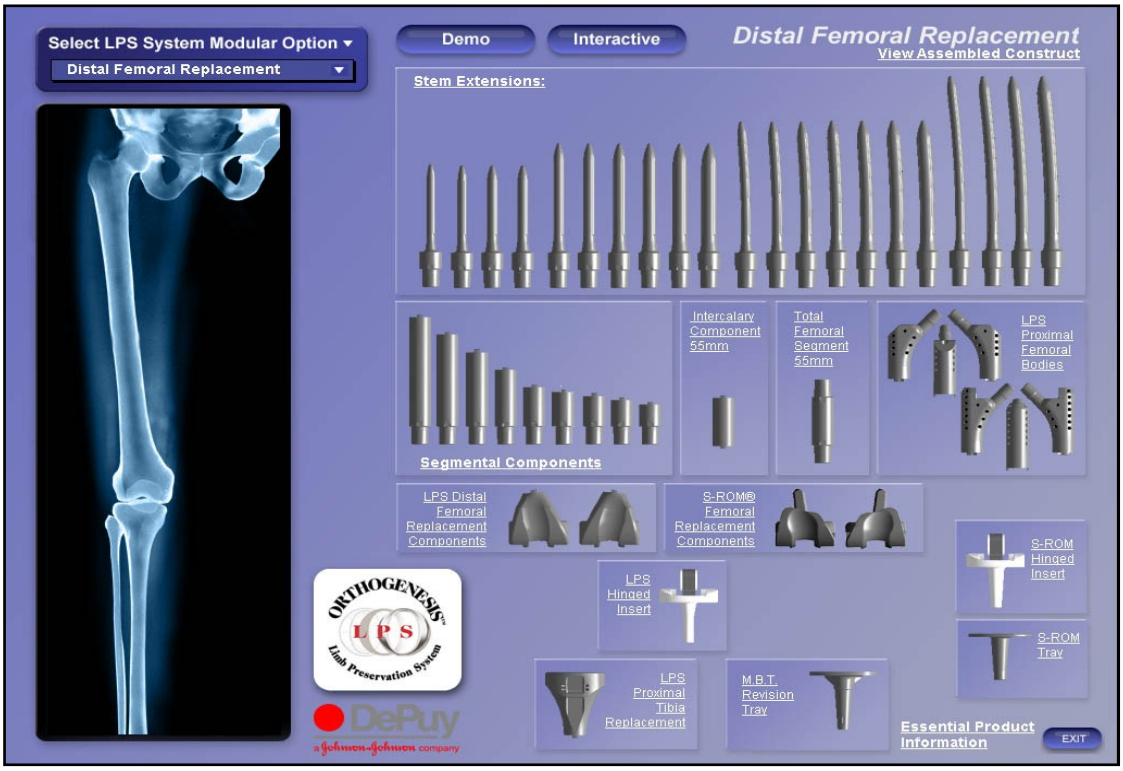


Fig.9: Components of the Limb Preservation System (from the LPS^{TM} planning software).

2.3 The S-ROM Noiles rotating hinge system

The S-ROM Noiles Mobile-Bearing Hinge Prosthesis (third generation of rotating hinge prostheses) is used for reconstruction in cases of deficient ligament stability. Resection, absence or incompetency of both cruciate ligaments (ACL/PCL) and insufficiency of the collateral ligaments (MCL/LCL) are the main indications for this prosthesis design. Additionally, the S-ROM Noiles device is indicated in cases of failed complex TKA.

2.3.1 Distal femoral replacement components

The S-ROM Noiles femoral and tibial diaphyseal stems are splined and slotted to enhance the rotational stability and the intramedullary fixation [5, 27, 31, 44, 47]. The femoral stems are available as straight (100 mm, diameters 9 mm-21 mm with 2 mm increments) or bowed versions (150 mm, diameters 11 mm-17 mm with 2 mm increments).

The S-ROM metaphyseal sleeves are stepped and textured to provide optimal fit for better bone ingrowth. Different sizes are available to manage wide metaphyseal deficiencies (femoral: 31, 34, 40 and 46; tibial: 37, 45, 53 and 61).
The S-ROM Noiles Femoral Component has a fixed physiologic valgus position of 7° degrees, it is anatomically formed (left or right) and therefore it allows normal knee kinematics. The prosthesis articulates from 6° degrees hyperextension to 110° degrees of flexion. The femoral trochlea groove is semi-circular deepened to prevent complications with the patella like subluxation or dislocation. The femoral component's sizes are extra-small, small and medium. There exist several augments (5 mm and 10 mm) additionally, to restore the joint line. The femoral component can be combined with M.B.T. Revision Tray, LPS™ proximal tibial replacement or S-ROM tibial tray component (Fig.10).
The S-ROM Hinged Tibial Insert Bearing has a conical designed central rotational stem with a length of 46 mm and a stem taper of 5° degrees. The sizes are extra-small, small and medium (all 12 mm-31 mm).
The articulating surface of the S-ROM Tibial Component is highly polished to provide a broad mobile surface for the polyethylene bearing component. Available sizes are extra-small, small, medium, large or extra-large.

Fig.10: S-ROM Noiles Hinged Tibial Insert Bearing and tibial component with metaphyseal sleeve (from Jones et al.; Clin Orthop Relat Res 2001:306-314).

2.4 The Global Modular Replacement System (GMRS™)

The Global Modular Replacement System (GMRS™, introduced in 2003) is a comprehensive modular implant system, which is used in the setting of limb

salvage surgery. This prosthesis is the evolution of its precursors, the Kinematic Rotating Hinge (KRH, 1979-1988), the Modular Rotating Hinge (MRH, 1988-2001) and the Modular Replacement System (MRS, 2001-2003). The GMRS^{TM} system permits the replacement of the proximal, distal or total femur and the proximal tibia.

2.4.1 Distal femoral and proximal tibial replacement components

The GMRS^{TM} femoral stems are available with a porous surface for press fit fixation or as cemented version with or without a porous coated body section. Three different stem designs are obtainable (straight fluted, bowed and long bowed). The diameter of the stem extensions varies. As well, the cemented design (straight and bowed) is available for 8-11 mm diameters (1 mm increments) and 13, 15 and 17 mm. The press fit stem is produced with 11 mm-19 mm diameters (1 mm increments). The GMRS^{TM} extension pieces increase in 10 mm and 20 mm steps (30 mm-80 mm, 100 mm-220 mm).

The GMRS^{TM} Distal Femoral Component is intended to replace the missing bone stock. The component is anatomic (left or right) with a deepened femoral trochlea groove and it is available in two sizes (small and standard). Additionally, there is a fixed 6° degrees physiologic valgus position (Fig.11).

The GMRS^{TM} Tibial Rotating Component has a cylindrical central rotational stem with a length of 47 mm and a stem taper of 0° degrees. Obtainable sizes are extra-small, small, medium and large. The articulating surface between the Rotating Component and the GMRS^{TM} Tibial Insert (UHMWPE) is congruent. The GMRS^{TM} Tibial Inserts have a thickness of 10, 13, 16, 20 or 24 mm.

The GMRS^{TM} Tibial Baseplate is available in four different sizes (S1, S2, M2 and L2), as a cemented or a porous coated version.

The GMRS^{TM} Proximal Tibia is designed for replacement of the proximal tibia in cases of severe bone loss (Fig.11). It is available in two sizes (small and standard). The GMRS^{TM} Proximal Tibia can be combined with the distal femoral component of the GMRS^{TM} or the MRH prosthesis.

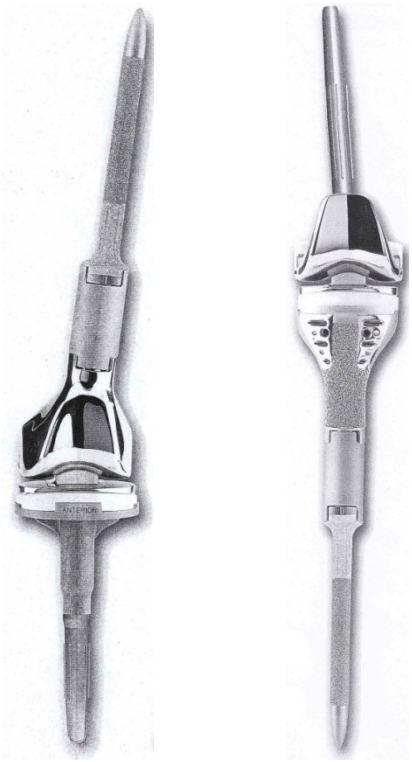


Fig.11: The GMRS^{TM} distal femoral and proximal tibial components (from the GMRS^{TM} product information).

3. SPECIAL PART

3.1 Biomechanical Apparatus

A biomechanical analysis was performed to establish the association between design of the central rotational stem within the vertical post-in channel and the implant´s stability. Therefore a self constructed biomechanical apparatus was used on a test bench in the laboratory (Fig.12).

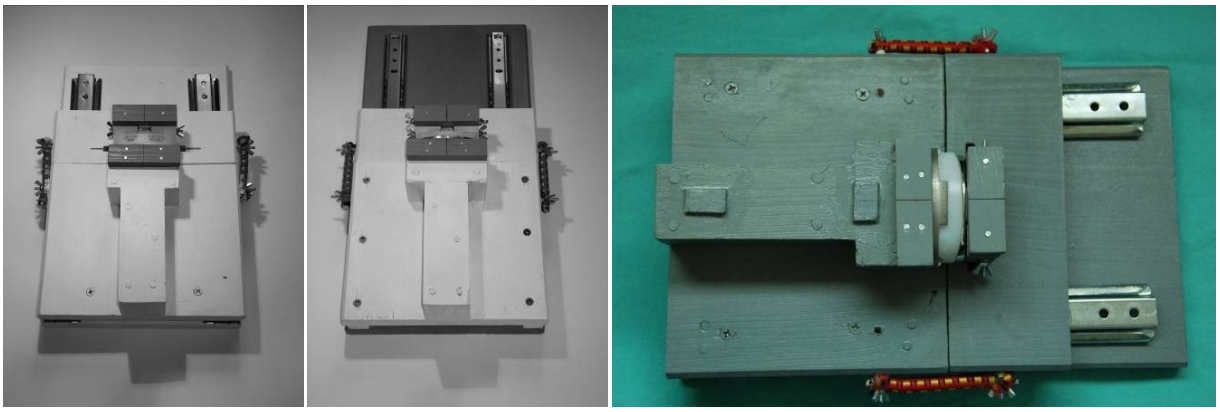


Fig.12: Biomechanical apparatus of the S-ROM Noiles, LPS™/M.B.T and GMRS™ rotating hinge knee.

3.1.1 Materials and Methods

The lengths and tapers of the central rotational stem of three different rotating hinge knee implants (Limb Preservation System-LPS™/M.B.T. [DePuy, a Johnson and Johnson Company]; S-ROM Noiles [DePuy, a Johnson and Johnson Company] and Global Modular Resection System-GMRS™ [Stryker]) were determined (Tab.3; Fig.13).

Fig.13: The tested PE-inlays/stems: LPS™/M.B.T., S-ROM Noiles and GMRS™.

Manufacturer	Stem length (mm)	Stem taper (deg)
Stryker- GMRS™	47	0°
DePuy-LPS™/M.B.T.	46	0°
DePuy-S-ROM Noiles	46	5°

Tab.3: Manufacturer, stem length and taper of the tested devices.

The degree of tilting of the central rotational stem within the vertical post-in channel was measured by extending the distraction, as well as the maximum amount of distraction before the stem's dislocation. For these measurements three different methods were used.

In the first method the central rotational stem/polyethylene inlay was fixed to the proximal (femoral) base plate of the biomechanical apparatus, which was mobile for imitating the distraction. The hinged bearing inserts were fixed to the proximal base plate with a mobile screw in a horizontal gliding slot to simulate the angulation/lateral movement (Fig.14).

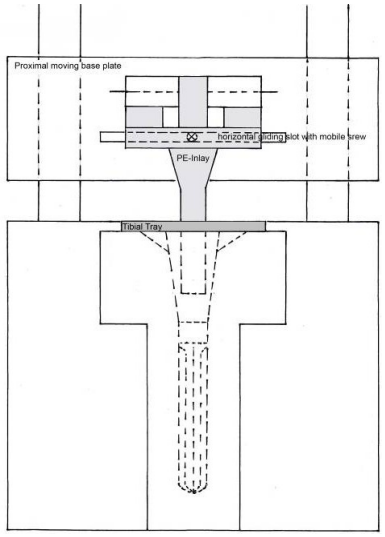


Fig.14: Outline of the biomechanical apparatus.

The lateral tilting of the central rotational stem within the tibial rotational cylinder was generated by pressure, which was produced by the observer. The stem's side displacement was measured with a standard goniometer. The distraction was increased by 5 mm increments, up to the increment that allowed dislocation, using metal platelets with 1 mm thickness. The point of dislocation was defined as the point, at that any laterally directed force caused the central rotational stem to jump out of the vertical rotational cylinder. After that measurements were made with 1

mm increments from the last 5 mm increment before the increment that allowed determining dislocation (Fig.15a&b).

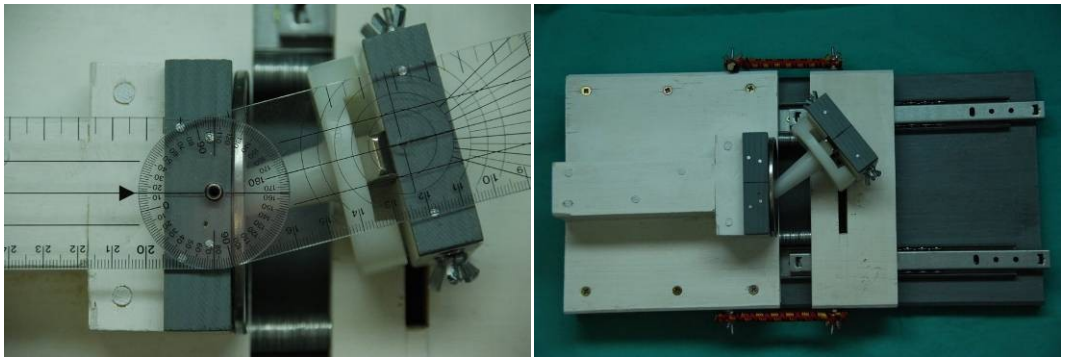


Fig.15a&b: a) Measurements of the biomechanical apparatus; b) Dislocated central rotational stem.

In the second method the fixation screw at the horizontal gliding slot was removed. We wanted to demonstrate that the horizontal gliding slot does not contribute the results additionally. For this method the vertical post-in channel was filled with the metal platelets under the tip of the stem to simulate distraction and the measurements were repeated the same as in the first method.

In the third method, the measurements were made by graphic designs of the prosthesis components. The graphics were of original size (Fig.16).

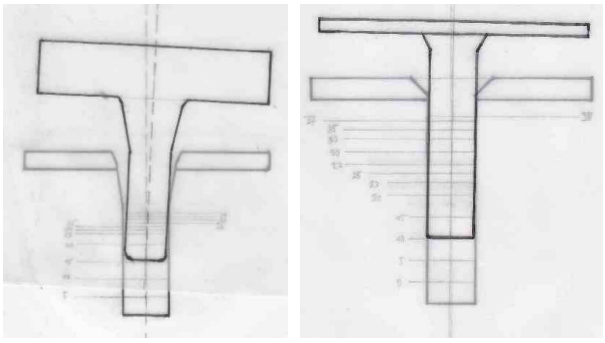


Fig.16: Graphic designs of the LPS™/M.B.T. and the GMRS™ prostheses

The measurements were performed by three independent observers (A.L., M.G., and J.F.). A distraction-angular displacement curve was generated for each device with the degrees of angular laxity plotted at each level of the component's distraction. The distraction-angular displacement curves were created with the mean results of the three different observers. The slope of the curve reflects the extent to which the angular laxity increases, with increasing distraction. The end

point of each curve demonstrates the last measureable angle before the implant's dislocation.

3.1.2 Results

The GMRS™ rotating hinge design with a stem length of 47 mm required 38 mm of distraction do dislocate. In comparison to that, the LPS™/M.B.T. and S-ROM Noiles (both have a stem length of 46 mm) dislocated at 27 mm respectively 26 mm of distraction. The GMRS™ Implant was the only design with tilting angles less than 10° degrees, at any given amount of distraction until dislocation. The S-ROM Noiles device with a stem taper of 5° degrees, had an angular laxity of 19,4° degrees at 25 mm of distraction, while the GMRS™ and LPS™/M.B.T. designs showed tilting angles of 3,2° and 11,2° degrees at the same increment (Tab.4).

Manufacturer	Stem length (mm)	Stem taper (deg)	Distraction to dislocate (mm)	Angular laxity at 25 mm of distraction (deg)
Stryker- GMRS™	47	0	38	3,2
DePuy-LPS™/M.B.T.	46	0	27	11,2
DePuy-S-ROM Noiles	46	5	26	19,4

Tab.4: Results of the biomechanical analysis.

The distraction-angular displacement curve of the S-ROM Noiles design showed a poorer increasement (high laxity) compared to the GMRS™ and the LPS™/M.B.T. design, which showed steep raising slopes (lower laxity) (Fig.17). These findings confirmed that shorter and more tapered stems have a greater angular laxity at any given amount of distraction.

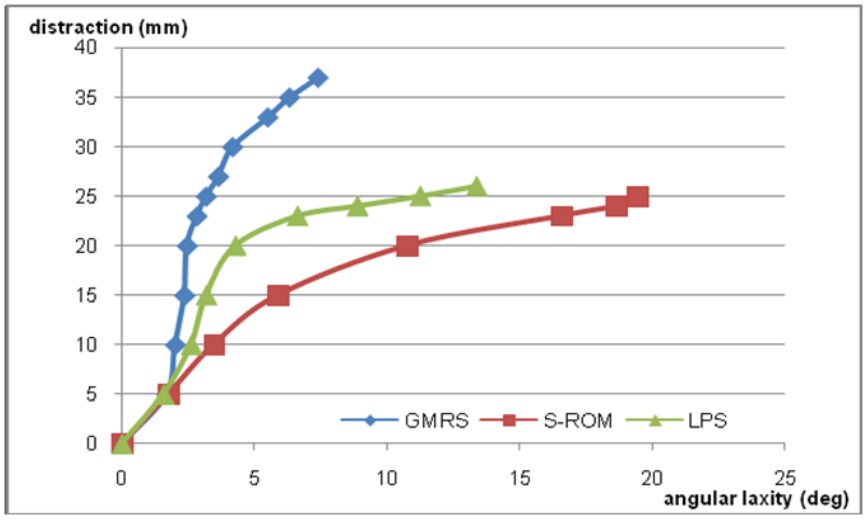


Fig.17: Distraction-angular displacement curves for the three tested knee designs. The final point of each curve (GMRS™ -37 mm, LPS™/M.B.T.-26 mm and S-ROM Noiles-25 mm) shows the last measureable angle before the implant's dislocation.

