“Knee Joints with controlled flexion damping for Transfemoral Amputees Clinical Cross Over Study: C-leg, Rheo knee, VGK, Orion.”
Translation of:

Knee Joints with controlled flexion damping for Transfemoral Amputees Clinical Cross Over Study: C-leg, Rheo knee, VGK, Orion.

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Kniepassteile mit geregelter Flexionsdampfung fur Oberschenkelamputierte im klinischen cross-over Vergleich: C-leg, Rheo-Knee II, VGK, Orion
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As of June 2013

Translated by an independent translator and proofread by Orthomobility.
Preamble:

This is a temporary translation of the Munster Publication on a variety of electronic knee joints and the VGK.

Orthomobility did make available a ‘Very Good Knee’ to the German Federal Ministry of Labour and Social Affairs for independent Research on its properties, and relative usefulness to the end user, the amputee.

As Mr Schüling writes in the Foreword, the knowledge gained was at risk of not being published for lack of funds, and as the study formally supports a large body of anecdotal evidence with respect to the VGK, Orthomobility decided to fund the final publication.

To allow the English Speaking world insight into this study, this translation is made available as a preview, but is still subject to final approval of the original authors for accuracy of content, and after that is expected to become a publication in its own right.
Foreword

Again, in the Munster Series for technical orthopedics, a monograph appears a report to the Clinical Department for Orthopedic Aids based in Munster. The extensive testing order of the Federal Ministry of Labour and Social Affairs (BMAS) was completed in late June 2013.

(Testing Order 14: "Comparative study between electronically controlled leg prosthesis knee joints and controlled by a cyclonic fluid control prosthetic leg knee component")

The authors are of the opinion that the scientific knowledge should be accessible to the general public, which corresponds to the self-understanding of scientific approach, all the more so because this research is independent from industry and is financed solely from funds from the public sector. However, a formal (Journal) publication is neither planned by the BMAS, nor are the clinical laboratory funds available for such publication. Here, the industry has jumped into the breach: Orthomobility has provided for costs of printing and those that covers the costs of publishing.

The development of modern Knee joints for leg prostheses has continued rapidly. For a long time, several providers are in competition with each other, and the product ranges of the major manufacturers provide increasingly differentiated supply options. A systematic allocation of independent indications and criteria from a clinical perspective but can only be done by a neutral body. Thereto exists the Clinical Department for Orthopedic Aids.

In the coming months remains to be seen whether a permanent existence of this industry-independent clinical scientific institute can be secured, since the Medical Faculty of the Westfälische Wilhelms-Universität operation of the Clinical test laboratory will not continue.

The authors of this monograph hope so.

The questions for further work are formulated, as the interest in the results is large, but still lacks a term sustainable funding concept. The trustees of the participating groups, payers, providers and representatives of the affected people with disabilities are now challenged to ensure the continued existence of Clinical Testing of Orthopedic aids.

Munster, in August 2013
Dr. Stefan Schüling
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1 Introduction

Introduction
After irretrievable loss of limb, the demand for prosthetic supply is still of great importance. In clinical practice, especially in rehabilitation clinics that look after amputees’ follow-up rehabilitation, it is a common observation that in discussing rehabilitation goals, patients refer to assuring statements of doctors who, before the amputation, presented the functional possibilities of currently available prosthetic legs, extremely optimistically. Patients harbour high expectations and are also influenced by high-level athletic performances of international athletes. The expectations for high performance of modern prosthetic fittings are further raised by the manufacturing industry, pursuing marketing with great expenditure and lay-reach advertising. On the other hand the price of modern prosthetic components is often complained about by cost carriers, namely prices of the electronically controlled knee joints, and an uncritical application due to generous indications. In the light of economic requirements that apply in varying severity but ultimately in all parts of the structured health system, a demand for equivalent (to the established C-Leg) but lower-cost alternatives is created. Proof of equal performance of a lower-cost knee joint would be a strong argument within the marketing objective of expanding market shares (i.e. those of a competing cost carrier). In case a statutory health insurance (German law article: SGB V) is carrying the costs, that knee joint would be preferable whenever a prescription for a well established but expensive knee joint is submitted for approval. There are only a few orthopaedic industrial companies developing and producing knee joints. They continually produce new models, advancements and innovative new concepts. An independent scientific assessment of the clinical features is more essential than ever as to provide decision guidance to
those interested in proper care practice. Precisely with this objective, the clinical test centre for orthopaedic aids in Münster was built.

2 Basics

2.1 Special situation of injured veterans
The number of veterans cared for at the expense of the KOV (Kriegs Opfer Versorgung: Veteran Health Care) is decreasing yet the high age of surviving veterans makes further complications. This results in participants of previous studies being unavailable or realistically not suitable to expect measurements from. However, the motivation and discipline of individual “KOV-ers” is extremely impressive.
There are increasingly more young individuals of the KOV sector who had to be amputated due to military service injury as well as injured veterans, needing to be cared for. Having said this, we deliberately set no age minimum for participants in this study. The influence of age on the study results will have to be discussed.