3.1.3 Discussion

The current study with the biomechanical apparatus demonstrated that the LPS^{TM}/M.B.T. and S-ROM Noiles implants require at least 26 mm respectively 27 mm of distraction to dislocate. On the contrary, the Stryker Global Modular Replacement System (GMRS^{TM} with a 10 mm polyethylene tray) with a cylindrical, non-tapered central rotational stem requires 38 mm of distraction to dislocate. The GMRS^{TM} implant also had the lowest tilting angles at any given amount of distraction until dislocation while, the S-ROM Noiles knee showed the highest angular laxity throughout the biomechanical analysis. This mechanical test confirmed that implant designs with a shorter and more tapered central rotational stem are not as stable as implants with a long cylindrical central rotational stem.

In 2003, Ward et al. performed a biomechanical analysis testing the stability of seven rotating hinge knee designs, which included the S-ROM Noiles device as well [102]. This study also showed better results for implant designs with a long, not tapered central rotational stem and the authors concluded that short and great tapered central rotational stems have greater instability and higher risk of dislocation at any given amount of distraction. On the contrary, the Endo-Model (Waldemar Link GmbH&Co) has the shortest central rotational stem compared to other rotating hinge devices and needs the least distraction to dislocate, nevertheless it seems to be a safe design because of the antidislocation feature [102, 103].

Mild distraction of the knee is observed following endoprosthetic reconstruction of the knee. As a consequence of the resection of the cruciate and collateral ligaments, as well as the entire capsule of the knee, a flexion-extension gap imbalance may occur because only the skin, the neurovascular bundle, the extensor mechanism and the implant have to maintain joint balance and stability [103, 104]. An imbalanced flexion-extension gap may result in instability throughout total range of motion. Gustke et al. suggested that if the flexion-extension spaces are not balanced, a rotating hinge can dislocate [35, 105]. Kabo et al. tested the rotational stability of a rotating hinge device and demonstrated the importance of the remaining soft tissues and even of the new formed

periprosthetic scar, to protect the hinged prosthesis from excessive rotational stresses [28].

The compromised soft tissues and the lack of ligaments can result in distraction between the femoral and tibial component during flexion. Extremely imbalanced knees, in combination with several millimeters of distraction of the central rotational stem, depending on the length and taper of the rotational stem, may result in a femoro-tibial dislocation. Investigations showed that instability of the replaced knee is most apparent to the patients in flexion when they lift the lower limb out of a seated position or leave the leg dangling [103, 104].

However, dislocation of rotating hinge knee prostheses is not often reported. In most cases this complication is associated with implant's breakage or fatigue failures. Theoretically, distraction disengagement is another mechanism for dislocation of such devices but it has never been reported in the literature.

Of the initial 55 joint reconstructions which were performed with the LPS^{TM}/M.B.T. and S-ROM Noiles rotating hinge knee, four dislocations occurred in three patients after a mean time of 26 months (range, 2-38 months). Two dislocations resulted from direct trauma to the knee after a fall, one dislocated due to a loosened femoral component and one implant dislocated after a fracture of the metal yoke inside the polyethylene inlay (overall complication rate in this series: 5%; Fig.18a-c). The LPS^{TM}/M.B.T. inlay dislocated three times and the S-ROM Noiles inlay one time. None of the affected patients had a flexion gap laxity or flexion-extension gap imbalance before dislocation. The hinged tibial insert was changed in all four cases and the extensor mechanism was adapted in two additionally.

Fig. 18a-c: a) Radiograph of a dislocated central rotational stem caused by loosening of the femoral component. b) Preoperative x-ray of a fractured and dislocated LPS^{TM}/M.B.T. metal yoke. c) Photograph of the explanted hinged tibial insert.

There are only some authors who reported cases of dislocated rotating hinge knees. Wang and Wang and Pacha-Vincente et al., using the Endo-Model rotating hinge knee for reconstruction, reported about two dislocations each [103, 106]. Wang and Wang did not comment if the prostheses were standard or had an antidislocation feature, while Pacha-Vincente et al. used the design with the antidislocation device. Joshi et al. also related three dislocations of the Endo-Model rotating hinge knee device [35].
David et al. reported dislocations of the Rotaflex knee and Ward et al. referred dislocations of four different designs (Howmedica, Techmedica, S-ROM Noiles and Finn RHK) [32, 104]. Kawai et al. related two tibial yoke fractures of the Finn RHK and one fractured tibial bearing insert [44]. The component's failures occurred nine, ten and 68 months after implantation. All broken components were replaced and as a consequence the tibial yoke was thickened about 50%. Zeegen et al. reviewed 141 patients in whom a modular endoprosthesis was used for limb salvage procedures [94]. The osseous defects were reconstructed with the Howmedica Modular Replacement System (HMRS). The authors reported seven dislocations, five in the hip, one in the knee and one of the patella.
In the most cases, except of Ward et al. and Joshi et al., dislocation occurred due to breakage of any prosthesis' component or fatigue of the tibial antidislocation device. All authors supposed excessive flexion gap instability and posterior dislocating forces to cause the mechanical failure of the prostheses.

Wang and Wang and Pacha-Vincente et al. emphasized the importance of the ligamentous balance of the knee, especially the flexion gap, and suggested constrained prosthesis with an antidislocation device in cases of ligamentous insufficiency [103, 106]. Ward et al. also recommended rotating hinge devices with a long (>5 cm), cylindrical central rotational stem or an effective mechanical antidislocation feature for patients with massive bone loss and/or severe soft tissue compromise [102, 104].

3.1.4 Conclusion

The results of the measurements with the biomechanical apparatus showed that the length and taper of the central rotational stem plays a major role in the stability

of a rotating hinge device and should be considered in the development of new rotating hinge total knee designs. According to Ward et al. we conclude that rotating hinge prostheses with a short and markedly tapered central rotational stem have the highest instability/angular laxity at any given amount of distraction and they may become unstable under conditions of mild joint distraction [102]. Prosthetic designs with a long, cylindrical central rotational stem, which require greater distraction to dislocate, should be used for treatment of flexion gap laxity or flexion-extension gap imbalance, especially in patients with severe compromised soft tissues. Excessive flexion-extension gap imbalance has to be corrected at the time of knee replacement or revision surgery. Non-observance may result in a poorer outcome, instability or even dislocation [7, 35, 102-104, 106].

3.2 Clinical Study

3.2.1 Introduction

In the past, amputation was the common surgical treatment for malignant bone tumor in distal extremities. Furthermore, arthrodesis or even amputation were chosen in revision procedures after failed previous total knee arthroplasty with gross bone loss, massive instability or persistent infection.

As a consequence of substantial advancements of chemotherapy regimes, improved radiographic imaging (CT or MRI) and improved surgical techniques, limb salvage surgery using modular or custom made endoprostheses became an accepted treatment for primary bone tumors or metastases of the extremities.

Due to the growing number of revision surgeries for conventional total hip and knee implants the market for megaprostheses has evolved additionally and today there are many modular and custom-made prostheses available [22, 36, 44, 73]. The advantage of modular devices is that the implant is shaped and adapted to the conditions encountered at the time of operation.

We performed a retrospective study of fifty-five patients who underwent total femoral, distal femoral or proximal tibial replacement with the LPS^{TM}/M.B.T. and/or S-ROM Noiles rotating hinge knee systems. Indications were resection of a malignant tumor, primary implantation and revision total knee arthroplasty. The aim of the clinical study was to test the “in vivo” stability of these rotating hinge devices and to detect any significant differences between the used implants concerning function, stability and measurable distraction. Therefor a clinical and radiographic evaluation was performed, using plain radiographs, ultrasonography and three rating systems. Additionally, the implant survival was calculated.

The study was approved by the ethics committee.

3.2.2 Materials and Methods

3.2.2.1 Patients

From January 2003 through December 2008, fifty-five patients (26 male and 29 female) underwent knee replacement using the LPS^{TM}/M.B.T. or the S-ROM Noiles rotating hinge prostheses at our department. There were forty-four distal femoral, eight proximal tibia and three total femur replacements (Tab.5). The mean age of the patients at the time of surgery was 61 years (range, 14-90 years). The average postoperative follow-up was 26 months (range, 1-58 months). We calculated postoperative follow-up from the date of prosthesis implantation to the last patient's encounter or death. Twenty-six knees were affected on the right side and 29 on the left side.

Localization	Primary implantation		Revision surgery		All
	tumor	non-tumor	tumor	non-tumor	
Distal femoral replacement	15	4	-	25	44
Proximal tibia replacement	7	-	-	1	8
Total femoral replacement	2	-	1	-	3

Tab.5: Number and sites of replacement.

3.2.2.1.1 Primary Implantation

Twenty-eight patients had a primary implantation of a rotating hinge knee prosthesis, 24 because of a malignant tumor (n=21) or metastatic bone disease (n=3). Another four primary implantations were performed due to degenerative osteoarthritis in two patients (n=2), femoral nonunion in one (n=1) and osteonecrosis in another one (n=1) (Tab.6).

All patients with a malignancy had a complete tumor assessment after clinical diagnosis including plain radiography of the limb and chest, bone scan, CT-scan and MRI of the involved site, followed by an open biopsy.

The tumor diagnosis was osteosarcoma in 13, chondrosarcoma in four, myxoid liposarcoma in one, synovialsarcoma in one, myxofibrosarcoma in one and follicular lymphoma in one case. The histopathological grading according to the Union Internationale Contre le Cancer (UICC) presented three G1, four G2 and 14 G3 tumors. According to Enneking and the Musculoskeletal Tumor Society,

surgical stages were: IA in two patients (10%), IIA in five (25%), IIB in twelve (60%) and IIIA in one (5%). Metastatic bone disease formed in three patients due to malignant melanoma, renal cell carcinoma and lung carcinoma. Two of these three patients presented with pathological fracture.

The surgical approach and margin was performed according to the general principles of limb salvage surgery. The mean resection length for malignancies in the femoral bone was 19 centimeters (range, 10-45cm). For tumors or metastases in the proximal tibia, the mean resection length was 14 centimeters (range, 10-21cm). In all patients an intra-articular resection was performed.

Reconstruction of extensor mechanism or restraint of the patellar tendon was performed in five cases following tumor excision. Additionally, reconstruction of the extensor mechanism and soft tissue coverage of the prosthesis was done in one case. All in all, additional soft tissue coverage of the prosthesis was performed in seven cases, six of the seven after proximal tibia reconstruction using a medial gastrocnemius flap. All patients received perioperative prophylactic antibiotics and thromboprophylaxis.

Fourteen patients received pre- and/or postoperative systemic intravenous chemotherapy (CTx) with regimens used in our institution at that time. Two patients had CTx before the definitive surgical procedure, nine had preoperative and postoperative CTx and three had only postoperative CTx. In addition, three patients got local radiation therapy.

Nine patients died within a mean follow-up of 9 months (range, 0-19 months) after surgery, seven of them died from their underlying disease and two died of another cause. Three of these patients received a proximal tibia replacement, five a distal femoral and one patient a total femoral replacement.

3.2.2.1.2 Reimplantation of a RHK prosthesis after failed TKA

Twenty-seven patients had repeated surgical procedures after a failed TKA. Nineteen cases were treated due to early or late deep prosthetic infection, three were revised because of periprothetic fracture, two patients showed severe ligamentous instability after TKA, two patients had loosened implants and one patient developed a pseudoarthrose after bone fracture (Tab.6). Reimplantation in cases of deep prosthetic infection was performed after microbiological evaluation

of aspired synovial fluid and intraoperative biopsies. Before reimplantation, a further debridement was performed and infection had to be excluded.

Pat. No.	Sex+age at OP (yrs)	Indication	Surgical stage	Primary/revision	Localization+side	Type of resection	Resection length	Device (fem./tib.)	Intraop. compl.	Reconstruction extensor mechanism	Soft tissue coverage	Number of revisions	CTx	FU (months)	Status
1	M, 70	Infection TKA		revision	distal femur, R			LPS/M.B.T.	no			3		11	0
2	M, 50	Infection TKA		revision	distal femur, L			S-ROM/S-ROM	no		medial gastrocnemius flap	5		20	0
3	M, 60	Infection TKA		revision	distal femur, R			S-ROM/S-ROM	no			1		52	0
4	F, 60	Infection TKA		revision	total femur, L			LPS/S-ROM	no			0		49	0
5	M, 58	Pseudoarthrose		revision	prox. tibia, R			S-ROM/LPS	no	no		0		5	0
6	F, 81	Infection TKA		revision	distal femur, R			S-ROM/M.B.T.	no			0		15	0
7	F, 84	Osteoarthritis		primary	distal femur, R			S-ROM/S-ROM	fracture			0		44	Lost to FU
8	M, 70	Chondrosarcoma G2	II A	primary	distal femur, R	wide resection	22	LPS/M.B.T.	no	no	no	4	no	37	NED
9	F, 83	Periprothetic fracture		revision	distal femur, R			LPS/M.B.T.	no			0		3	0
10	M, 75	Infection TKA		revision	distal femur, R			LPS/S-ROM	no			1		26	0
11	M, 55	Metastasis (malignant melanoma)	NA	primary	prox. tibia, L	wide resection	14	S-ROM/LPS	no	no	medial gastrocnemius flap	0	yes	2	DOD
12	F, 46	Osteosarcoma G3	III A	primary	prox. tibia, L	wide resection	10	S-ROM/LPS	no	no	no	2	yes	15	DOD
13	F, 79	Infection TKA		revision	distal femur, L			S-ROM/S-ROM	no			0		40	0
14	F, 76	Infection TKA		revision	distal femur, L			S-ROM/S-ROM	fracture			2		30	0
15	M, 14	Osteosarcoma G3	II B	primary	distal femur, L	wide resection	15	LPS/S-ROM	no	biceps femoris muscle tendon	no	2	yes	53	NED
16	F, 78	Instability TKA		revision	distal femur, R			S-ROM/S-ROM	no			0		30	Lost to FU
17	M, 21	Osteosarcoma G3	II A	primary	distal femur, R	wide resection	17	LPS/S-ROM	no	no	sartorius transposition	1	yes	13	DOOC
18	F, 40	Synovialsarcoma G2	II A	primary	prox. tibia, L	wide resection	10	S-ROM/LPS	no	no	free scapula flap	0	yes	5	DOD
19	F, 54	follicular Lymphoma G3	NA	primary	distal femur, L	wide resection	17	LPS/S-ROM	no	no	no	2	yes	51	NED
20	F, 64	Osteosarcoma G3	II A	primary	prox. tibia, R	wide resection	15	S-ROM/LPS	infracture	no	medial gastrocnemius flap	0	yes	18	NED
21	F, 62	Infection TKA		revision	distal femur, L			S-ROM/S-ROM	no			0		36	0
22	M, 29	Osteosarcoma G3	II B	primary	prox. tibia, R	wide resection	15	S-ROM/LPS	no	no	medial gastrocnemius flap	0	yes	23	NED
23	M, 17	Osteosarcoma G3	II B	primary	distal femur, R	wide resection	23	LPS/S-ROM	no	semimembranous restraint	no	0	yes	34	NED
24	M, 48	Infection TKA		revision	distal femur, L			LPS/S-ROM	no			3		31	0
25	M, 19	Osteosarcoma G3	II B	primary	prox. tibia, L	wide resection	21	S-ROM/LPS	no	no	medial gastrocnemius flap	1	no	58	NED
26	M, 73	Infection TKA		revision	distal femur, L			S-ROM/S-ROM	no			0		48	0
27	F, 90	Loosening		revision	distal femur, R			LPS/S-ROM	no			0		43	0
28	F, 79	Periprothetic fracture		revision	distal femur, R			LPS/S-ROM	no			0		4	0
29	F, 78	Infection TKA		revision	distal femur, R			S-ROM/S-ROM	no			0		40	0
30	F, 24	Osteosarcoma G1	II B	primary	distal femur, L	wide resection	11	LPS/S-ROM	no	semimembranous restraint	no	1	no	13	NED
31	F, 76	Periprothetic fracture		revision	distal femur, R			LPS/S-ROM	no			2		35	0
32	F, 81	Pseudoarthrose		primary	distal femur, L			LPS/S-ROM	no			0		4	0
33	F, 72	Osteoarthritis		primary	distal femur, R			S-ROM/S-ROM	no			0		8	0
34	M, 78	Metastasis (renal cell carcinoma)	NA	primary	distal femur, L	wide resection	24	LPS/S-ROM	no	no	no	0	no	0	DOD
35	M, 15	Osteosarcoma G3	II B	primary	distal femur, L	wide resection	20	LPS/S-ROM	no	semimembranous restraint	sartorius transposition	0	yes	54	NED
36	F, 66	Metastasis (lung carcinoma)	NA	primary	distal femur, R	wide resection	14	LPS/S-ROM	no	no	no	0	yes	19	DOD
37	M, 72	Loosening		revision	distal femur, L			LPS/M.B.T.	no			3		11	0
38	F, 81	Myxofibrosarcoma G3	II B	primary	distal femur, L	wide resection	24	LPS/S-ROM	no	no	no	1	no	18	DOD
39	F, 14	Osteosarcoma G3	II B	primary	total femur, L	wide resection	45	LPS/M.B.T.	no	no	no	0	yes	4	Lost to FU
40	M, 46	Osteosarcoma G3	II B	primary	prox. tibia, L	wide resection	11	S-ROM/LPS	no	no	medial gastrocnemius flap	2	yes	43	NED
41	F, 69	Chondrosarcoma G1	I A	primary	distal femur, R	wide resection	10	LPS/S-ROM	no	no	no	1	no	6	Lost to FU
42	F, 38	myxoid Liposarcoma G2	II A	primary	distal femur, L	wide resection	22	LPS/M.B.T.	no	biceps femoris & sartorius muscle ten	no	0	no	19	NED
43	M, 28	Chondrosarcoma G2	II B	primary	distal femur, L	wide resection	12	LPS/M.B.T.	no	no	no	0	no	9	NED
44	F, 79	Infection TKA		revision	distal femur, L			LPS/M.B.T.	no			0		10	0
45	F, 76	Chondrosarcoma G1	I A	primary	total femur, L	wide resection	10	LPS/-ROM	no	no	no	0	no	5	DOOC
46	M, 69	Osteosarcoma G3	II B	primary	distal femur, L	wide resection	12	LPS/M.B.T.	no	no	no	4	no	6	DOD
47	M, 84	Infection TKA		revision	distal femur, R			LPS/M.B.T.	no			1		14	0
48	M, 40	Osteosarcoma G3	II B	primary	distal femur, R	wide resection	20	LPS/M.B.T.	no	semimembranous restraint	no	2	yes	44	NED
49	F, 63	Osteonecrosis		primary	distal femur, L			LPS/S-ROM	no			1		36	0
50	M, 79	Infection TKA		revision	distal femur, R			S-ROM/S-ROM	no			1		49	0
51	F, 76	Instability TKA		revision	distal femur, L			S-ROM/S-ROM	no			1		10	0
52	M, 37	Infection TKA		revision	distal femur, R			LPS/S-ROM	no			1		43	0
53	M, 69	Infection TKA		revision	distal femur, L			LPS/S-ROM	no			8		40	0
54	M, 75	Infection TKA		revision	distal femur, R			S-ROM/S-ROM	no			0		19	0
55	F, 68	Infection TKA		revision	distal femur, R			LPS/S-ROM	no			0		28	0

Tab.6: Data of the 28 primary and 25 revised patients; CTx-Chemotherapy, FU-follow-up, 0-cured, NED-no evidence of disease, DOD-death of disease, DOOC-death of other cause.