2.2 Knee joints
The range of items available on the German market knee joints for prostheses is extensive and continues to grow. The clinical testing in 2009 had more than 170 prosthetic knee joints or recognised joint variants listed in the catalogue. For about 15 years electronically controlled knee joints have been on the market (C-Leg 1997, Rheo Knee 2004), they are firmly established in practice as well as being very well studied clinically and scientifically, and also in several studies and Test Orders at the clinical test centre of orthopaedic aids in Münster. The prescription criteria was for several years a central issue and it has been shown that contrary to the original manufacturer information,
elderly and less active transfemoral amputees can benefit from the features of electronically controlled knee joints. 

In addition, tests to check individual functional benefits have been developed and widely standardised. The practicalities in everyday clinical decision-making had priority, notably a qualitative statement, rather than a detailed gradation or prognosis of the ultimately achievable performance level in terms of a quantitative statement. 

In the test report for Test Order 10 we stated as follows: 

“In recent years, the trend to supply transfemoral amputees with electronically controlled knee joints has become an established practice but it seems that mainly younger and more active amputees, to whom these are recommended, prescribed and approved to. Not least due to extensive advertising and marketing activities of the manufacturer, the C-Leg is a prominent representative of the electronically controlled knee joints and is widely known as the only form.”

Manufacturers have now taken products to the market with functionally similar or equivalent, partially even further-reaching technological possibilities. Due to patent and trademark restrictions of free access to proven technology, different technical solutions had to be found. Next to microprocessor-controlled models, which are inevitably dependent on an external power supply, there is at least one knee joint that should realise equivalent function using purely mechanical means. 

With the knee joints in the present study, several new knee joints are simultaneously tested in comparison with the electronically controlled knee joints. 

A similar arrangement was used in Test Order 10 (C-Leg versus Rheo-Knee II) however in both test joints of the current Test Order 14 the technical implementation of swing and stance phase safety differ (see below) and the expected differences are small as the manufacturer did not postulate superiority (over the C-Leg for example) but equal value.
All joints used in the study have a hydraulic stance phase control. The valve function is either electronically controlled by means of microprocessors (C-Leg, Rheo Knee II, Orion) or mechanically controlled (VGK). Also, the swing phase in all joints is controlled with damping cylinders, C-Leg, Rheo Knee II and VGK hydraulically, and in the Orion pneumatically. The VGK uses a (mechanical) fluid cyclone technology controlling the valve function whereas C-Leg, Rheo Knee II and Orion use microprocessors. To power the sensors and control elements an external power supply provided by lithium-ion batteries is needed. The electronically controlled joints C-Leg and Rheo Knee were the first to offer technical prerequisites to go down ramps and stairs by enabling a controlled and unlimited knee flexion under load (yielding). According to manufacturer’s information both study joints have this property including the purely mechanically controlled VGK. All test joints are monocentric. The manufacturers declare the technical properties of the study joints. Verification of these properties is not the task of the test centre but the functional consequences in regard of the user, therefore advantages or disadvantages of application to the user of the prosthesis are investigated, documented and assessed. The study joints are either property of the clinical test centre (C-Leg) or have been provided by the BMAS for study purposes. There are no economic links between the test centre and the manufacturers of test joints.

2.2.1 C-Leg
With the introduction in 1997 the Otto Bock Company presented a microprocessor controlled prosthetic knee joint to the German market for the very first time. For a long time the C-Leg set new standards to live up to
competitive requirements of stability on the one hand and high mobility on the other.
The technical innovation consisted of the utilisation of a microprocessor controlled control unit. Electronic sensors register different parameters with a measurement frequency of 50 Hertz; adjustment of the flexing resistance is carried out via controlling different valves of the built-in hydraulics. By using different settings, the needs of the prosthesis wearer in regard to safety and manoeuvrability are met. A certified orthopaedic technician configures the control unit’s settings using a PC with software issued by the manufacturer and a Bluetooth connection. The settings of the separate standing and swing phase control are saved in the joint and cannot be changed by the user.

![Fig. 1:C-Leg belonging to this study](image)

Ever since the C-Leg’s introduction, several advanced versions have been brought to the market. Externally, they are easily distinguished: the first model was silver and light blue (3C98), the successor anthracite grey (3C98-1), the current version is metallic brown (3C98-2). In total, participants with pre-provision had all three versions represented; they were viewed under as one group.
According to manufacturer’s specifications the C-Leg is suitable for operation with amputation levels of knee disarticulation or higher with activity class 3 and 4 as stated by the “Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen e.V. (MDS)” (i.e. *Umbrella Organisation of Health Insurers*) with a maximal body weight of 125 kg.