3.2.2.2 Prostheses

We used the LPS™ distal femoral replacement component in 30 patients (55%), 17 for primary implantation (57%) and 13 in revision cases (43%). The S-ROM Noiles device was used in 14 patients (25%), two in primary cases (14%) and twelve for revision settings (86%). The proximal tibial replacement component was used in eight patients (15%), seven for primary implantation (88%) and one revision surgery (12%). The LPS™ total femoral replacement components were used in three patients (5%), two for primary implantation (67%) and one for revision surgery (33%).

The LPS™/M.B.T. hinged tibial insert was used in eleven distal femoral (20%), eight proximal tibial (15%) and one total femoral replacement (2%).

Femoral and tibial components were press-fitted in thirteen patients (24%) and hybrid or totally cemented in forty-one cases (76%). In all patients, who had a deep prosthetic infection, antibiotic-impregnated cement (Vancomycin) was used. The patella was never resurfaced.

3.2.2.3 Complications

3.2.2.3.1 Perioperative Complications

Three patients had an intraoperative complication during implantation of the rotating hinge device. In two cases the medial femoral condyle fractured and the third one had a cortical infracture of the tibial bone. In all cases cerclage wires were used for refixation of the bone fragments.

3.2.2.3.2 Postoperative complications

All in all, 43 complications occurred in 26 patients resulting in 56 revision procedures. Twenty-four revisions (43%) in 16 patients (62%) were related to the implanted prostheses (Fig.19). The overall infection rate was 25% (14 cases), loosening occurred in 13% (seven cases), dislocation in 5% (three cases) and periprothetic fracture in 2%. Hematoma, seroma and delayed wound healing showed an overall complication rate of 24% (13 cases).

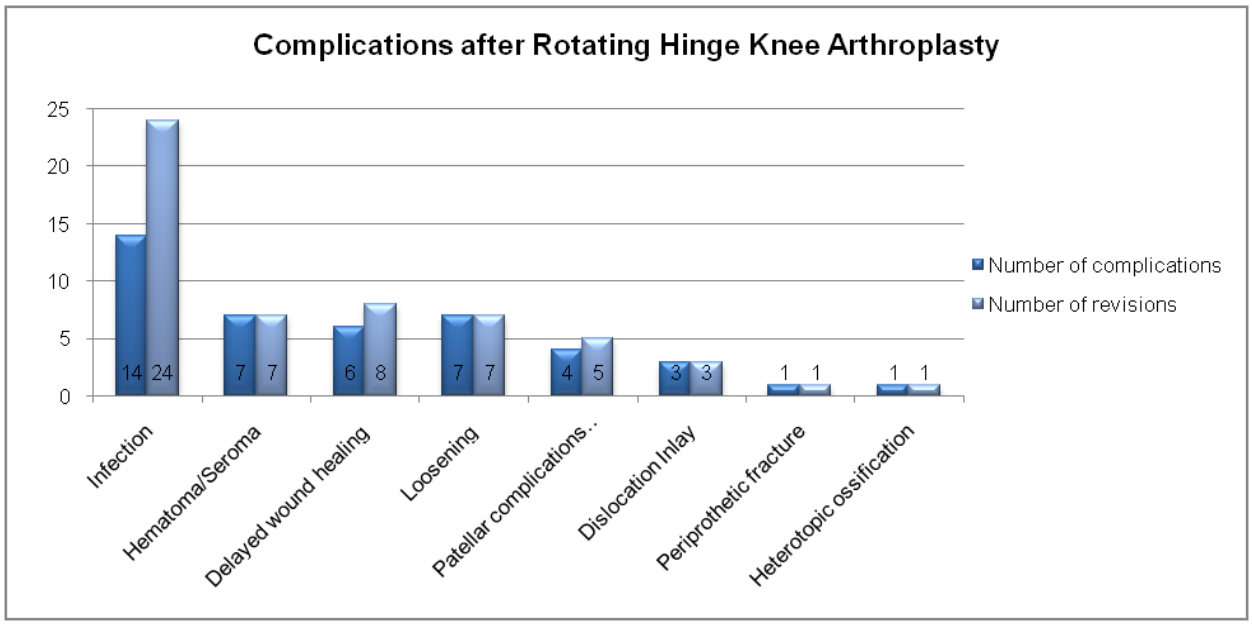


Fig.19: Number of complications and revisions performed in 26 patients.

3.2.2.3.2.1 Early and late complications after primary implantation

Eighteen of all 43 complications (42%) occurred in 13 patients following primary implantation of the rotating hinge device. These 18 complications required 24 of all 56 revision surgeries (43%). Eleven (46%) of the 24 repeated surgical procedures were related to the prosthesis itself (Fig.20). The mean time from index surgery to the first revision procedure was 9 months (range, 0-34 months).

Six deep prosthetic infections (21% of all complications in this group) in five patients resulted in 10 revision procedures. Three prostheses were revised in one-stage exchange arthroplasties and two in a two-stage revision procedure. In one patient, re-infection of the prosthesis occurred 8 months after first revision due to deep prosthetic infection. In this case, infection was treated with a three stage revision procedure (spacer-spacer-reimplantation).

Three dislocations (11% of all complications in this group) of the hinged tibial insert in two patients, 2, 34 and 38 months after implantation, were treated by changing the polyethylene inlay and by adaptation of the extensor mechanism. Two dislocations were due to a direct trauma to the knee and one occurred after fracture of the metal yoke inside the hinged insert.

Two cases of femoral stem loosening (7% of all complications in this group) after 3 and 36 months, were resolved by using a cemented stem respectively a porous coated stem with a bigger diameter.

Four cases of delayed wound healing (flap necrosis, fistulation, wound dehiscence; 14% of all complications in this group) within 2 weeks to 7 months after index surgery resulted in five revision procedures. Delayed wound healing, fistulation and wound dehiscence were treated with split-skin graft, excision and secondary suture. One patient with proximal tibia replacement was revised due to necrosis of the medial gastrocnemius flap. A vastus lateralis muscle flap was used for secondary soft tissue coverage. Following recurrent flap necrosis, soft tissue coverage of the prosthesis was achieved by using a rectus abdominis flap.
Dislocation and fracture of the patella (7% of all complications in this group), in one each, were treated with a sartorius muscle plasty (realignment) and cerclage wires, which were removed after two months. One case of periprothetic femoral shaft fracture (4% of all complications in this group), 15 months after implantation, was treated with open reduction and internal fixation.

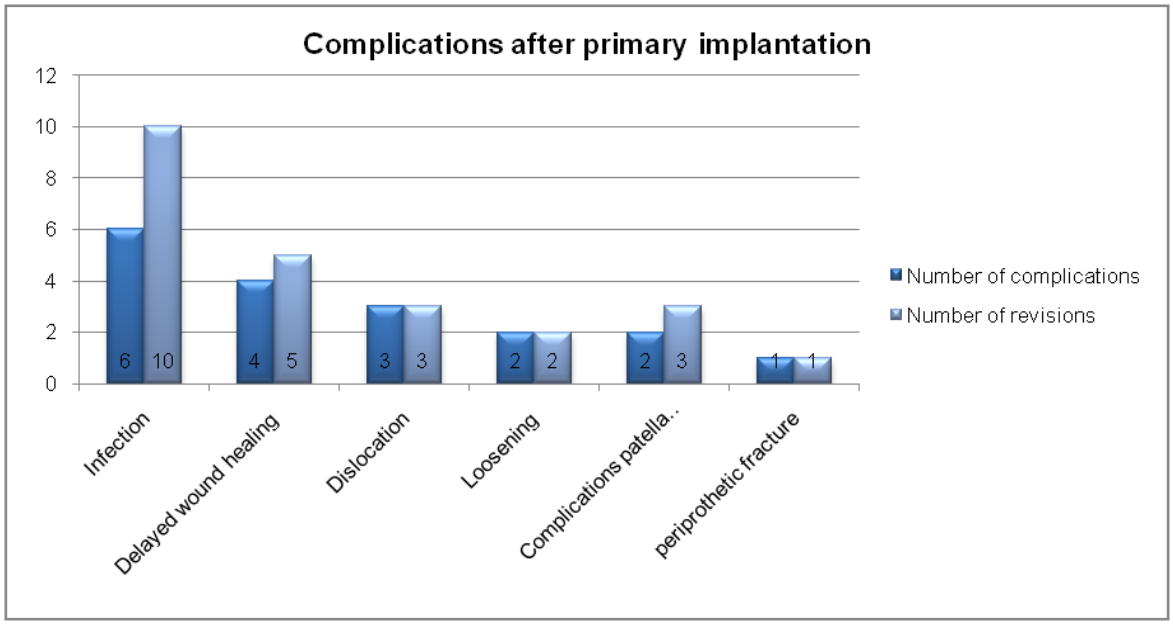


Fig.20: Complications after primary implantation of rotating hinge knee prostheses.

3.2.2.3.2.2 Early and late complications after reimplantation of a RHK

Twenty-five of all 43 complications (58%) resulted in 32 reoperations (57% of all revisions), which were performed in a group of 13 patients, after a failed prior TKA (Fig.21). Thirteen revision procedures (41% of all reoperations in this group) in eight patients were associated with the prosthesis itself. The first revision was

done at an average time of 5 months (range, 0-14 months) after the index revision procedure.

Seven cases of hematoma, hemato-seroma or seroma (26% of all complications in this group) in six patients were evacuated surgically within a mean time of one month (range, 0-6 months). The hinged tibial bearing was additionally changed in two cases. One patient was treated twice with incision and drainage, the first time two weeks after reimplantation of the RHK prosthesis and the second time six months after a one-stage revision arthroplasty due to a deep prosthetic infection.

Fourteen reoperations were necessary due to eight cases of deep prosthetic infection (30% of all complications in this group). The septical arthritis got apparent within 4 months (range, 12 days to 14 months) after reimplantation of the prosthesis or another revision procedure. Three infections became manifest within 4 to 15 days (mean, 10 days) after surgical evacuation of a hematoma or hemato-seroma. All three cases were treated with lavage and one-stage revision arthroplasty. After an infection-free interval of 11 months, one of these three patients had a recurrent deep prosthetic infection. This patient was revised three times before definitive reimplantation (spacer-spacer-spacer-reimplantation). Reinfection occurred 2 weeks later and it was treated with a one-stage revision procedure. Another case of prosthetic infection, 14 months after implantation, was treated with implant removal and insertion of a spacer. One month later, arthrodesis of the knee was done. The remaining two infection cases were treated with two stage exchange arthroplasties.

Five patients with prior revision procedures due to deep prosthetic infection were revised because of loosened implants (19% of all complications in this group), which occurred after a mean time of 15 months (range, 7-29 months). Refixation of the prosthesis was achieved by using bigger sized, cemented stems and autologous bone-grafting.

In one patient, refixation of a ruptured patella tendon, excision of a fistula and delayed wound healing, which was treated with a medial gastrocnemius flap (in all 7% of all complications in this group), was done.

Osteoarthritis and dislocation of the patella (7% of all complications in this group), 13 and 2 months after index surgery and heterotopic ossification (4% of all complications in this group) occurring within 11 months, were treated with patella-

resurfacing, changing the hinged insert accompanied by a lateral release and excision of the heterotopic ossification.

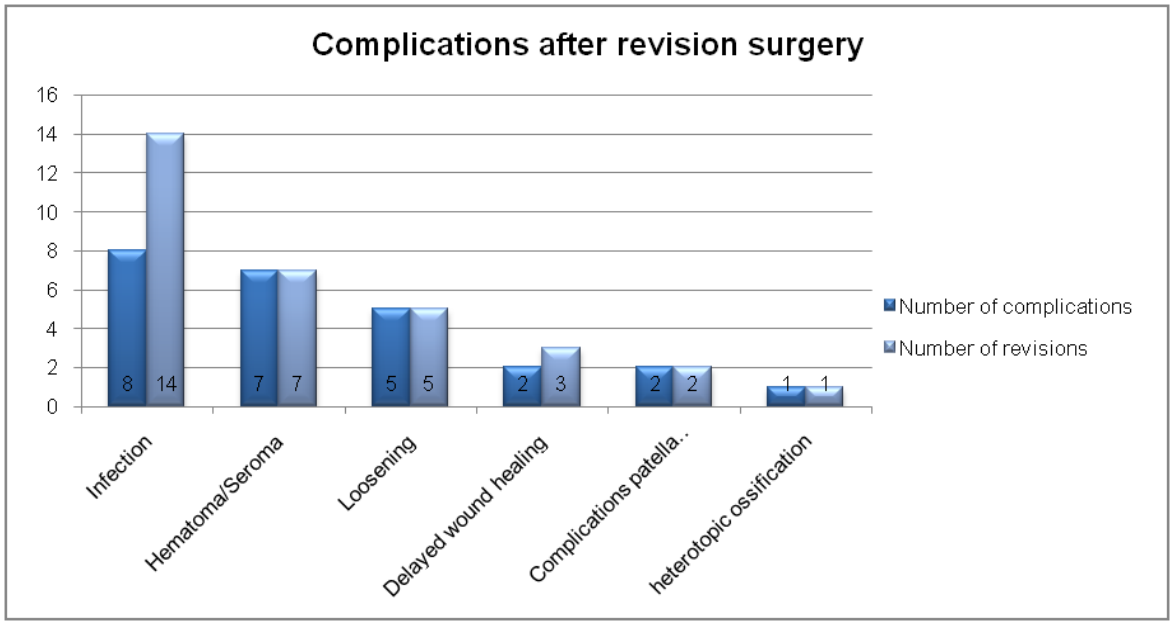


Fig.21: Complications after revision of a prior failed TKA.

3.2.3 Assessment of results

3.2.3.1 Scoring systems

Functional evaluation was performed by using three different rating systems. In the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC SCORE) three parameters–pain, rigidity and restriction in daily activities–were evaluated and rated from zero to four. Zero points was the best and 96 points the worst result.

Categorical points of the Knee Society Score (KSS) were divided into two parts. The first part included the evaluation of pain (0-50 pts), total range of flexion (1-25 pts), stability (anteroposterior: 0-10 pts, mediolateral: 0-15 pts), flexion contracture (minus 2-15 pts), extension lag (minus 5-20 pts) and tibio-femoral angle (minus 0-30 pts). The second part included parameters like walking (0-50 pts), stair climbing (0-50 pts) and used walking aids (minus 0-20 pts). All scores were added to produce a total KSS of hundred points for each part [107].

The third rating system was the Musculoskeletal Tumor Society Score (MSTS-Score). This score is a clinician scored system, rated from zero to five, assessing

pain, function and emotional acceptance in patients for upper and lower extremities. The need for supports, gait and walking ability are additionally evaluated in patients with lower extremity reconstructions. All scores are added to obtain the overall functional score and expressed as percentage rating of a total score of thirty points. Better functional outcome is indicated by a higher percentage [108].

3.2.3.2 *Physical examination/Function*

For functional evaluation, the active and passive total range of motion (ROM) and the clinical stability of the implant were tested. Furthermore, the circumferences of tight and shank were measured to determine, if the soft tissues of the popliteal fossa influence the amount of distraction of the hinged tibial insert during flexion. Additionally, the Body Mass Index (BMI) was calculated to verify, if patients with a higher BMI had higher circumferences of tight and shank.

3.2.3.3 Radiographic evaluation

For radiographic evaluation no rating system was used. Antero-posterior and lateral radiographs in extension were examined to look out for signs of loosening (changes in implant position, migration, radiolucency lines), instability or malaligment (Fig.22a&b).
In addition, conventional radiographs and radiographs of the knee made by a c-arm were taken from lateral in flexion. Both uptakes were made with a reference ball (diameter: 25 mm and 17 mm) to determine the distraction of the hinged tibial insert (Fig.22b&c). For the radiographs with the c-arm the patients were sitting on the edge of the examination table, with the knee in flexion (90° degrees). The leg was dangling and the distraction of the inlay was produced by the force of gravity.
Ultrasonography of the knee was performed to quantify the medial and lateral lift off distances in flexion and extension. Therefore a 9 MHz device (Siemens Elegra, Siemens AG, Erlangen, Germany) was used. The ultrasound head was positioned on the medial and lateral side of the knee until the echo of the hinged insert was detected (yellow arrow, Fig.22a). The ultrasound response of bone and metal was reported and differs from the distinct hyperechogenic signal of the hinged tibial

insert [109]. On freeze images the medial and lateral distance between the femoral and tibial component were measured in flexion and extension (blue arrow, Fig.23a). These measurements were repeated with varus and valgus stress for medial and lateral lift off (Fig.23a-h). To determine the medial and lateral lift off distances in each position, the measured distances in neutral position were subtracted from the measured distances made with stress.

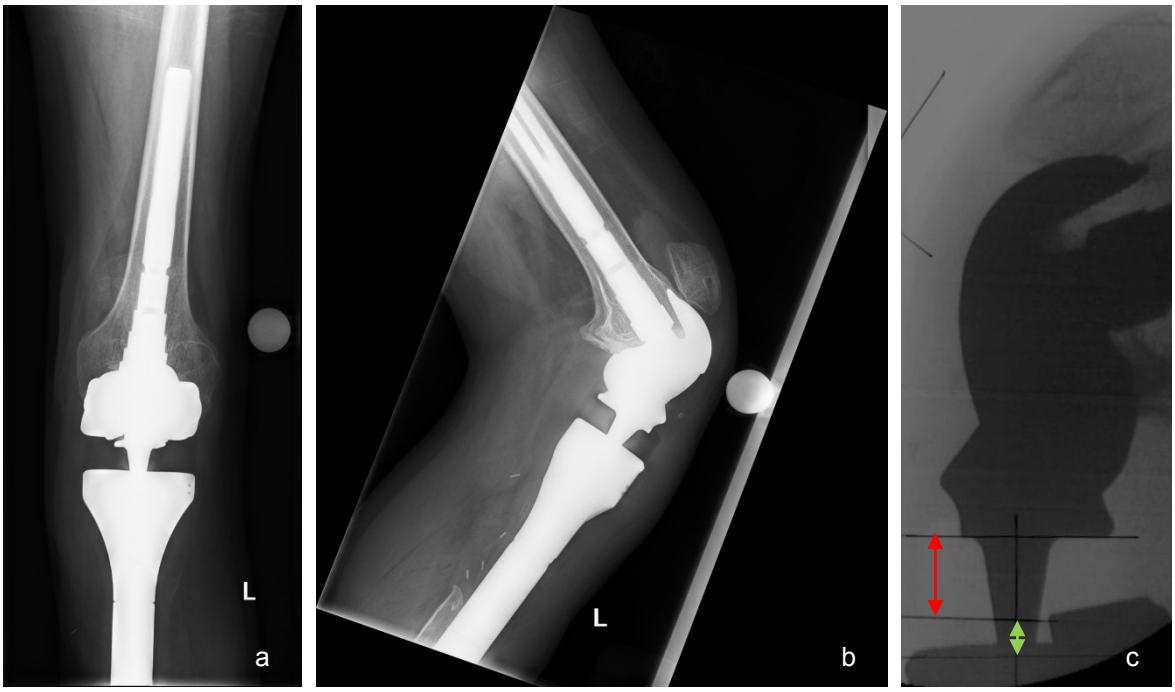


Fig.22a-c: a&b) Anterior-posterior and lateral radiograph of a LPS^{TM} prosthesis used for reconstruction of a proximal tibial osteosarcoma. c) Lateral view of the same prosthesis using a c-arm. The red arrow demonstrates the height of the 21 mm hinged tibial insert, while the green one demonstrates the distraction of the insert.