The manufacturer further states the following indications:
- Contralateral joint instabilities
- Arthrosis at joints of lower extremity
- Contralateral amputation below the knee
- Amputations at the upper extremity
- Complicated post traumatic condition
- Multiple disablements
- Clear neuromuscular deficits at extremities (e.g. plexus paralysis) including deficits of stump motor functions

Requirements or prerequisites posed by the manufacturer are:
- Greater speeds of 5 km/h and / or daily walking distances longer than 5 km
- Frequent walking on uneven ground, slopes or stairs (>100 per day)
- Employed with occupation requiring a high measure of safety
- Amputees with a fast change of direction due to a certain situation
- Amputees who can gain benefit from an additional mode (riding a bike)

The Otto Bock Company gives the following contra indicators for provision by C-Leg:
- Amputees with mobility grade 1
- Mental state or living environment whereby correct handling and maintenance of the C-Leg are not expected.
2.2.2 Rheo Knee II
The Össur Company introduced the Rheo Knee I to the German market in 2004 and thereby offered a competing product to the C-Leg. The advanced model Rheo Knee II is used in this study and has only been available since 2009.

The knee joint doesn’t, like the C-Leg, use hydraulic valves but regulates the knee joint properties with sensor information (sampling frequency 10000 Hertz, regulation frequency 200 Hertz) by means of a magneto rheological liquid. By creating an electrically induced magnetic field small spherical ferromagnetic particles (1 to 10 micro meters carbonyl iron) in a suspension fluid to form long chains. The flexing resistance is thereby controllable by changing the flow properties.

The upgrade of the Rheo Knee I to the Rheo Knee II is an additional mechanical extension aid (intern torsion spring), a maximal flexing resistance six percent higher, a 125g lighter part and an increase of the maximal body weight from 100 kg to 125 kg.

A certified orthopaedic technician configures the control unit’s settings via Bluetooth using a PDA (Personal Digital Assistant) issued by the manufacturer with integrated software. The settings of the separate stance and swing phase control are saved in the joint and users can (via a PDA) change settings themselves.

The manufacturer describes the software as “self-learning”, independent adapting configurations of joint parameters are made depending on situation by continuous monitoring.

The Rheo Knee II is (according to manufacturer’s specifications) intended for activity classes 2 to 4 (classification of MDS) on the German market, “mobility grade: low, medium, high (2-4, without sport)” [Össur 2010/1]. It can be used for leg amputees with amputation level knee disarticulated or transfemoral with a maximal body weight of 125 kg.
User profile according to manufacturer’s specifications:

- In- and outdoor walking
- Working users
- Ability / potential for varying walking speeds
- Ability / potential to cope with stairs and slopes

Contra indicators:

- Amputees of mobility grade 1

### 2.2.3 Orion

The prosthetic knee joint Orion is a monocentric microprocessor controlled hybrid joint. It was developed by the Blatchford Company in England and presented on German markets early 2011 by the Endolite Deutschland GmbH Company. The Orion knee joint has a hydraulic stance and pneumatic swing phase control and is controlled by a battery dependent microprocessor. The implemented electronic sensors gather different parameters with a sampling frequency of 50 Hertz, which can for example enable a swing phase adaption to different walking speeds. By means of measurement sensors anterior and posterior within the knee chassis flexing moments can be registered. This data serves to control the valves within the implemented hydraulics to progressively change the flexing resistance in stance phase. Thereby walking down stairs leg over leg,
overcoming slopes and a change from stance to swing phase is ensured. On the basis of the positioning of the sampling sensors secure flexion motions” should be enabled. According to the manufacturer the swing phase control is self-learning and functional after only a short test run. There is a rotating pyramid connection fitted proximal on the knee joint flexible by 130° over the monocentric axis. The microprocessor’s base settings and calibration takes place anteriorly directly at the knee joint. Two push-button switches in conjunction with different glowing LEDs can program the following base settings.

The base programming is carried out in four fixed steps:
- Calibration of trigger point for transition from stand to swing phase
- Setting the hydraulic stand phase resistance for yielding (limited flexing with load)
- Adaption of swing phase in crude switching cycles
- Adaption and gait pattern detection by fine adjustment of swing phase control (adaptable to different walking speeds)
- Manual / mechanical settings of hydraulic extension dampeners

According to the manufacturer the battery has a capacity enabling function of 48 to 72 hours and can be fully charged within two hours. The knee joint has total mounting height of ca. 25 cm with a mass of 1350 g. The Orion is permitted for transfemoral and knee disarticulated amputees of activity class 2 and 3 with a body weight up to 125 kg, and users with an activity class of 4 only up to 100 kg.

2.2.4 VGK
The VGK (“Very Good Knee”, Volksgelenk) is produced by the Orthomobility Company and marketed in Germany by the Disano Company (since 2011). The prosthetic knee is a monocentric fluidic-hydraulic controlled knee joint.
According to the distributing company, the hydraulic fluid cyclone control regulates the flow and power levels within the joint using intuitive fluid-driven feedback mechanisms. Stand and swing phase properties are influenced by this control technology. The swing phase is triggered by weight dependent forefoot load and shortly after the beginning of swing phase, the knee joint switches back to stand phase modus lowering stumbling risks.

According to the manufacturer, it is waterproof and has three different socket adapter options. Alternating walking down stairs and overcoming slopes (yielding) is possible on top of speeds up to 9 km/h. The whole component weighs 1.4 kg. The prosthetic knee joint is permitted for a maximal weight of 125 kg (patient weight) plus 15 kg occasional carry load. The manufacturer describes it as suitable “for all activity levels and patients” and recommends it for the activity classes 2 and 3 (http://disano-gmbh.plenymarket.net/kniegelenke/).

The manufacturer does not specify a maximum knee flexion, but rather it must be ensured that at maximum knee flexion the distal femur socket touches the hydraulic cylinder only at a distance of 100 mm to the joint axis. This knee joint offers an own biking-function activated with a lever mechanism. The special thing about this joint within the biking-modus is that it (via a ball-valve mechanism) prevents unintentional flexion when suddenly dismounting onto the prosthesis side.
- The joint offers six adjustable settings:
  - Heel rise – Regulation of flexing angle resistance
  - Yield – Regulation of flexing resistance with load
  - Swing – Setting of swing phase resistance
  - Swing release – Swing phase trigger setting
  - Safety trigger – Stumble prevention
  - Cycle off/on – Biking modus on/off

2.3 Study hypotheses

The following hypotheses were formulated:

- **The clinically relevant effects on gait dynamic and standing safety by use of the VGK or Orion are not equivalent to those of the C-Leg**
- **The functional differences between VGK or Orion and electronically controlled joints will be more significant in higher activity classes**
- **For transfemoral amputees of lower activity classes the VGK and Orion present a provision without significant disadvantages compared to the C-Leg**
3 Materials and methods

3.1 Participants
For this study the following inclusion criteria presented itself:
One sided transfemoral amputees, irrespective of cause of amputation.
Experienced prostheses user with fitting prosthetic socket.
Activity class 2 or higher without upper or lower age limit.

3.1.1 Recruitment of participants
From previous participants, those meeting the inclusion criteria (according to existing data) were addressed. The contact to a self-help organisation intensified during previous Test Orders proved to be useful.
Also, the interim launch of the Genium-knee made participants come to the clinical test centre. Patients considering the Genium-knee were suggested to take part in this study.
Total measurements were carried out with twenty-three volunteers. Two participants were not included in the analysis. In one participant (the oldest of the twenty-three) no kinetic data could be collected because the step length was too small so that no measurable single foot load on the force measurement plates could be established. Another participant was excluded because of serious indications of misplaced motivation.
Of the twenty-one fully evaluated participants for the study ten had already participated in previous studies. One participant was sent from an OVSt., eight were addressed at ambulant appointments in orthopaedic workshops at UKM. Two participants came through a trade association as part of a requested Genium-provision.

3.1.2 Range of participants
Of twenty-one participants nineteen were male, two were female. The right leg was amputated in eight participants, the left one in the other thirteen.
3.1.3 Medical findings in participants

Cause of amputation

Due to the design of the study, medical findings in participant’s amputations are skewed. Considering that a lot of war-wounded took part, one cause of amputation “trauma” is more strongly represented than in the real amputee population. This shift of focus is thus intended.

Thirteen of the twenty-one completely analysed participants were amputated after trauma, three due to peripheral vascular disease (PVD). A malignant tumour was cause of amputation in three participants (osteosarcoma in two, Ewing’s sarcoma in one). The other causes were: one time elective amputation of a congenital malformation and one time chronic osteomyelitis.

Diagram 1: Cause of amputation
Age / Age on amputation / Time since amputation

The mean age of the twenty-one completely analysed participants at time of testing for the study was 51 years (youngest 18, oldest 74). The posttraumatic amputees had a mean age of 53 (youngest 26, oldest 74), PVD-patients had ages of 58, 69 and 41 (mean age: 55.3) and malignoma amputees had ages of 24, 57 and 59 (mean age: 46.7). The chronic osteomyelitis amputee was 54 and the amputee because of congenital malformation was 18.

The mean age of (all) participants at age of amputation was 28.8 years (youngest 11, oldest 61).