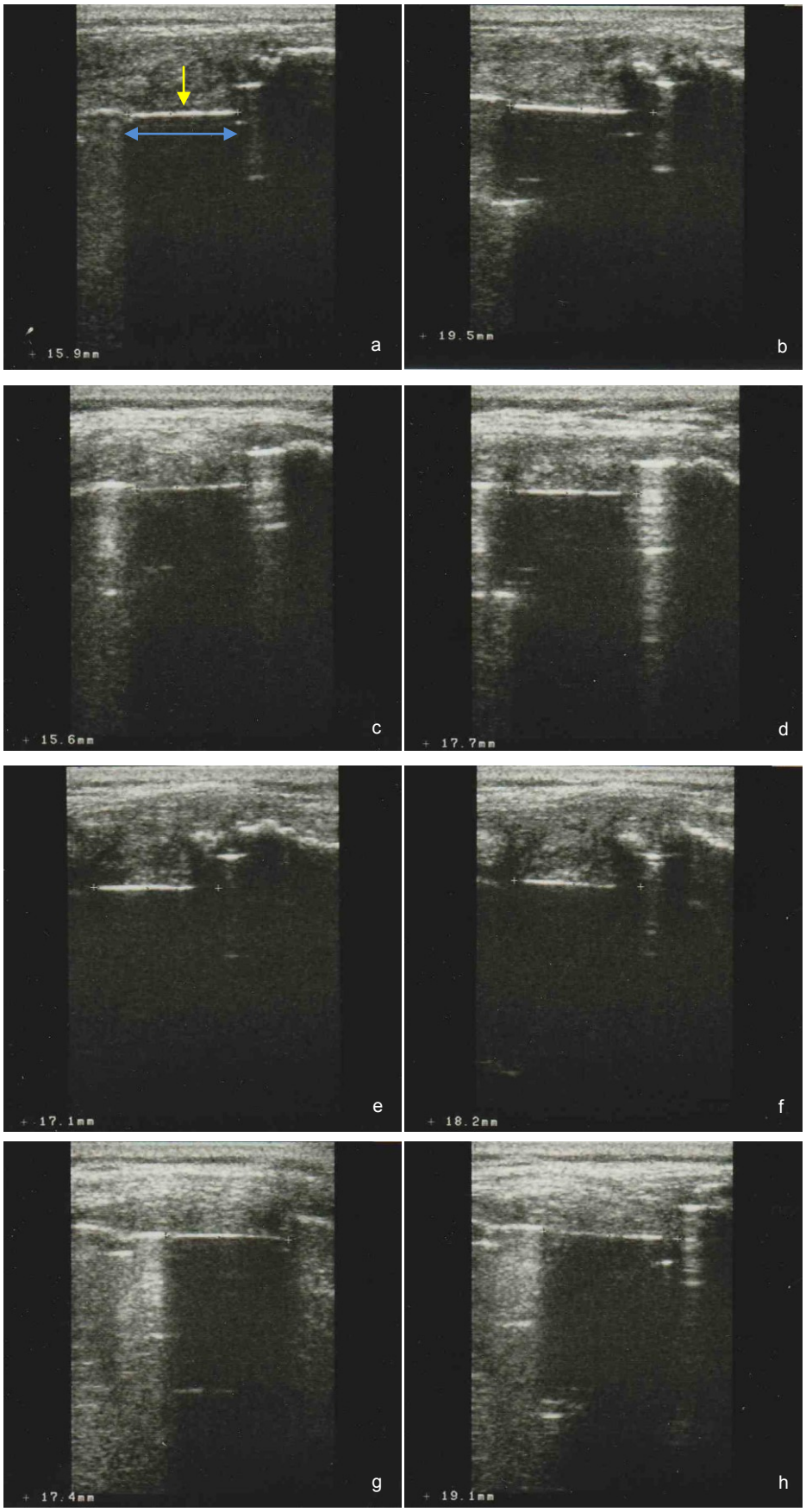


Fig.23a-h: Ultrasonography of the knee of a 28-years old patient after distal femoral replacement due to a chondrosarcoma G2. a-b) lat. extension with & without varus stress, c+d) med. extension with & without valgus stress, e+f) lat. flexion with & without varus stress, g+h) med. flexion with & without valgus stress.

3.2.4 Results

3.2.4.1 Study population

Of the initial 55 patients, nine died and the remaining 46 were asked if they wanted to take part in the clinical examination. Five patients were lost to follow-up, two of them returned to their home countries and three were not reachable. Twenty-five patients did not proceed with our request because of lack of interest. All in all, 16 (29%) of the 55 patients were followed-up. Demographic data of the patients divided by the used hinged insert bearing are shown in Table 7a&b.
The LPS^{TM}/M.B.T. hinged tibial insert was used in nine patients and the S-ROM Noiles insert was implanted seven times.

Pat. No.	Sex+age at operation (yrs)	Diagnosis	Localisation+side	Hinged insert	FU (months)
3	60, M	Infection TKA	femur distal, R	S-ROM	52
19	54, F	follicular Lymphoma G3	femur distal, L	S-ROM	51
21	62, F	Infection TKA	femur distal, L	S-ROM	36
24	48, M	Infection TKA	femur distal, L	S-ROM	31
26	73, M	Infection TKA	femur distal, L	S-ROM	48
50	79, M	Infection TKA	femur distal, R	S-ROM	49
54	75, M	Infection TKA	femur distal, R	S-ROM	19

Tab.7a: Data of patients with S-ROM Noiles hinged tibial bearing.

Pat. No.	Sex+age at operation (yrs)	Diagnosis	Localisation+side	Hinged insert	FU (months)
1	70, M	Infection TKA	femur distal, R	LPS	11
6	81, W	Infection TKA	femur distal, R	LPS	15
22	29, M	Osteosarcoma G3	tibia prox., R	LPS	23
25	19, M	Osteosarcoma G3	tibia prox., L	LPS	58
40	46, M	Osteosarcoma G3	tibia prox., L	LPS	43
42	38, F	myxoid Liposarcoma G2	femur distal, L	LPS	19
43	28, M	Chondrosarcoma G2	femur distal, L	LPS	9
44	79, F	Infection TKA	femur distal, L	LPS	10
48	40, M	Osteosarcoma G3	femur distal, R	LPS	44

Tab.7b: Data of patients with LPS^{TM}/M.B.T. hinged tibial insert.

3.2.4.2 Scoring systems

Patients, who had distal femoral or proximal tibial replacement with a LPS^{TM}/M.B.T. hinged insert bearing, had a mean WOMAC-Score of 18 points (range, 1-43 pts). The outcome was rated as excellent in five patients, as good in

two, as fair in one and as poor in one. Patients treated with an S-ROM Noiles device had an average WOMAC-Score of 26 points (range, 5-88). Four outcomes were excellent, one was good, one was fair and one was rated as poor. Figure 24 illustrates the average outcome of the WOMAC-Score for both implants. Overall, patients of the LPS™/M.B.T. group had less pain, stiffness and restrictions in daily activities compared to patients with the S-ROM Noiles device. These differences were statistically not significant (p=0,529).

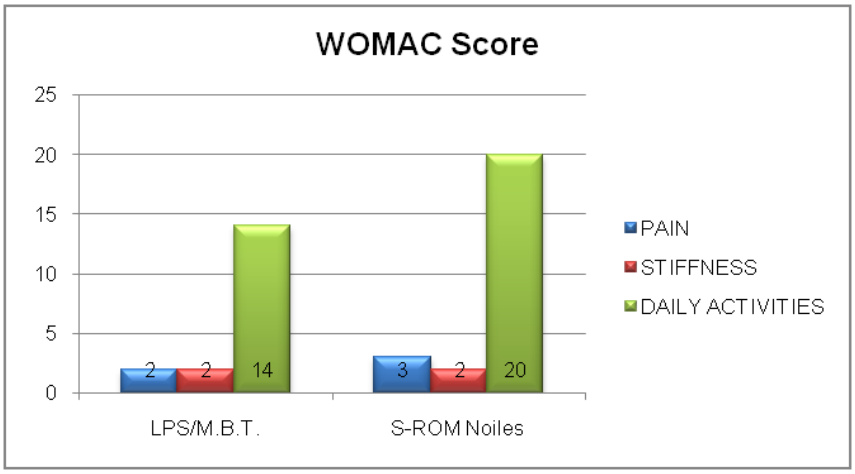


Fig.24: Average results of the WOMAC-Score, divided by category for each device.

The results of the first part of the KSS, assessing the function of the knee, were satisfying in both groups. The average score was 86 points (range, 65-100 pts) for patients with the LPS™/M.B.T. inlay. Six patients had excellent results, two patients had good results and one had a fair result. In comparison to that, the mean score for the S-ROM Noiles group was 84 points (range, 51-99 pts). Six results were rated as excellent and one as poor (Fig.25).

The second part of the KSS, evaluating the functional parameters walking, stair stepping and used walking aids, showed nearly the same results like the first part. If a patient had a good or excellent result with the first part, the result of the second part was also good or excellent. The reached maximum score for the LPS™/M.B.T. inlay was 100 points and the worst result was 55 points (mean, 79 points). All in all, the results of five patients were rated as excellent, three as good and one as poor.

Figure 26 shows the results of the S-ROM Noiles group, which were a bit worse than the results of the LPS™/M.B.T. group. The mean score was 63 points (range, 20-100 pts). Three results were poor, one was fair and three were excellent.

The poor results of the second part of the KSS in both groups arose from deduction for using walking aids like a cane or crutches. All in all, the differences between the groups were statistically not significant, neither for the first (p=0,855) nor for the second part (p=0,193) of the KSS.

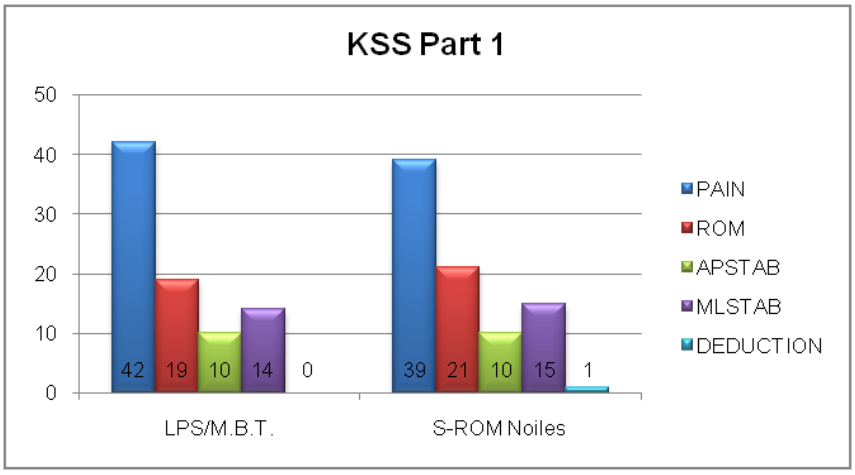


Fig.25: The Knee Society Clinical Evaluation, mean scores divided by category; APSTAB-anteroposterior stability, MLSTAB-mediolateral stability.

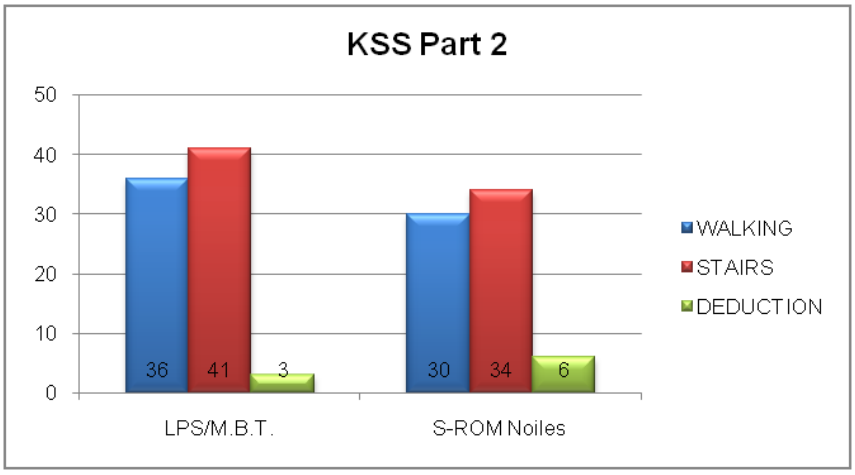


Fig.26: Mean scores for walking distance, stair climbing and used walking supports for each device group.

Patients, who had good or excellent results with the WOMAC-Score and the KSS, even had good or excellent results with the MSTS-Score. The mean percentage rating of the total score of thirty points was 74 percent (range, 40-100%) in the LPS™/M.B.T. group and 67 percent (range, 16-93%) in the S-ROM Noiles group.

Figure 27 shows the mean results of each parameter in both groups. The parameters pain, emotional acceptance, walking distance and used supports were better in the LPS^{TM}/M.B.T. group though six patients had a limb salvage situation due to a malignancy of the distal femur or the proximal tibia. Results for function and gait were better in the S-ROM Noiles group because the soft tissues in revision cases (six patients) were not as compromised as following wide tumor resection.

Overall, statistical analysis comparing the results of this scoring system showed not significant differences between the groups (p=0,537).

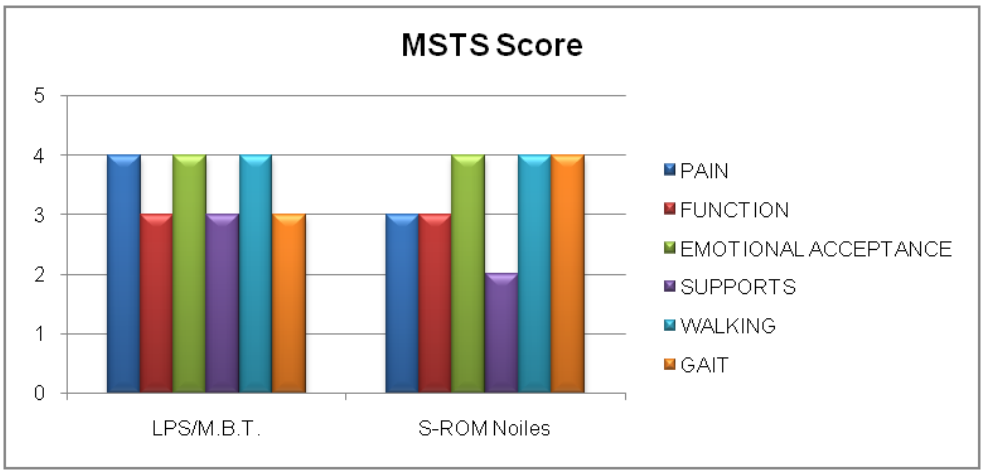


Fig.27: Average results of the MSTS-Score.

Two female patients had poor results in all three rating systems. One woman who underwent distal femoral replacement due to a follicular lymphoma G3, suffered from continuing pain and her walking distance was restricted to the household (Case 19; S-ROM Noiles group). She was unable to climb stairs and she had to use two canes to ambulate.

The diagnosis in the second case was a myxoid Liposarcoma G2 (Case 42; LPS^{TM}/M.B.T. group). The affected woman had pain occasionally but her total range of flexion was limited to 30° degrees due to resection and reconstruction of the extensor mechanism. Additionally, stair climbing was problematic.

3.2.4.3 Physical examination/Function

Flexion was measured with the patients lying on their backs on the examination table. The active total range of motion for the LPS^{TM}/M.B.T. implant ranged from

30 to 125 degrees (mean, 94 deg.), while the passive mobility showed 96 degrees (range, 30-125 deg.). The statistical analysis showed a highly significant correlation between active and passive ROM (Pearson: 0,998; p<0,00). Both the active and the passive total range of motion for the S-ROM Noiles implant ranged from 80 to 120 degrees (mean, active: 101 deg., passive: 105 deg.) and this correlation was also highly significant (Pearson: 0,947; p=0,001). An analysis of variance (ANOVA), comparing the total range of motion of the LPS^{TM}/M.B.T. and S-ROM Noiles implants showed no significant difference between the implants, neither for the active (p=0,585) nor for the passive arc of motion (p=0,497).

The clinical stability was tested with varus and valgus stress in extension. The stress was produce by an assistant, while the angulation was measured with a standard goniometer by an observer. The mean results of both implants are shown in Figure 28. Comparing the measured lift off-degrees of both implants showed no significant difference, neither for the medial (p=0,342) nor the lateral (p= 0,273) lift off. Testing the correlation between medial and lateral lift off for each implant, was also insignificant (LPS^{TM}/M.B.T.: p=0,552; S-ROM Noiles: p=0,973)

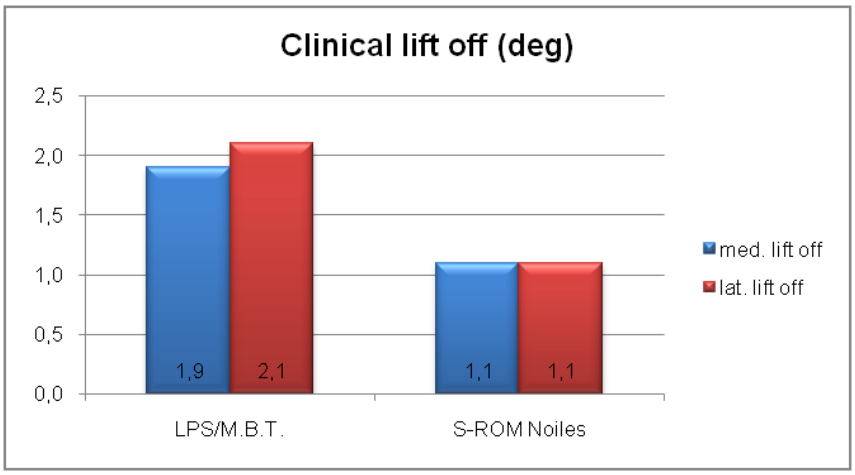


Fig.28: Results of the clinical stability test.

The mean Body Mass Index (BMI) of nine patients with the LPS^{TM}/M.B.T. implant was 25,3 (range, 21,5-34,5). The average circumferences of tight and shank were 39,5 cm (range, 35–43 cm) and 36,4 cm (range, 34–40 cm). Calculating the correlation between BMI and each circumference showed no significant result (tight: Pearson: 0,260, p=0,50; shank: Pearson: -0,106, p=0,786). Even the correlation between the circumferences of tight and shank was insignificant

(Pearson: 0,638, p=0,065). The BMI for seven patients in the S-ROM Noiles group ranged from 24,8 to 34,6 (mean, 28,5). The mean circumference of the tight was 41,5 cm (range, 38-44 cm) and 37,4 cm (range, 35-41cm) for the shank. In this group, the correlation between BMI and the tights' circumference was not significant (Pearson: 0,314, p=0,493). There was a correlation between BMI and the shank (Pearson: 0,768, p<0,04). The correlation between these circumferences was statistically significant (Pearson: 0,767, p<0,04).
Comparing the results of both implant groups showed no significant differences (BMI: p=0,102, cirr. tight: p=0,129, cirr. shank: p=0,397).
The correlation between distraction and the BMI was settled additionally. These results were statistically not significant, neither for the LPS™/M.B.T. nor the S-ROM Noiles implant (Tab.8).

Implant	Correlat. BMI/Distraction plain radiograph	Correlat. BMI/Distraction c-arm
LPS™/M.B.T.	Pearson: -0,165; p=0,671	Pearson: -0,069; p=0,859
S-ROM Noiles	Pearson: 0,098; p=0,834	Pearson: 0,217; p=0,640

Tab.8: Results of the calculated correlation between the BMI and the measured distraction for both implants.

3.2.4.4 Radiographic evaluation

In the anteroposterior and lateral plain radiographs, there were no signs of loosening, progressive or complete radiolucent lines or signs of instability. All components were found to be stable. One patient had clinical signs of a mal-rotated device because the lower leg made an external rotation throughout flexion.
The average distraction measured in the plain radiographs was 0,9 mm (range, 0-3,7 mm) for the LPS™/M.B.T. hinged tibial insert and 1,3 mm (range, 0-4,7 mm) for the S-ROM Noiles implant (Fig.29). An ANOVA analysis of the mean results showed no significant differences between the used inserts (p=0,53). The measurements with the c-arm resulted in a range of distraction between 0 to 7,1 mm (mean; 1,5 mm) for the LPS™/M.B.T. insert and 0 to 9,7 mm (mean, 2,5 mm) for the S-ROM Noiles insert. However, the p-value of the ANOVA analysis comparing the measured distraction of the two groups was also insignificant (p=0,49). There was only a significant correlation between the distraction measured in the plain radiographs and the x-rays of the c-arm (LPS™/M.B.T.: Pearson: 0,969; p<0,00001 and S-ROM Noiles: Pearson: 0,934; p=0,002).

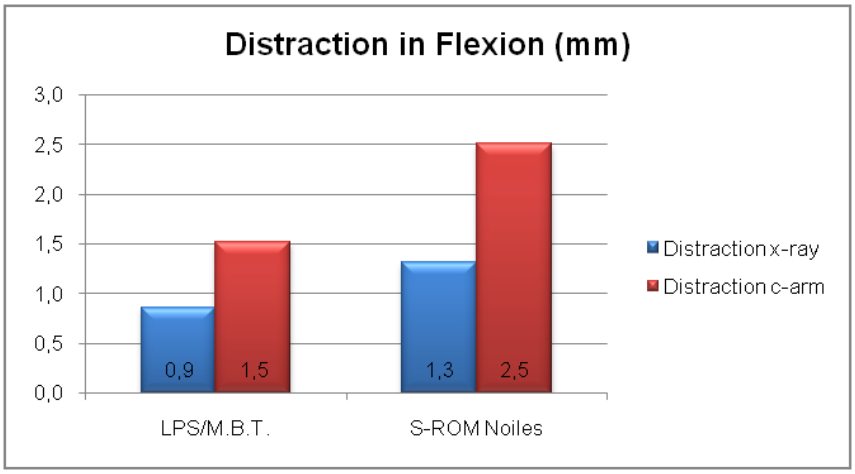
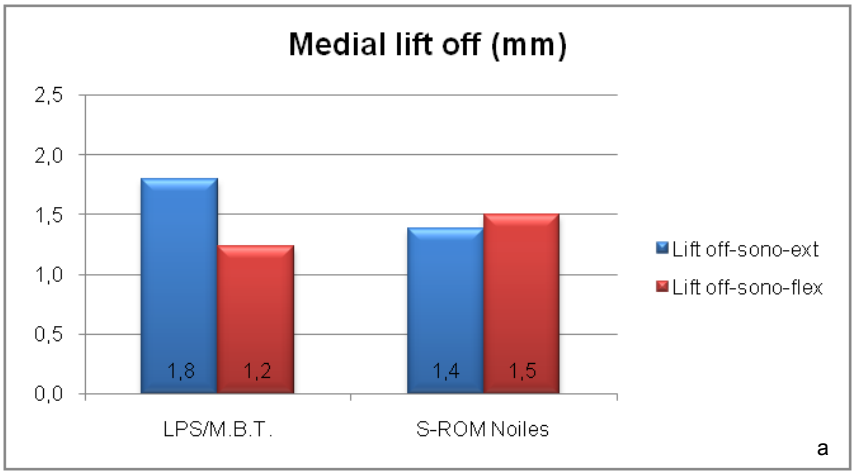


Fig.29: Mean distraction of each implant, measured in flexion with x-ray and c-arm.

Testing medial and lateral lift off with ultrasonography showed nearly the same results like the clinical stability check (Fig.30a&b). The LPS^{TM}/M.B.T. rotating hinge device showed higher medial and lateral lift off distances in comparison to the S-ROM Noiles implant, in flexion and in extension.

The measurements in extension showed a significant correlation between medial and lateral lift off distance for the S-ROM Noiles implant (Pearson: 0,829; p=0,021), while the lift off distances during flexion revealed a significant correlation for the LPS^{TM}/M.B.T. device (Pearson: 0,699; p=0,036).

Comparing the medial and lateral lift off distances during flexion and extension (ANOVA) presented insignificant results.



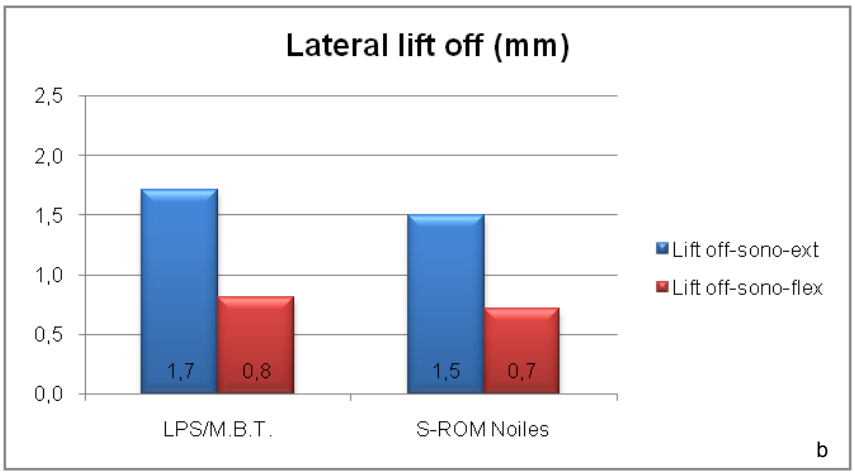


Fig.30a&b: Average results of the lift off test with ultrasonography.

3.2.4.5 Prosthesis survival

The method of Kaplan-Meier was used to compile the survival data of the prostheses. The analysis was done by using the Statistical Package for the Social Science (Version 16.0, SPSS Inc.).

Infection or implant loosening, requiring complete removal or revision of the majority of the implant, were used as events in the Kaplan-Meier analysis.

Time until the failure in months was the interval between the date of implantation and the date of revision. All other complications, which resulted in a revision procedure, were considered not to be a failure of the prosthesis. A censored observation was performed in all patients who had their original implant in place. The generated Kaplan-Meier survivorship curves between the LPS and S-ROM Noiles prostheses were compared with a log rank test. A p-value of <0,05 was considered to be significant.

With revision for infection or aseptic loosening as the endpoint, the estimated mean duration of prosthetic survival after primary implantation was 44 months (95% CI, 30 to 48 months) for the LPS^{TM} rotating hinge device and 48 months for the S-ROM Noiles prosthesis (Fig.31). There were no events in the two patients with the S-ROM Noiles prosthesis used for primary implantation. Therefore a prosthetic survival was not estimated. Overall, 76% and 61% of the LPS^{TM} prostheses were in place after 24 months and 48 months. After 44 months none of the S-ROM Noiles knees were revised. Testing the consistency of implant survivorship was not significant (log rank test, p=0,438).

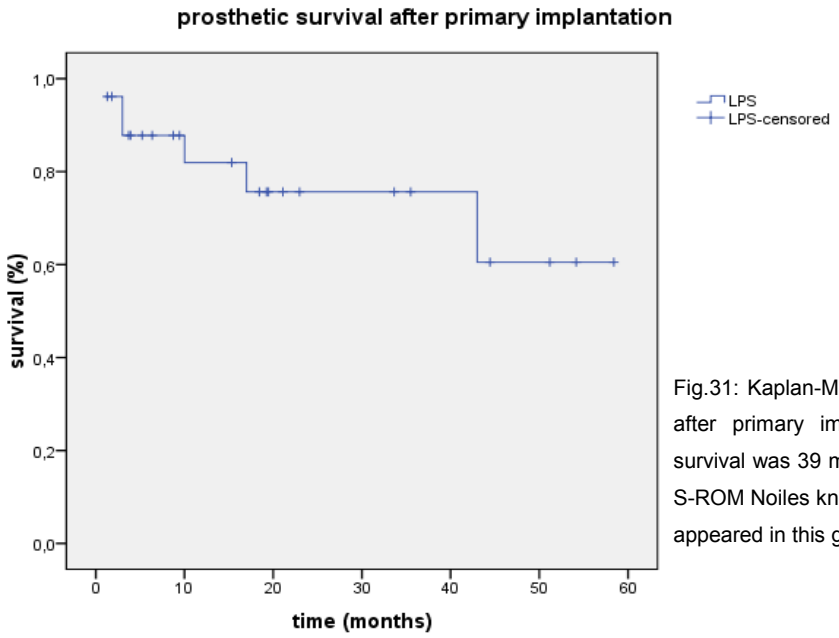


Fig.31: Kaplan-Meier curve of the LPS™ prosthesis after primary implantation. The mean estimated survival was 39 months. The Kaplan-Meier curve for S-ROM Noiles knee is not shown because no events appeared in this group.

The expected mean prosthetic survival in patients with a rotating hinge knee used for revision of a failed prior TKA was 30 months for the LPS™ prosthesis (95% CI, 19 to 41 months) and 45 months for the S-ROM Noiles knee (95% CI, 36 to 54 months). After 24 and 48 months, 64% and 48% of the LPS™ prostheses were in place. In comparison to that, 82% of the S-ROM Noiles prostheses survived the same period (Fig.32). Testing the distribution of implant survival for the LPS™ and S-ROM Noiles prostheses demonstrated no significant differences (log rank test, p=0,116).

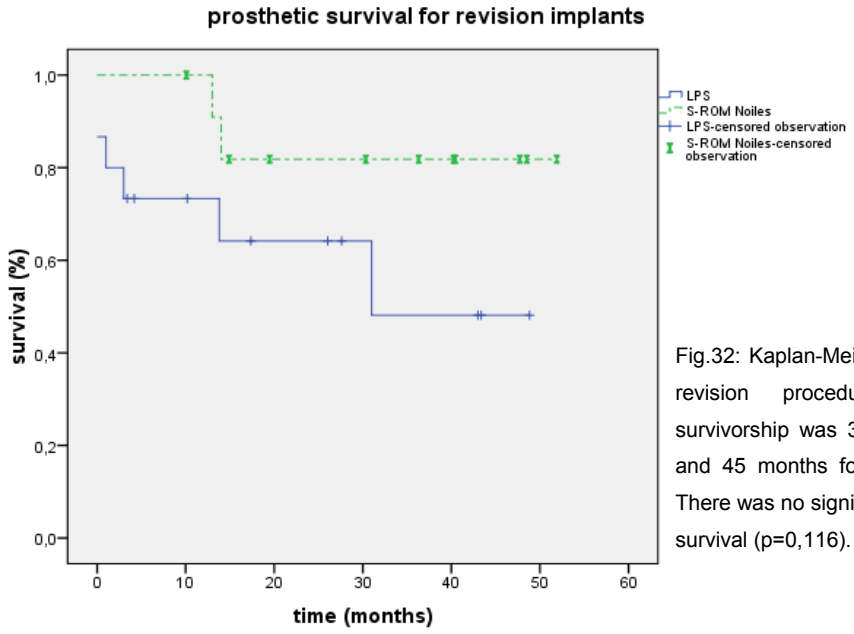


Fig.32: Kaplan-Meier curves of prostheses used for revision procedures. The expected mean survivorship was 30 months for the LPS™ implant and 45 months for the S-ROM Noiles prosthesis. There was no significant difference in time of implant survival (p=0,116).

Taking the two groups together (primary implantations and revision procedures) the approximated mean survival of the LPS™ prosthesis was 41 months (95% CI, 32 to 49 months) for aseptic loosening and infection, while the survival for the S-ROM Noiles prosthesis ranged from 37 to 54 months (mean, 46 months). After a period of 24 and 48 months, 72% and 57% of the LPS™ prostheses and 83% of the S-ROM Noiles implants were in place (Fig.33). The distribution of the implant survival was not significant (log rank, p=0,177).

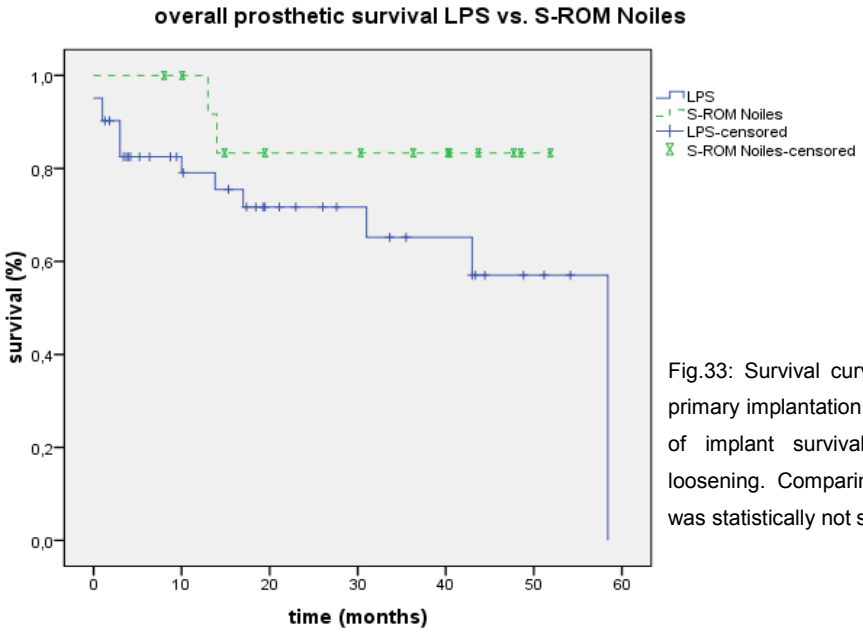
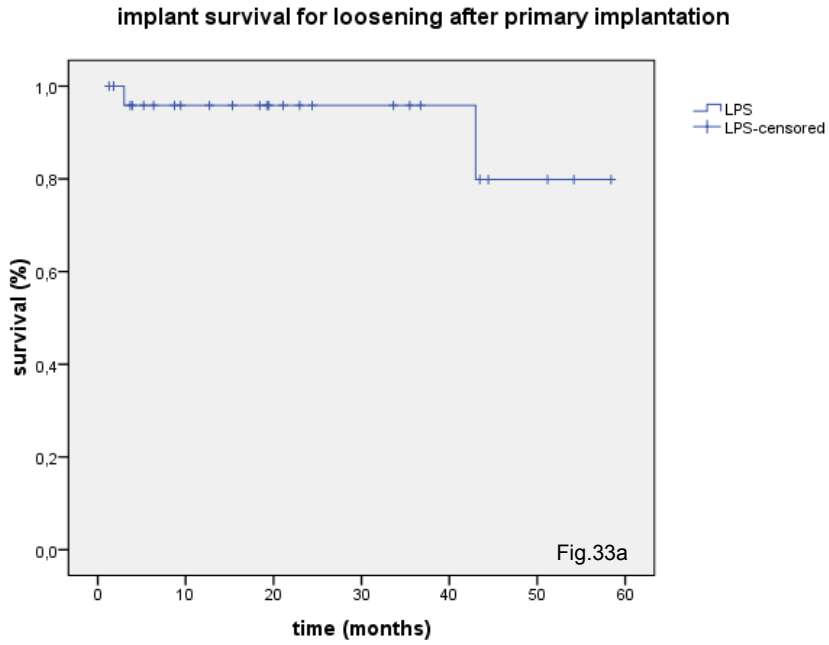


Fig.33: Survival curves of the prostheses used for primary implantation and revision surgery. Endpoints of implant survival were infection and aseptic loosening. Comparing the time of implant survival was statistically not significant (p=0,177).

Comparing the Kaplan-Meier curves of the LPS™ and S-ROM Noiles implants, used for primary and revision surgery with infection and aseptical loosening as the endpoint, showed no significant differences within the implant-groups, neither for the LPS™ (estimated mean prosthetic survival: 44 vs. 30 months; log rank: p=0,286) nor the S-ROM Noiles device (log rank, p=0,752).

The estimation for aseptic loosening after primary implantation and revision surgery yield mean survivals of 54 months (95% CI, 48 to 60 months) and 37 months (95% CI, 29 to 46 months) for the LPS™ implant (Fig.34a&b). There was no case of aseptic loosening in the S-ROM Noiles group and therefore statistical assessment could not be performed. Comparing the results of the Kaplan-Meier analysis revealed no significant discrepancy between both implants after primary implantation (log rank, p=0,617) but a significant better survival for the S-ROM Noiles implant after revision surgery (log rank, p=0,035).