Diagram 2:

The post-traumatic amputees had a mean of 24.3 years at age of amputation (youngest 18 oldest 42), the PVD-patients had ages of 32, 40 and 61 at age
of amputation (mean age: 47.7). Malignoma amputees had ages of thirteen, 23 and 48 (mean age: 28) at age of amputation. The time since amputation (all participants) was a mean of 22 years, shortest time one year, longest time 48 years. Post-traumatic amputees had a mean of 28.5 years since amputation, shortest time one year, longest time 48 years. The three vascular patients had a time of 7, 7 and 9 years since amputation. For tumour patients the time since amputation was one year, eleven and 45 years.

**Activity class**

All participants were, by the same test centre doctor assigned to an activity class (K-level according to MDS) on the basis of the questionnaire. Two participants had K2, thirteen participants K3 and 6 participants K4.

**Diagram 3: activity class according to MDS (n=21)**

For K-2 patients, age was the deciding factor: both participants were the oldest out of the whole group. One (participant 3) had had a posttraumatic amputation since 33 years, the other (participant 6) had an amputation due to
PVD since 7 years, both with stumps of medium length without relevant scar problems. Both had been provided with the C-Leg.

3.1.4 Stump findings

Stump length
Participant no. 4 had a short stump with a residual bone length under a third; participant no. 9 had a long stump with end of femur stump by means of autologous patella (Gritti-Stokes stump). The 14 other participants had medium length stumps with some variation.

The clinically measured stump lengths (Spina iliaca anterior superior to tip of stump) were between 58 cm for the longest and 23 cm for the shortest stumps, the other stumps were between 30 and 42 cm.
Diagram 4 shows the stump length of participants who in chronological order according to dates of measurement for this study have been enumerated continuously.

**Diagram 4**

**Scar condition**
Participants had very varied scar conditions from unproblematic to very problematic.
Both participants are activity class 4 meaning the stumps are exposed to high loads. Restrictions to the use of the prosthesis due to invaginated scars are only of minor magnitude. The recurring skin irritations are essentially caused by intensive load with regular full-day prosthesis wear period and high walking workload.

**Stump force**

The active force of the stump has been clinically examined for all participants. 20 of twenty-one participants had full force against manual resistance in all directions corresponding to force grade 5/5 according to Janda (Grade 5). This refers to the individual relative force and not to the absolute force output. With longer stumps one expects higher absolute force or torsional moments than with shorter stumps due to leverage ratios and more extensively preserved muscles. “Force Grade 5 according to Janda” mainly means that there are no paralytic or other faults with muscle function. A qualified investigation of stump force was not conducted since there is no standard method.
Participant nineteen had a minor constraint in force in abduction (GRADE 4) the force of hip flexion had noticeable restrictions (GRADE 3). This is due to the polytrauma leading to the amputation of the leg namely a partial paralysis of the plexus lumbalis. To decrease paralysis muscles of the abdomen had been transplanted to the thigh in 2002.

**X-ray findings**
Multiple participants had x-ray images:

![X-ray image]

*Fig. 11: short stump (participant no. 4) with osteosynthesis material*

*Fig. 12: medium length posttraumatic stump with fixed healed distal femur fragment in situ (participant no. 22)*
Fig. 13: medium length stump with wide Exostosis (participant no. 10)

Fig. 14: long stump after Gritti-Stokes (participant no. 9)
Fig. 14: knee disarticulation stump (participant no. 18)

Producing x-ray images within the study was not possible due to legal and ethical reasons.

Findings on sound leg
Eleven out of twenty-one fully analysed participants had pathological findings on the sound leg. Three participants had surgical scars without further functional restrictions. Four participants had diagnosed an arthrosis in the last upper ankle joint and another four had diagnosed arthritis. One participant had a flawlessly working knee endoprothesis. One participant had lost a toe and another had an orthotically cared for chronic peroneal paralysis on the sound leg.

Findings on trunk
Eight out of twenty-one participants had restrictions on trunk and spine. Five participants had been treated due to a degenerative spine disorder, two had spondylosis, one of which cervical, due to a slipped disk, and the other lumbar, due to scoliosis. In one participant multiple ribs had been (partially)
resected due to metastases. At point of study no participant required acute treatment in this respect.

**Findings on upper extremities**
Three patients had arthritis on joints of upper extremities and had required treatment. At point of study, no participant required acute treatment in this respect.

**Sensory impairment**
Nine participants were wearing glasses, one had a hearing aid, Relevant sensory impairment did not exist.

**Grade of disablement**
(For your reference see http://www.einfach-teilhaben.de/DE/StdS/Schwerbehinderung/GdB_Ausweis/ausweis_node.html)
All participants had a severely disabled ID card. Acknowledged GdB (grade of disablement) was at least at 60, highest of 100. 17 were marked “G”, four were not sure. Five participants were marked “aG” two of which also had “B” and one of those also “H”- One participant (GdB 100, G) also had “RF”.