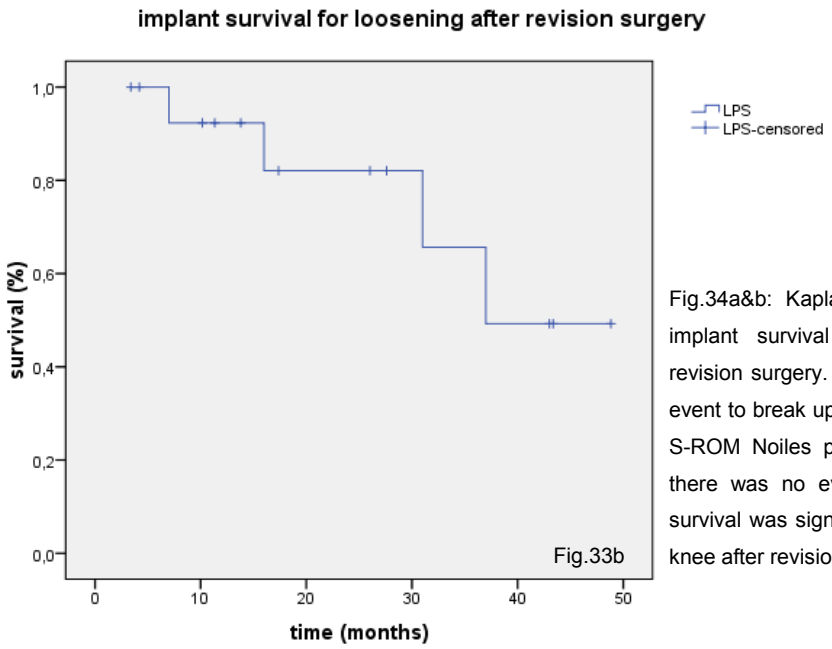


Fig.34a&b: Kaplan-Meier estimation of the LPS™ implant survival after primary implantation and revision surgery. Aseptic loosening was used as an event to break up the observation. The curves of the S-ROM Noiles prosthesis are not shown because there was no event in both groups. The implant survival was significant better for the S-ROM Noiles knee after revision surgery (p=0,035).

An overall comparison of the Kaplan-Meier curves for both implants and groups together, with aseptical loosening as indication for revision surgery and as endpoint of observation, showed no significant differences (log rank, p=0,095). The estimated mean survival was 49 months for the LPS™ rotating hinge knee (95% CI, 42 to 56 months). No revision had to be done for aseptical loosening in the S-ROM Noiles patients, neither after primary implantation nor after failed previous TKA.

Six patients in the LPS^{TM} group were revised due to aseptical loosening, two after primary implantation and four after revision surgery. There were no worth mentioning differences for the LPS^{TM} implant survival when comparing the primary and revision group (estimated mean prosthetic survival: 54 vs. 37 months; p=0,144) (Fig.35).

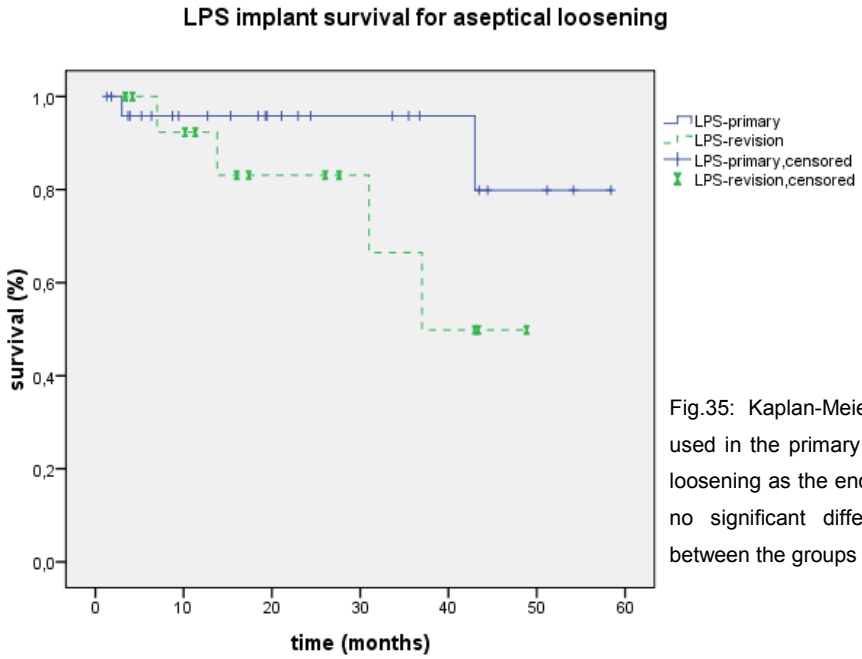
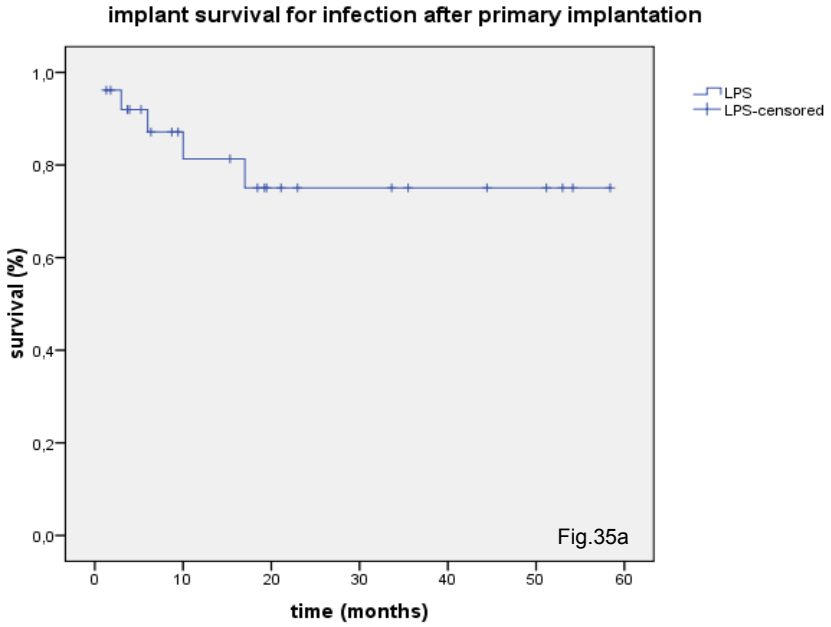


Fig.35: Kaplan-Meier curves of the LPS^{TM} device used in the primary and revision group with aseptic loosening as the endpoint of observation. There was no significant difference in the implant survival between the groups (p=0,144).

Five revision procedures due to early or late deep prosthetic infection had to be done in the LPS^{TM} group after primary implantation. The mean prosthetic survival for this device was 46 months (95% CI, 36 to 56 months). In the two patients with the S-ROM Noiles knee, there was no event (Fig.36a). The log rank test showed no differences for implant survival (p=0,521). Another six patients in the revision group (four LPS^{TM} and two S-ROM Noiles prostheses) had reoperations due to prosthetic infection. The estimated survival was 36 months for the LPS^{TM} (95% CI, 25 to 47 months) and 45 months for the S-ROM Noiles implant (95% CI, 36 to 54 months; Fig.36b). Differences of implant survival were statistically not significant (log rank, p=0,391).



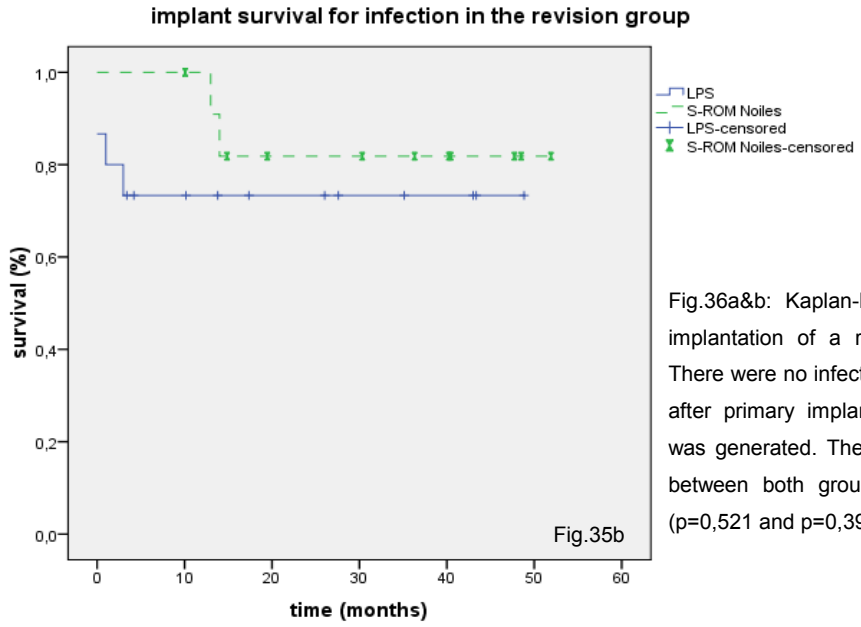


Fig.36a&b: Kaplan-Meier curves of infection after implantation of a rotating hinge knee prosthesis. There were no infections in the S-ROM Noiles group after primary implantation and therefore no curve was generated. There was no significant difference between both groups in time of implant survival (p=0,521 and p=0,391).

Overall, the estimated mean prosthetic survival was 46 months (95% CI, 39 to 54 months) for the LPS^{TM} device and 46 months for the S-ROM Noiles implant (95% CI, 37 to 54 months) for infection as reason for implant removal (Fig.37). The log rank test showed no significant differences between the devices (p=0,499).

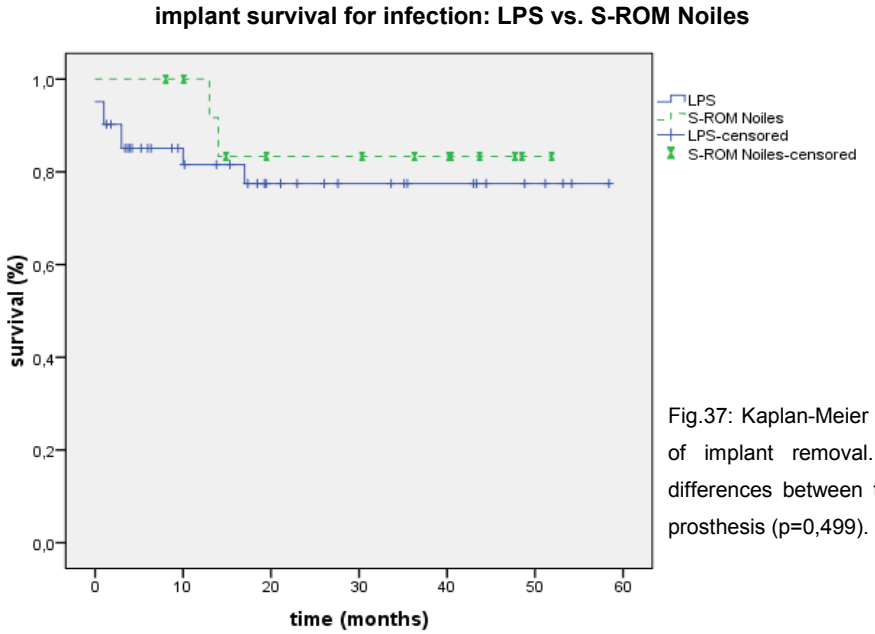


Fig.37: Kaplan-Meier curves of infection as a cause of implant removal. There were no significant differences between the LPS™ and S-ROM Noiles prosthesis (p=0,499).

Comparing the implant survival (LPS™ or S-ROM Noiles prostheses) between the primary and the revision group, for infection as the endpoint, was insignificant (log rank: p=0,539 and p=0,662). The mean survival for the LPS™ device was 46 months (95% CI, 36 to 56 months) after primary and 36 months (95% CI, 35 to 47 months) after revision surgery (Fig.38a). The S-ROM Noiles knee had a mean survival of 45 months (95% CI, 36 to 54 months) after revision surgery (Fig.38b). There were no infections in patients with S-ROM Noiles prostheses after primary implantation.

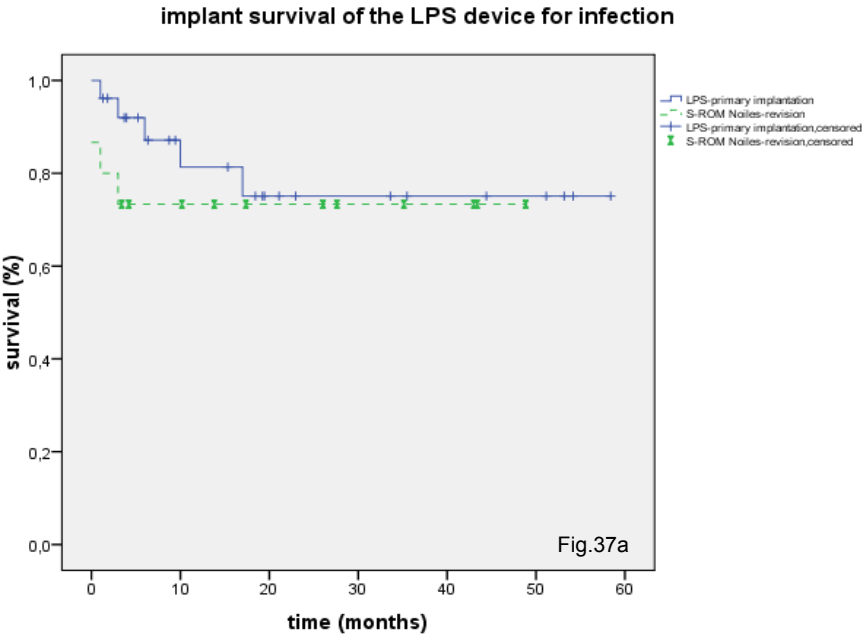


Fig.37a

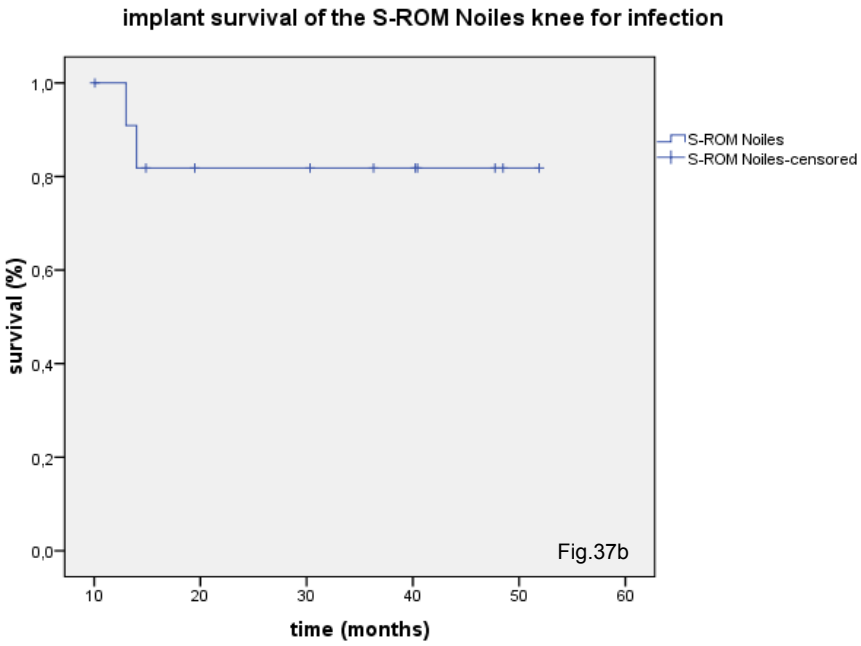


Fig.38a&b: Kaplan-Meier curves comparing the implant survival for infection used for primary implantation and revision procedures, separated for each device. There was no significant difference of the survival between the LPS™ and the S-ROM Noiles prosthesis (p=0,539 and p=0,662).

3.2.5 Discussion

At the beginning “megaprostheses” with a fixed hinge or rotating hinge articulation were custom made and only used for reconstruction of the knee following tumor resections [5, 25, 36, 43, 44, 62]. By increasing experiences with limb salvage procedures, the demand of megaprostheses rose by using these prostheses in cases of metastatic disease, comminuted periarticular fracture and salvage revision total knee arthroplasty [8, 31, 34, 36, 42, 47, 56, 62, 110].

With the evolution of adjuvant and neo-adjuvant chemotherapy, improvement of radiographic imaging and surgical technique, limb salvage surgery has become a universally accepted treatment for primary bone tumors of the extremities [8, 10, 15, 25, 28, 29, 37, 40, 46, 49, 50, 73, 77, 78, 80, 82, 83, 86-89, 95, 96, 101, 111-119]. The most common sites of primary bone tumors and metastatic lesions are the distal femur and the proximal tibia [8, 15, 25, 26, 29, 46, 49, 51, 52, 80, 82, 86, 101, 116, 117, 120, 121]. Wide resection and reconstruction with an endoprosthesis, osteoarticular allograft, allograft-prosthetic composite, arthrodesis or rotation plasty were described for treatment of neoplasms at this site [10, 22, 25, 29, 37, 46, 49-51, 65, 73, 77-86, 89, 96, 100, 101, 115, 117, 121]. Indications for endoprosthetic reconstruction in patients with metastatic disease are extensive bone loss, revision of failed conventional intralesional reconstruction and selected cases with isolated solitary metastases with the intent to cure [62, 110]. Several studies showed that patients treated with limb salvage surgery had equal or even better survival rates than patients treated with amputation [8, 15, 22, 26, 29, 46, 50, 51, 82, 87, 88, 96, 100, 115, 117, 119, 122]. Nonetheless, there is a small increase in risk of local recurrence (reported range, 1-10%), which is often accompanied by a worse prognosis [15, 26, 29, 44, 50, 78, 80, 87, 89, 114-117]. Zimel at al. recently showed similar recurrence rates in patients having implant reconstruction and those having condyle sparing allografts (11% vs. 18%). In cases of local recurrence both techniques were accompanied by a fourteen times higher likelihood to die of the underlying disease ($p<0,0001$) [89]. According to Enneking et al., a wide resection has to be accomplished to avoid a relapse [67].

Overall, the 5-year survival rate of patients with tumor endoprostheses increased from 20% to 85% in the last 30 years, depending on the tumor's entity [10, 11, 15, 28, 43, 49-51, 69, 73, 82, 83, 87, 94, 111, 113, 120, 121].
Revision total knee arthroplasty is often complicated by severe bone defects, global ligamentous instability and compromised soft tissues. Akin to limb salvage procedures for tumor entities, non-neoplastic disorders in revision total knee arthroplasty often require a modular rotating hinge implant to maintain continuity of the skeleton [5, 34, 56, 74]. Currently there is a trend towards modular revision implants that offer a variety of reconstruction options but constrained condylar components remain the benchmark for revision total knee arthroplasty [5, 23, 41, 45, 60]. Independent from the indication and compared to other methods of joint reconstruction, endoprosthetic replacement offers several advantages such as early stability, mobilization and weight bearing [8, 11, 15, 25, 40, 41, 43, 44, 47, 48, 50, 62, 78, 79, 83, 85, 86, 96, 111, 113, 115, 121].

The latest generation of hinged prostheses incorporates a rotating hinge articulation with a metal-on-polyethylene bearing surface which allows axial rotation. This mechanism is intended to address failures of earlier fixed hinge designs and produced good short-term and mid-term results [5, 25, 27, 29, 32, 37, 38, 42, 45, 55, 60, 111, 121, 123].

The functional result of limb salvage procedures for tumoral and non neoplastic indications depends on the extent of bone and soft tissue resection, the used reconstructive technique, the prosthesis design, efforts of rehabilitation and motivation and cooperation of the patient [25, 57, 73, 80]. Renard et al. described significant better functional outcome after limb saving surgery compared to ablative procedures (p=0,0001), while a comparison of different limb salvage procedures (endoprosthetic reconstruction vs. arthrodesis vs. rotationplasty) produced no significant differences [118, 119]. Earlier series found that disability and impairment scores were slightly better in patients with a rotating hinge knee compared to patients with fixed hinge prostheses [8, 25, 43, 44, 48, 73, 77, 85, 116, 121]. Distal femoral resection and reconstruction produces better functional outcome than proximal tibial reconstruction [37, 44, 49, 85, 113, 114]. On the

contrary, Balke et al. described best results for proximal tibial reconstruction followed by distal femoral replacement [87].

In the present study, the functional outcome and the scoring systems revealed good to excellent results for the LPS^{TM}/M.B.T. and S-ROM Noiles devices. Like in earlier series, slightly better function was found in patients treated for non-tumor conditions compared to patients treated for neoplasms [38, 124]. Overall, the total range of motion was excellent in both implant groups, except for two patients with a LPS^{TM}/M.B.T. device, whose flexion was limited to 30° and 50° degrees. Extensive soft tissue resection or compromise, resulting in a weak extensor mechanism, was responsible for the worse arc of motion.
In addition, revision procedures in tumor patients gave poorer results than in non-tumor patients. Overall, comparing the functional results and the results of the scoring systems showed no significant differences between the implant groups.
Wirganowicz et al. and Ward et al. found a reduction in functional rating after revision procedures, while several others investigators declared that a second revision procedure does not cause a deterioration [15, 25, 28, 41, 48, 73, 79, 85, 86, 95, 111, 113, 119, 125]. Springer et al., using the Kinematic Rotating Hinge for complex knee arthroplasty, observed improvements in pain relief and ROM but the functional results did not improve compared to the preoperative situation [56].
A gait and stair stepping analysis showed that young patients with rotating hinge knee prostheses were able to carry out the activities of daily life with little significant differences from normal. Older patients were able to complete the functions as well as patients treated with semi-constrained prostheses [57]. In the current study most patients were content with their way of walking even though they had to use a walking aid. All patients preferred limb salvage situation with limited function than arthrodesis or amputation.

The clinical stability test, showed low varus-valgus angulation for both implants in extension, although little higher degrees for medial and lateral lift off could be observed in patients with a LPS^{TM}/M.B.T. implant. This finding was verified by measurements with ultrasonography in flexion and extension which even showed that the S-ROM Noiles rotating hinge knee was more robust against varus and valgus stress. On the other hand, the measured distraction was lower in patients

with the LPS™/M.B.T. prosthesis than for patients with the S-ROM Noiles knee system. Most of the LPS™/M.B.T. implants were used in patients who had an intraarticular tumor resection, with a loss of all ligaments required for joint stability. For this reason, the implant, the new formed capsule and the remaining soft tissues have to maintain joint stability. It seems that soft tissue reconstruction, especially in tumor cases, prevents distraction of several millimeters but it does not influence implant's stability against lateral directed forces.

Prosthetic survival and clinical outcome of all modular tumor and revision systems are clearly inferior compared to conventional total hip or total knee systems [36, 45, 49, 126]. This established and approved fact is caused by large osseous defects which need to be bridged, soft tissue defects, more difficult fixation techniques and more complex restoration of joint biomechanics [7, 22, 24, 32, 36, 40, 41, 43, 53, 54, 60, 80, 84, 87, 89, 95, 115, 124, 127, 128].
Mechanical failure, aseptic loosening, infection and periprothetic bone fracture are still the most common complications [25, 29, 37, 40, 41, 50, 51, 56, 60, 73, 84, 87, 94, 96, 113, 116, 117, 120, 121, 125].
Several authors showed in their series that the trend for prosthetic survival from best to worst was proximal femur, proximal humerus, distal femur, proximal tibia and distal humerus [37, 47, 49, 66, 83-86, 96, 119, 120]. Anatomical site, poor quality cement fixation and the extent of bone resection were associated with revision, while the patient's age had no effect on the prosthetic survival [11, 26, 40, 83, 84, 94, 100, 116, 119, 120]. Griffin et al. and Capanna et al. described small stem diameters associated with increased prosthetic failure rates (p=0,01) [10, 96, 116]. Additionally, the body weight and level of activity were identified as independent predictors of early revision [25, 84, 111, 119, 120]. Gitelis et al. found higher failure rates in patients who underwent chemotherapy but the fixation techniques (press-fit vs. cementation) did not affect implant's survival [96].

Aseptic loosening:

Segmental endoprosthetic reconstructions following tumor excision or revision total knee arthroplasty are at risk of aseptic loosening. Several studies suggested, that aseptic loosening is the most frequent cause of failure, followed by infection

[10, 11, 15, 39, 43, 48, 51, 69, 73, 79, 84, 85, 100, 113, 119, 120, 125]. It is well known that single hinge prostheses have higher loosening rates (range, 0-35%) [10, 11, 15, 22, 36, 37, 40, 48, 51, 62, 73, 79, 80, 83-85, 111, 112, 116, 120, 123], than rotating hinge knee prostheses (range, 0-17%; Tab.9) [8, 24, 34, 39, 41-45, 50, 56, 60, 89, 100, 114, 117, 121, 123, 124].

Overall, the rate of aseptic loosening was 13% (seven cases) for the femoral component in the current series. Two implants were loosened after primary implantation (7% of all complications after primary implantation of a RHK) and five devices, used for revision procedures (19% of all complications in the revision group). There were no loosened tibial implants. All prostheses were cemented or hybrid, except one press fitted implant in a young patient. Gitelis et al. as well observed a high loosening rate of 15% in cemented femoral stems [96]. Nevertheless, the rate of aseptic loosening was comparable to the rates of aseptic loosening reported in the literature (range, 9-17%, Tab.9) [34, 56, 60, 89].

Aseptic loosening often occurs in the distal femur, followed by the proximal tibia and in younger patients due to a higher level of activity [15, 65, 73, 79, 84, 87, 111, 113, 115, 120, 129]. In the current study, the mean age of patients with loosened implants was about 63 years (range, 17-85 years). Therefore it is plausible to conclude that the age and the level of activity were not responsible for implant loosening. We only found that four of seven cases of implant loosening got apparent at a mean time of 12 months after deep prosthetic infection (= secondary aseptical loosening).

Reports in the literature demonstrated that the risk of aseptic loosening of single hinge or rotating hinge prosthesis is related to the percentage of femoral bone loss (at least 40 percent) and anatomical location [11, 25, 36, 40, 79, 84, 116, 120]. Unwin et al. identified patients, under the age of twenty years with more than 60% of the bone resected, who had the poorest prognosis for prosthetic survival [120]. The extent of soft tissue resection is another important factor on the impact of prosthetic survival. Total or subtotal resection of the extensor mechanism is associated with poorer outcome, because the impaired function of the quadriceps increases the transferred stress to the fixation interface [11, 25, 40, 86, 94, 101, 125, 129]. Morris et al. and Capanna et al recommended arthrodesis of the knee, if the whole quadriceps muscle was resected [95, 130].

Blunn and Wait and Kabo et al. hypothesized that aseptic loosening is caused by mechanical failure at the bone-cement-implant interface and poor cementing technique [28, 100, 129]. Blunn and Wait suggested tapered, partially coated stems as a suitable alternative to reduce the incidence of implant loosening [85, 129]. Jeon et al. also found a significant trend of less aseptic loosening in uncemented prostheses at two and five years follow-up (p=0,041) [86]. Joshi et al. advised the application of appropriated sized stems, based on the metaphyseal bone loss but the fixation technique can be individualized [35].

The cementation of the condylar surface of the prosthesis and the usage of press-fit stems prevent stress shielding seen in cemented stems [53, 126]. Wood et al. reported a prosthetic survival rate of 98% at 12 years for aseptic loosening using press fit stems in revision TKA. This study suggested that press-fit stems in revision TKA provide similar outcome as cemented stems, regardless of increasing prosthetic constrained [126].

Several manufacturers provide components with circumferential extramedullary porous ingrowth material and porous coated intramedullary stems to address the problem of aseptic loosening [25, 29, 34, 73, 101]. Ward et al. postulated that a new formed periprothetic fibrous capsule grows into the circumferential extramedullary porous material, proximal to the bone-prosthesis interface and therefore bone lysis caused by debris-laden synovial fluid, is prevented [39].

Shin et al. reported their 10-20 years experience with large tumor prostheses and extracortical bone bridging (EBB) [124]. These authors and several others did not conclude that EBB was responsible for extended longevity of megaprostheses but it enhances the strength of fixation at the prosthesis shoulder-host bone interface. Therefore several forces are transmitted to the cortex of the host bone directly [25, 36, 39, 43, 44, 48, 82, 100, 124]. Samuelson and Riaz related satisfactory short-term results using cementless components and bone grafting for revision of failed cemented total knee arthroplasty [53, 131]. Steens et al. even reported their satisfying results of revision TKA using hinge or rotating hinge knee prostheses combined with impaction bone grafting (IBG) [75].

Nevertheless, there is no conclusion whether the stem should be cemented or press fitted but it should be individualized to the patients' situation.

Infection:

Infection is one of the worst complications after endoprosthetic reconstruction because it causes bone resorption and therefore loss of bone stock. Reconstruction following infection is difficult and often unsuccessful. Deep prosthetic infection is more frequent in hinged and rotating hinge knee arthroplasty, even for non tumoral disease [12, 22, 25, 34, 46-48, 73, 123]. In the literature, infection rates range from 0 to 36% for tumor entities [8, 10, 11, 15, 29, 36, 37, 40, 44, 46, 50, 62, 73, 80-85, 89, 94, 96, 100, 111, 112, 114, 116, 120] and from 0 to 19% for non tumoral disorders [5, 24, 27, 34, 38, 41, 42, 45, 56, 60, 123, 127].

In the current series, the overall infection rate was very high (25%) due to the non-homogenous group of patients (primary implantation vs. revision surgery). Six infections occurred after primary implantation (= infection rate of 21% following primary implantation of a RHK), while eight occurred after the revision of a previous failed TKA (infection rate of 30% after the usage of a RHK for revision surgery). Several other studies, using rotating hinge prostheses, revealed high infection rates ranging from 10 to 17% (Tab.9) [24, 37, 45, 56, 73, 127]. Early infections were treated by a one-stage revision procedure with debridement of all infected tissue, lavage and replacement of the polyethylene inlay, such as described in the literature [87]. In cases of a deep prosthetic infection, a two- or more-staged revision procedure with a temporary antibiotic loaded cement spacer, prior to reimplantation, became inevitable [46]. Uncontrollable persistent infection often necessitates secondary arthrodesis or amputation, sometimes thought to give more satisfactory results [10, 46, 59, 70, 73, 76, 84, 87]. Azzam et al. advocated a second two-stage revision TKA in cases of persistent infection to avoid arthrodesis or amputation [76]. The reported amputation rates range from 0,02 up to 6%, otherwise there are success rates of 97 to 100% related after two-stage exchange arthroplasty [70]. Nevertheless, delayed aggressive treatment of deep infection leads to progressive bone loss and secondary implant loosening.

Primary muscle flap coverage of megaprostheses serves to decrease infection rates, especially when the proximal tibia replacement component is used. In addition the muscle act as bed for split-skin graft and can be used for reconstruction of the extensor mechanism [29, 39, 44, 46, 48-52, 71, 73, 80-82,

87]. Grimer et al., Myers et al. and Horowitz et al. reported several patients with proximal tibial reconstruction following tumor resection [29, 46, 51]. Their initial results were poor due to high rates of wound breakdown and infection. Grimer et al and Myers et al. showed a significant reduction of the infection rate using a medial gastrocnemius flap for implant coverage. In this series, one case of deep prosthetic infection occurred after proximal tibial replacement, despite soft tissue coverage.

To ensure complete implant coverage, Chim et al. and Bickels et al. proposed the use of supplementary muscle flaps such as the hemisoleus, gracilis and semimembranosus [8, 81]. These authors reviewed five distal femoral and five proximal tibial reconstructions and no complications related to the megaprostheses (infection, loosening or polyethylene wear) occurred at a mean follow-up of 32 months. Kawai et al. found a higher risk of skin necrosis and/or infection when most of the quadriceps muscle was resected [40].

Dislocation/Mechanical failure:

Dislocation and mechanical failures of modern rotating hinge knee prostheses are rare complications. In most cases, dislocation is associated with implant's breakage or fatigue failures. Distraction disengagement is another mechanism for dislocation, but it has never been reported in the literature until now.

There are only some reported cases of dislocated rotating hinge knee prostheses [32, 35, 44, 94, 104, 106]. In most cases, dislocation occurred due to the breakage of any prosthesis' component or fatigue of the tibial antidislocation device. Excessive flexion gap instability and posterior dislocating forces were supposed to cause the mechanical failure of the prostheses.

Of the initial 55 joint reconstructions in the current series with the LPS^{TM}/M.B.T. and S-ROM Noiles rotating hinge knee, four dislocations occurred (overall complication rate: 5%). Two dislocations resulted from direct trauma to the knee, one device dislocated due to a loosened femoral component and one implant dislocated due to a fractured metal yoke, inside the polyethylene inlay. The complication rate of 5% was within the reported limits for dislocation and mechanical failures (range, 1-16%, Tab.9) [8, 24, 34, 44, 56, 89, 100, 114, 123].

3.2.6 Conclusion

Following tumor resection or revision total knee arthroplasty, implant selection is based on the severity of bone loss, the status of the ligaments and the soft tissue stabilizing structures. Though there are several methods of reconstruction, all of them have several drawbacks that might outweigh the potential benefits. The benefit of the early functional returning is often offset by the outlook of a revision procedure in the future.

The clinical study revealed that a stable joint reconstruction could be achieved with both tested rotating hinge devices. Although patients with the LPS^{TM}/M.B.T. implant had higher lift off distances, the distraction of this implant was lower compared to the S-ROM Noiles device. The majority of the patients were satisfied with their functional outcome and even the scoring systems revealed good to excellent results, despite deductions for using walking aids in some cases.

We recommend rotating hinge devices with a long, cylindrical central rotational stem because the biomechanical studies of Ward et al. and ours, showed, that these implants are more stable than implants with a short or markedly tapered central rotational stem [102].

The current study also showed that infection (overall infection rate: 25%, 21% after primary implantation vs. 30% after revision surgery), aseptic loosening (overall loosening rate: 13%, 7% following primary implantation vs. 19% past revision surgery) and delayed wound healing (overall complication rate: 24%, 14% following primary implantation vs. 7% past revision surgery) are still problems, which should be mentioned. On the other hand, the number of mechanical failures was low (5%). Overall, the complication rates were within the limits reported in the literature.

Nevertheless, modular endoprostheses with a rotating hinge type articulation should be considered as the treatment of choice for limb salvage surgery for tumoral and non-neoplastic indications.

Year	Study	Type of prosthesis	Number of patients	Infection rate (%)	Aseptic loosening (%)	Mechanical failure (%)	Overall complication rate (%)	5-year prosthetic survival (%)	10-year prosthetic survival (%)
hinged prostheses									
1987	Bradish et al.	Stanmore; CM	40	7,5	7,5	n/a	n/a	94	80
1991	Roberts et al.	Stanmore; CM	135	6,8	6	n/a	n/a	75	59
1994	Capanna et al.	KMFTR	95	12	0	7	55	n/a	n/a
1996	Unwin et al.	Stanmore; CM	1001	21,9	35,2	12,4	n/a	n/a	n/a
1998	Kawai et al.	Lane-Burnstein; CM	40	10	27,5	25	43	67	48
1999	Phillips et al.	St. Georg	21	5	0	n/a	19	n/a	n/a
2001	Wunder et al.	KMFTR	64	6	n/a	9	16	85	n/a
2002	Plötz et al.	Link, Howmedica, S&G, ESKA; CM	60	3	5	40	n/a	34	25
2005	Torbert et al.	n/a	139	2,2	n/a	n/a	22	78	65
2005	Griffin et al.	KMFTR	99	10,1	2	6,1	25,2	77	n/a
2006	Biau et al.	GUEPAR I & II; CM	91	24	20	25,2	n/a	80	52
2006	Heisel at al.	MUTARS	50	12	22	10	n/a	n/a	n/a
2007	Park et al.	METS and Stanmore CM	58	0	1,7	0	19	n/a	n/a
single hinge and rotating hinge knee prostheses									
1995	Malawer	GUEPAR and Kinematic RHK; CM	82	13	5	4	44	83	67
1998	Ham et al.	Spherocentric and Endo Modell	32	n/a	n/a	n/a	41	87	80
1999	Kawai et al.	Lane-Burstein and Finn RHK	82	6	22	18	n/a	71	50
2001	Mittermayer et al.	KMFTR and HMRS	100	9,7	27		n/a	79	71
2001	Ilyas et al.	HMRS	48	14,6	4,8	2,4	39	94	65
2004	Zeegen et al.	HMRS	141	10	8	2	28,3	87	n/a
2006	Ahlmann et al.	HMRS	211	5,2	2,4	4,3	16,6	78	60
2007	Chim et al.	HMRS	10	0	0	0	n/a	n/a	n/a
2008	Gitelis et al.	HMRS and Wright Medical Technology	80	2,5	15	7,5	n/a	85	58
rotating hinge knees									
1987	Rand et al.	Kinematic RHK	36	16	6	16	52	n/a	n/a
1988	Kester et al.	Noiles RHK	12	17	83	0	100	n/a	n/a
1991	Eckard et al.	Kinematic RHK	78	3	3	8	36	68	n/a
1996	Choong et al.	Kinematic RHK	30	n/a	3,3	0	30	90	n/a
1999	Kawai et al.	Finn RHK	32	6,2	3,1	12,5	n/a	81	n/a
2000	Westrich et al.	Finn RHK	24	0	0	0	12,5	n/a	n/a
2000	Barrack et al.	S-ROM Noiles	22	0	0	0	7	n/a	n/a
2001	Springer et al.	Kinematic RHK	58	14,5	14,5	10	27	n/a	n/a
2001	Jones et al.	S-ROM Noiles	26	0	0	0	n/a	n/a	n/a
2002	Bickels et al.	Kinematic RHK	110	5,4	5,4	5,4	13,6	93	88
2004	Springer et al.	Kinematic RHK	25	19	15	4	31	n/a	n/a
2004	Petrou et al.	Endo Modell	80	2	0	1	n/a	96,1	96,1
2006	Morgan et al.	HMRS, OSS, LEAP, CM-RHK	105	7	17	7	36,5	73	59
2007	Pour et al.	Kinematic and Finn RHK	43	11	9	0	18	68,2	n/a
2008	Deehan et al.	Kinematic RHK	72	7	n/a	0	36	n/a	n/a
2009	Zimel et al.	Kinematic RHK	47	7	17	11	38	64	36
2009	Berend et al.	Finn RHK	37	8	0	0	18	83	n/a
2009	Guenoun et al.	Endo Modell	85	10,6	3,5	0	28,4	89,4 (3yrs)	n/a
2009	Current study	LPS and S-ROM Noiles	55	25	13	5	n/a	n/a	n/a

CM-custom made, n/a-not applicable, LEAP-Lewis Expandable Adjustable Prosthesis

Tab.9: Complication rates and 5 to 10 year prosthetic survival.