![Diagram 5: acknowledged GdB (Grade of disablement) (n=21)](image)
**General Health**

Concerning the risk factor of overweight the waist-to-height-ratio (Lee et al. 2008) was determined for all participants. Eight participants had uncritical results but thirteen participants showed critically too high results and seven are considerably overweight. Besides that, the following continuously treated non-orthopaedic complaints were found: Arterial hypertonia in seven participants, diabetes mellitus and coronary heart disease in three participants each, chronic obstructive lung sickness, psoriasis and benign prostatic hypertrophy in one participant each, likewise drug allergy, neurodermatitis, peripheral polyneuropathy and a cerebral seizure disorder in one participant each. Fifteen out of twenty-one participants took medicaments regularly (including contraceptive) between one and five preparations. With increasing age the number of medications tends to be higher. Hypertension reducing medication was taken most commonly.

This image shows the number of regularly taken medication (long-term medication) depending on age of participants.

![Diagram 6: intake of medication](image)
3.1.5 Overview of amputation stumps
Chronology according to “current participant number”, used as in text.
3.1.6 Technical orthopaedic findings in participants

Within the scope of the orthopaedic technical diagnosis-survey, the artificial limbs were examined with regards to a correct socket shape, volume, suspension and alignment. This included an inspection of the static prosthesis alignment of prosthetic knee and foot as well as a dynamic analysis. The individual documented aspects are described below:

Socket shape
The twenty-one participants had different socket shapes. Exact distribution is shown in diagram 7. In the Test Order concerning

"classification of socket systems and weight bearing” the clinical test centre ascertained that the ischial containing socket shape provides crucial benefits compared to the ischial seat socket system. The documentation of socket shapes shows an improvement of fitting quality. During Test Order 10, 37.5% of study participants were prescribed to an ischial seat socket, in the current study this amount is reduced to 4.7% (one participant).
Of the twenty-one tested transfemoral prosthesis wearers, eleven had an ischial containing and two a ramus containing socket shape, one participant had an ischial seat socket. Two participants couldn’t be accurately classified so that they were recorded as hybrid. The remaining five knee disarticulated participants had been classically provided with an end-loadable socket system.

**Suspension**

As Test Order 11 showed there are no unitary indication criteria for a liner fitting.

**Diagram 8: Suspension type of prosthesis socket of study participants (n=21)**

Ten of the twenty-one participants of this study had been provided with a silicon liner and nine with an adhesion suction socket. Two additional knee disarticulated amputees had a soft inner socket (WWIT) for supracondylar suspension of their prosthesis socket.

The liner locking mechanism was present in the forms of a vacuum system (seal-in) for five participants and by means of a snap-pin-closing-system and
for one participant via the KISS® feed system. One participant had the silicon liner without suction system as it was only providing shape balancing. Of the ten participants with silicon liner with different locking options, seven were transfemoral amputees. For transfemoral amputees full contact including volume control is strived for, Eighteen of twenty-one participants had this. For one participant end contact was not possible because of medical reasons. According to the remaining two participants they deliberately had no end contact, as they wanted to stick to their socket shape without end contact.

The technical orthopaedic test of fitting socket volume, by means of clinical inspection as far practical as there possibly are soft part bulges, produced predominantly good results: nineteen of twenty-one amputees had a good socket volume, the other two had slightly too large volume; this was however not disqualifying.

**Knee joints**

**Diagram 9: Number of knee joints of the 21 subjects**
Within the technical orthopaedic findings the currently prescribed prosthesis was recorded. The number of knee joints as worn is shown in diagram 9. In total nineteen nineteen of twenty-one participants had been (at point of study) prescribed with an electronic knee joint; fifteen of those had the C-Leg of the Otto Bock Company and two transfemoral amputees had the Orion of the Blatchford Company and the Plié 2.0 of the Freedom Innovation Company. The represented mechanical knee joints included the OP5 (Medi Company) and of the Teh-Lin (Teufel Company).

**Feet fittings**
The twenty-one subjects had different types of prosthetic feet. The exact distribution of the fitted feet is shown in diagram 10.

**Diagram 10: frequency of feet fittings (n=21)**
The C-Walk was the most represented- sixteen of twenty-one participants wore a foot of the Otto Bock Company. This portion is connected to the number of C-Leg wearers. Twenty participants wore an energy storing carbon foot; one wore a mechanical joint foot. The hydraulic monocentric prosthetic feet Echelon and Echelon VT are each combined with the Orion-prosthetic-knee-joint from the previous fitting.

Alignment of prosthesis
The alignment was controlled by means of the L.A.S.A.R.-posture of the Otto Bock Company in the sagittal and frontal plane. The alignment of the frontal plane turned out to be correct in all twenty-one participants. The sagittal plane was set up correctly for nineteen of the participants the flexion contracture of the remaining two had not been taken into account. These setup faults were fixed before measurements.

3.2 Tested joints of participants
All participants were examined on at least two days since a maximum number of two joints were tested per day. The order of the joints was picked at random. Measurements started after one hour of acclimatisation once the new joint had been fitted.
Of the twenty-one evaluated subjects nineteen had been prescribed with electronic joints, of which fifteen with the C-Leg (Otto Bock) and one participant each with the Rheo II (Össur) and the Plié 2.0 (Freedom Innovations), and two with the Orion-joint (Endolite). The remaining two had been prescribed with mechanical joints, each with the The-Lin (Teufel) and the OP5 (Medi).
The following table gives an overview of the selection and number of tested joints depending on previous fitting:
Table 1: frequency of tested joints

<table>
<thead>
<tr>
<th>Tested joints</th>
<th>C-Leg</th>
<th>Rheo</th>
<th>Orion</th>
<th>VGK</th>
<th>Other previous fitting</th>
<th>Series of measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous fitting</td>
<td>C-Leg</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Rheo</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Orion</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Plie</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>5</td>
</tr>
<tr>
<td>Mech.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>5</td>
</tr>
</tbody>
</table>

Those fitted with the Orion were tested with Orion, VGK, C-Leg and Rheo II. If participants had a different fitting (mechanical or like in one case the Plie 2.0) five different test series were produced: the previous fitting, the C-Leg, the Rheo II, the Orion and the VGK.

3.3 Measurement procedure
The order of tested joints was picked at random for each participant. As presented in table 1 each participant was tested with their previous fitting, the Orion and the VGK. Depending on the type of previous fitting the C-Leg or Rheo was also tested.

We started with the Vicon-/Kistler measurement (within the plane and without further task). This was followed by data taking with the Gaitrite, firstly with speed of choice, and then with maximum speed, walking in the dark, walking backwards, overcoming obstacles in 1.5 fold stride length with speed of choice and walking up and down a ramp. Two evaluable measurements were made for each assignment; the two values were then averaged. Maximum speed was an exception; here the measurement with highest reached speed was used.

After Gaitrite-measurements, came the clinical course with the timed-up-and-go-test, the four-square-step-test, circulation of a row of cones consisting of five cones (one time round the right and one time round the left) and walking in a spiral. For the spiral, measurements were taken once for the right and once for the left way round as well as in and outwards.

At the end the testing, the laboratory physician interviewed the participants.
3.4 Evaluation scheme
All measured values were analysed with a new scheme, since the old analysis method of functional benefits had multiple serious weaknesses. With the previous seven criteria of functional benefits each criteria was weighted equally even though differing amounts of data influenced the criteria. To determine “safety” six different measurement methods were used, whereas “speed” and “exertion (of force)” was only examined with three different methods. They were however weighted equally. Besides, some data sets were used as indication for different criteria such as the reduction of asymmetry for Gaitrite measurements. They classified as improvements for “safety”, “gait pattern” and partly “divided attention”. In a statistical diploma thesis K.Kuhr determined differently big links of the seven criteria among one another (KUHR 2008). Even the following developed reduction to four criteria of functional benefits did not eliminate the basic weakness of uneven and multiple content use.
To improve this method the evaluation was changed as follows:
Only the two criteria “safety” and “gait physiology” are considered. An increase in safety is an essential criterion for joint selection, particularly for lower activity classes. Whereas an improved gait physiology is only a sufficient criteria, becoming more important with higher activity classes. An improvement of gait physiology at expense of safety with a certain knee joint does therefore not lead to an overall judgement of “improvement” for the respective joint.
If results for safety and gait physiology are identical the total evaluation is not difficult.
In case of improvement of safety at expense of gait physiology for a certain joint, a precise weighting depending on activity class and subjective prioritisation of participant is necessary.
The Vicon measurements (exclusively in the plane) and the Gaitrite measurements (with six different tasks, see fig. 13 below) were looked at under different aspects and respectively assigned to one of the categories “safety” (orange coloured) or “gait physiology” (coloured green). Here, each considered aspect was only used once; overlapping within the evaluation matrix does not exist. In the end sixteen data sets go into “safety” and fifteen go into “gait physiology” so that both criteria are virtually equally weighted.
The Vicon measurements (five repeated measurements go into each joint) subdivide into kinematic (hip and knee angle) and kinetic (hip and knee
moment) observation. For both (kinematic and kinetic) data sets standard deviation should ideally be low, consequently having a high reproducibility of the gait pattern. This is seen as an indication for “safety”. If the participant allows knee flexion moments on the prosthesis side or rather reduces the extending moments it is also an indication of an increased sense of security with the respective joint.