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QUESTIONNAIRES

KNEE SOCIETY SCORE-PART 1

Part 1 - Knee Score (max. 100)

Pain	Points	Mild (Walking and Stairs)	30
None	50	Moderate – Occasional	20
Mild / Occasional	45	Moderate – Continual	10
Mild (Stairs only)	40	Severe	0

Total Range of Flexion	Points	61-65	13
0-5	1	66-70	14
6-10	2	71-75	15
11-15	3	76-80	16
16-20	4	81-85	17
21-25	5	86-90	18
26-30	6	91-95	19
31-35	7	96-100	20
36-40	8	101-105	21
41-45	9	106-110	22
46-50	10	111-115	23
51-55	11	116-120	24
56-60	12	121-125	25

Stability (Maximum movement in any position)	Points	Mediolateral	
Antero-posterior		<5°	15
<5mm	10	6-9°	10
5-10mm	5	10-14°	5
>10mm	0	15°	0

Flexion Contracture (deduction)	Points	Extension Lag (deduction)	Points
5°-10°	2	<10°	5
10°-15°	5	10°-20°	10
16°-20°	10	>20°	20
>20°	15		

Tibiofemoral Angle (deduction)	Points
5°-10° (valgus)	0
0°-4° (varus, max.15 pts [3 pts/°])	
11°-15° (valgus, max.15 pts [3 pts/°])	

Total	

KNEE SOCIETY SCORE-PART 2

Part 2 - Function Score (max. 100)

Walking	Points	Staires	Points
Unlimited	50	Normal up and down	50
> 2 km	40	Normal up and down with rail	40
1-2 km	30	Up and down with rail	30
< 1 km	20	Up with rail, down unable	15
Household	10	Unable	0
Unable	0		

Walking aids used (deduction)	Points
None used	0
Use of cane/Walking stick deduct	5
Two canes/sticks	10
Crutches or frame	20

Total	

Grading for the Knee Society Score	
100-80	Excellent
70-79	Good
69-60	Fair
below 60	Poor

WOMAC SCORE (Western Ontario and McMaster Universities Osteoarthrithis Index)

WOMAC SCORE (Western Ontario and McMaster Universities Osteoarthritis Index)

Schmerzfragen (Schmerzen in den letzten 2 Tagen verspürt)

Wie starke Schmerzen haben Sie beim...	keine	leicht	moderat	stark	extrem
Gehen auf ebenen Boden?	0	1	2	3	4
Treppensteigen (hinauf/hinunter)?	0	1	2	3	4
Nachts im Bett?	0	1	2	3	4
Sitzen oder Liegen?	0	1	2	3	4
Aufrecht stehen?	0	1	2	3	4

Fragen zur Steifigkeit (verspürte Steifigkeit in den letzten 2 Tagen)

Wie stark ist die Steifigkeit nach dem Erwachen am Morgen?	0	1	2	3	4
Wie stark ist Ihre Steifigkeit nach Sitzen, Liegen oder Ausruhen im späteren Tagesverlauf?	0	1	2	3	4

Fragen zur körperlichen Tätigkeit (Fähigkeiten im Alltag/Selbstversorgung in den letzten 2 Tagen)

Wie groß sind Ihre Schwierigkeite beim Treppen hinuntersteigen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Treppen hinaufsteigen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Aufstehen vom Sitzen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Stehen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim sich zum Boden bücken?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Gehen auf ebenem Boden?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Ein- und Aussteigen in ein Auto?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Einkaufen gehen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Socken/Strümpfe anziehen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Aufstehen aus dem Bett?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Socken/Strümpfe ausziehen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Liegen im Bett?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim ins Bad/aus dem Bad steigen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim Sitzen?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite beim sich auf die Toilette setzen/aufstehen von der Toilette?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite bei anstrengenden Hausarbeiten?	0	1	2	3	4
Wie groß sind Ihre Schwierigkeite bei leichten Hausarbeiten?	0	1	2	3	4

MSTS-SCORE (Musculoskeletal Tumor Society Score)

	PAIN	FUNCTION	EMOTIONAL ACCEPTANCE	SUPPORTS	WALKING	GAIT
L O W E R L I M B	5 none	no restriction	enthused	none	unlimited	normal
	4 ____	____	intermediate	____	____	____
	3 modest	recreational restriction	satisfied	brace	limited	minor cosmetic
	2 ____	____	intermediate	____	____	____
	1 moderate	partial disability	accepts	1 cane/1 crutch	inside only	major cosmetic, minor HCAP
	0 severe	total disability	dislikes	2 canes/2 crutches	unable unaided	major HCAP

Total Score _____

Maximum Score _____

% Rating _____

APPENDIX

The systematic approach and usage of literature was accomplished with OvidSP and Pubmed. Statistical analysis was performed using the SPSS program.

LEGEND TO FIGURES

Fig.1: Knee joint and axis of movement (red: horizontal axis, green: vertical axis, blue: sagittal axis) [from www.athletic-preparation.com].

Fig.2: First generation of hinged prostheses: MARK IV, SHIERS, STANMORE, GUEPAR and BLAUTH (from Manning et al.; Revision Total Knee Arthroplasty, 219-236).

Fig.3: The SHEEHAN, HERBERT and ATTENBOROUGH prostheses (from Manning et al.; Revision Total Knee Arthroplasty, 219-236).

Fig.4: SPHEROCENTRIC prosthesis, KINEMATIC rotating hinge and the schemas of the NOILES total knee device (from Manning et al.; Revision Total Knee Arthroplasty, 219-236).

Fig.5: FINN Knee, S-ROM Noiles, NEXGEN and HMRS (from www.depuy.de, www.zimmergermany.de).

Fig.6a&b: Weight-bearing forces transferred through the femoral condyles throughout total range of motion (from www.zimmergermany.de).

Fig.6c shows a technique for soft tissue coverage of the prosthesis with a medial gastrocnemius and a hemisoleus flap. The reattached patella tendon is presented additionally (from Chim et al.; Ann Plast Surg 2007;59:398-403).

Fig.7: Anderson Orthopaedic Research Institute classification (AORI). Grade 1 deficit has intact metaphyseal bone, Grade 2a deficit involves metaphyseal bone of only one condyle or plateau, Grade 2b deficit involves metaphyseal bone of either condyles or plateaus. A Grade 3 deficit has massive cavitary defects with severe metaphyseal bone loss (from Baumann et al.; Clin Orthop Relat Res (2009) 467:818–824).

Fig.8: Surgical margins for benign (intralesional, marginal) and malignant (wide or radical) soft tissue neoplasms according to Enneking (from www.med.uni-marburg.de).

Fig.9: Components of the Limb Preservation System (from the LPS™ planning software).

Fig.10: S-ROM Noiles Hinged Tibial Insert Bearing and tibial component with metaphyseal sleeve (from Jones et al.; Clin Orthop Relat Res 2001:306-314).

Fig.11: The GMRS™ distal femoral and proximal tibial components (from the GMRS™ product information).

Fig.12: Biomechanical apparatus of the S-ROM Noiles, LPS™/M.B.T and GMRS™ rotating hinge knee.

Fig.13: The tested PE-inlays/stems: LPS™/M.B.T., S-ROM Noiles and GMRS™.

Fig.14: Outline of the biomechanical apparatus.

Fig.15a&b: a) Measurements of the biomechanical apparatus; b) Dislocated central rotational stem.

Fig.16: Graphic designs of the LPS™/M.B.T. and the GMRS™ prostheses

Fig.17: Distraction-angular displacement curves for the three tested knee designs. The final point of each curve (GMRS™ -37 mm, LPS™/M.B.T.-26 mm and S-ROM Noiles-25 mm) shows the last measureable angle before the implant's dislocation.

Fig. 18a-c: a) Radiograph of a dislocated central rotational stem caused by loosening of the femoral component. b) Preoperative x-ray of a fractured and dislocated LPS™/M.B.T. metal yoke. c) Photograph of the explanted hinged tibial insert.

Fig.19: Number of complications and revisions performed in 26 patients.

Fig.20: Complications after primary implantation of rotating hinge knee prostheses.

Fig.21: Complications after revision of a prior failed TKA.

Fig.22a-c: a&b) Anterior-posterior and lateral radiograph of a LPS^{TM} prosthesis used for reconstruction of a proximal tibial osteosarcoma. c) Lateral view of the same prosthesis using a c-arm. The red arrow demonstrates the height of the 21 mm hinged tibial insert, while the green one demonstrates the distraction of the insert.

Fig.23a-h: Ultrasonography of the knee of a 28-years old patient after distal femoral replacement due to a chondrosarcoma G2. a-b) lat. extension with & without varus stress, c+d) med. extension with & without valgus stress, e+f) lat. flexion with & without varus stress, g+h) med. flexion with & without valgus stress.

Fig.24: Average results of the WOMAC-Score, divided by category for each device.

Fig.25: The Knee Society Clinical Evaluation, mean scores divided by category; APSTAB-anteroposterior stability, MLSTAB-mediolateral stability.

Fig.26: Mean scores for walking distance, stair climbing and used walking supports for each device group.

Fig.27: Average results of the MSTS-Score.

Fig.28: Results of the clinical stability test.

Fig.29: Mean distraction of each implant, measured in flexion with x-ray and c-arm.

Fig.30a&b: Average results of the lift off test with ultrasonography.

Fig.31: Kaplan-Meier curve of the LPS^{TM} prosthesis after primary implantation. The mean estimated survival was 39 months. The Kaplan-Meier curve for S-ROM Noiles knee is not shown because no events appeared in this group.

Fig.32: Kaplan-Meier curves of prostheses used for revision procedures. The expected mean survivorship was 30 months for the LPS^{TM} implant and 45 months for the S-ROM Noiles prosthesis. There was no significant difference in time of implant survival (p=0,116).

Fig.33: Survival curves of the prostheses used for primary implantation and revision surgery. Endpoints of implant survival were infection and aseptic loosening. Comparing the time of implant survival was statistically not significant (p=0,177).

Fig.34a&b: Kaplan-Meier estimation of the LPS^{TM} implant survival after primary implantation and revision surgery. Aseptic loosening was used as an event to break up the observation. The curves of the S-ROM Noiles prosthesis are not shown because there was no event in both groups. The implant survival was significant better for the S-ROM Noiles knee after revision surgery (p=0,035).

Fig.35: Kaplan-Meier curves of the LPS^{TM} device used in the primary and revision group with aseptic loosening as the endpoint of observation. There was no significant difference in the implant survival between the groups (p=0,144).

Fig.36a&b: Kaplan-Meier curves of infection after implantation of a rotating hinge knee prosthesis. There were no infections in the S-ROM Noiles group after primary implantation and therefore no curve was generated. There was no significant difference between both groups in time of implant survival (p=0,521 and p=0,391).

Fig.37: Kaplan-Meier curves of infection as a cause of implant removal. There were no significant differences between the LPS^{TM} and S-ROM Noiles prosthesis (p=0,499).

Fig.38a&b: Kaplan-Meier curves comparing the implant survival for infection used for primary implantation and revision procedures, separated for each device. There was no significant difference of the survival between the LPS^{TM} and the S-ROM Noiles prosthesis (p=0,539 and p=0,662).

LEGEND TO TABLES

Tab.1: Anderson Orthopaedic Research Institutes classification (AORI) for femoral and tibial bone loss, according to Manning et al..

Tab.2: Enneking staging system for musculoskeletal neoplasms.

Tab.3: Manufacturer, stem length and taper of the tested devices.

Tab.4: Results of the biomechanical analysis.

Tab.5: Number and sites of replacement.

Tab.6: Data of the 28 primary and 25 revised patients; CTx-Chemotherapy, FU-follow-up, 0-cured, NED-no evidence of disease, DOD-death of disease, DOOC-death of other cause.

Tab.7a: Data of patients with S-ROM Noiles hinged tibial bearing.

Tab.7b: Data of patients with LPS^{TM}/M.B.T. hinged tibial insert.

Tab.8: Results of the calculated correlation between the BMI and the measured distraction for both implants.

Tab.9: Complication rates and 5- to 10-year prosthetic survival.

CURRICULUM VITAE

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Education:

1990-1994: VS Pölfing Brunn and VS Geidorf/Muchargasse.

1994-2002: BG/BRG Lichtenfelsgasse Graz.

January-September 2003: Served in the Austrian army.

October 2003: Humanmedicine: Medical University of Graz.

September 2004: Finishing the first part of medical studies.

October 2007: Started doing scientific work at the Department of Orthopedic Surgery, Medical University of Graz.

July 2008: Finishing the second part of medical studies.

June 2009: Finishing the third and last part of medical studies.

Languages:

Native language: German

Basics in medical English (spoken and written).

Some knowledge in Italian. No medical Italian.

PRESENTATIONS:

2008/First author:

Lipofibromatosis of a 25-year-old female patient.
J. Friesenbichler, A. Leithner, A. Beham, R. Windhager.
University Clinic of Orthopedic Surgery; Medical University of Graz; Austria.
EMSOS 2008; Warszawa (Short oral presentation & poster, published)

Lipofibromatosis of a 25-year-old female patient.
Joerg Friesenbichler, Andreas Leithner, Alfred Beham, Reinhard Windhager.
Ortop Traumatol Rehabil 2008;10(S1):44.

Neurological symptoms caused by a rare soft tissue tumor: A case of non-pediatric lipofibromatosis.
J.Friesenbichler, A. Leithner, A. Beham, R. Windhager.
University Clinic of Orthopedic Surgery, Medical University of Graz.
XXXVI Biennial World Congress of the International College of Surgeons-Abstract book; 83:PO193;DEZ 3-6, 2008; Vienna, Austria. (Poster, published)

2009/First author:

Evaluation of Stability of Rotating Hinge Knee Prostheses: A biomechanical analysis
J. Friesenbichler, A. Leithner, M. Glehr, R. Windhager.
University Clinic of Orthopedic Surgery; Medical University of Graz; Austria.
EMSOS 2009; Stuttgart, Germany. (Poster, published)

Evaluation of stability of rotating hinge knee prostheses: a biomechanical analysis. Friesenbichler J, Leithner A, Glehr M, Windhager R. Abstract book of the 22nd EMSOS meeting 2009;225:7.P.10.

Distraction of Rotating Hinge Knee Prostheses: A Biomechanical Study
J. Friesenbichler, A. Leithner, M. Glehr, R. Windhager.
11th EFORT Congress; June 2-5, 2010; Madrid, SPAIN. (Poster, accepted)

2009/Co-author:

Weichteilsarkom 13 Jahre nach femoropoplitealen Bypass.
Leithner A., Friesenbichler J., Windhager R., Liegl-Atzwanger B., Hessinger M.: Krebs:hilfe! 2009;2:44-45. (Case Report, published)

Silberbeschichtete Endoprothesen nach Protheseninfekten - Follow up.
Egner-Höbarth S., Windhager R., Lovse T., Friesenbichler J., Gössler W. Wissenschaftliche Sitzung der Österreichischen Gesellschaft für Orthopädie und orthopädische Chirurgie; MAR 20, 2009; Steyr, Austria. (Oral Communication, published)

Prosthetic joint infection following total hip replacement patients: Results of one stage versus two stage exchange.
Clar, H; Lovse, T; Friesenbichler, J; Hochegger, M; Glehr, M; Feierl, G; Windhager, R
Abstract CD of EBJIS 2009, S06.7; 2009; 16-17.-EBJIS 28th Annual Meeting; SEP 17-19, 2009; Vienna, AUSTRIA. (Oral Communication, published)

CLINICAL ELECTIVES:

2006: Department of Otorhinolaryngology (4 weeks); Austria; Graz; Organization: Medical University of Graz.

2007: Department of Neurosurgery (3 weeks); Austria; Graz; Organization: Medical University of Graz.

2007: Department of Radiology (2 weeks); Austria; Graz; Organization: Medical University of Graz.

2007: Department of Dermatology (2 weeks); Austria; Graz; Organization: Medical University of Graz.

2007: Department of Orthopedic Surgery (3 weeks); Austria; Graz; Organization: Medical University of Graz.

2008: Department of Orthopedic Surgery (5 weeks); Austria; Graz; Organization: Medical University of Graz.

2008: Department of Orthopedic Surgery (6 weeks); Austria; Graz; Organization: Medical University of Graz.

PRACTICAL TRAINING (6th Year of medical studies)

2008: Department of Angiology (10 weeks); Austria; Graz; Organization: Medical University of Graz.

2008: Department of Otorhinolaryngology (5 weeks); Austria; Graz; Organization: Medical University of Graz.

2009: Family practitioner Mag.DDr. Anton Harler (5 weeks); Austria, Ehrenhausen

2009: Department of Orthopedic Surgery (10 weeks); Austria; Graz; Organization: Medical University of Graz.

ADDITIONAL COURSES

Bewegungsstörungen im Alter (Neurologie)
Anfälle und Stürze im Alter (Neurologie)
Anthroposophische Medizin: Methode und Praxis (Orthopädie)
Anthroposophische Medizin (Orthopädie)
Case Reports: Anleitung zu wissenschaftlichen Arbeiten (Orthopädie)
Tumororthopädie (Orthopädie)
Gender in der Orthopädie (Orthopädie)
Schleudertrauma der Halswirbelsäule (Gerichtsmedizin)
Forensische DNA Analytik (Gerichtsmedizin)
Molekulare Erregerdiagnostik (Hygiene)
Bioklimatologie (Hygiene)
Phantomübungen für Anästhesiologie & Intensivmedizin (Anästhesie)
Physikalische Therapie I & II + Exkursion (Med. Physik)
Medizinisches Lernen mit neuen Medien II-IV (Medizinische Informatik)
Dermatopathologie (Dermatologie)
Teledermatologie (Dermatologie)
Einführung in die konventionelle Röntgendiagnostik (Radiologie)
Häufige kinderchirurgische Erkrankungen in der Praxis (Kinderchirurgie)
Ausgewählte Kapitel aus der Kinderchirurgie (Kinderchirurgie)