A high congruence between sound and amputated side of the kinematic such as the kinetic parameters are seen as an increased symmetry and thereby evaluated as a harmonisation of gait pattern summarised under “gait physiology”. In the event of a decrease in occurring moments on the sound side, it is seen as a relief for the sound side and also falls into the category of “gait physiology”.

The Gaitrite measurements is absolved under six different tasks, walking with maximum speed, walking in the dark, walking backwards, overcoming obstacles in 1.5 fold stride length with speed of choice and walking up and down a ramp. The speed, stride length of amputated side, stride length asymmetry of stand phase duration (sound and amputated side) are considered. For the Gaitrite measurement, only two measurements are completed per task (the system records and analyses multiple steps for each measurement). The two measurement values were then averaged. Maximum speed was an exception; here the best measurement was used. Walking at speed of choice is not included in evaluation because the imprecise task can lead to different interpretations and the reached speed is thereby (more than for other tasks) influenced by many irrelevant factors such as motivation, fatigue, current state of physical and psychological nature, etc.

An increase of speed and a bigger stride length with the amputated side is evaluated as a higher safety for all tasks. The tasks “overcoming obstacle” and “walking down a ramp” are exceptions. When overcoming obstacles the stride length is fixed and the stride length asymmetry is thereby forced to be lower. The speed is only dependent on the cadence because of the fixed stride length. Since the given stride length can vary from joint to joint (in dependence of stride length at speed of choice) the speed in task “overcoming obstacles” is not a suitable indication.

When walking down a ramp fast, walking over the prosthesis (stiff joint) can occur which is not the aim of the fitting. When walking down a ramp, only asymmetry of stride length and stand phase duration are indicators of increased or decreased safety.
Decreased asymmetry of stride length and stand phase duration are seen as an improvement of “gait physiology” for all tasks (except for walking down a ramp, this belongs to “safety”, see above). Exception: when overcoming obstacles the asymmetry of stride length is no sensibly evaluable parameter (see above). This leads to the upper given thirty-one individual data used as respectively fifteen or sixteen indicators for “safety” or “gait physiology”. This finally results in a list of priorities with the criteria “safety” and “gait physiology”.
Fig. 16: new evaluation scheme

<table>
<thead>
<tr>
<th>Vicon:</th>
<th>Standard deviation (low as possible)</th>
<th>Congruence (high as possible)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kinematic</td>
<td>Hip angle</td>
<td>Hip angle</td>
</tr>
<tr>
<td></td>
<td>Knee angle</td>
<td>Knee angle</td>
</tr>
<tr>
<td>Kinetic</td>
<td>Hip moments</td>
<td>Hip moments</td>
</tr>
<tr>
<td></td>
<td>Knee moments</td>
<td>Knee moments</td>
</tr>
<tr>
<td>Prothesis side:</td>
<td>Sound side:</td>
<td></td>
</tr>
<tr>
<td>Inflection moment high, extension moment low</td>
<td>Reduced moments, particularly extension</td>
<td></td>
</tr>
<tr>
<td>Hip moments</td>
<td>Hip moments</td>
<td></td>
</tr>
<tr>
<td>Knee moments</td>
<td>Knee moments</td>
<td></td>
</tr>
</tbody>
</table>

| Sum | Safety | Gait physiology |

**Gaitrite:**

<table>
<thead>
<tr>
<th>Speed</th>
<th>Stride length amp. Side</th>
<th>Stride length asymmetry</th>
<th>Stand duration asymmetry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dark</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Backwards</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstacles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ramp up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ramp down</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Sum | Safety | Gait physiology |

| Total | Safety | Gait physiology |

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3.5 Reliability and acclimatisation period

To verify reliability and acclimatisation periods, multiple measurements with the Orion and VGK were carried out. With nine of the twenty-one participants, double measurements were conducted, and in one case a triple measurement. These took place partly after multiple days long acclimatisation period with the joint at home and the joints were partly measured for a second time on the second test day just like on the first day, after a one hour acclimatisation period.

The following gives an overview of the number of multiple measurements:

**Table 2: multiple measurements:**

<table>
<thead>
<tr>
<th></th>
<th>Orion</th>
<th>VGK</th>
</tr>
</thead>
<tbody>
<tr>
<td>With acclimatisation period</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Without acclimatisation period</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

For three participants the Orion was measured after one, two or also three day long acclimatisation period at home. For two participants, the VGK was measured after two or also four day long acclimatisation periods. For one participant the VGK was measured on three days; on the first day after one hourly acclimatisation period and after two and nine days of acclimatisation period at home.

For one participant, the Orion as well as the VGK was measured with acclimatisation period, the Orion with one day and the VGK with five days acclimatisation period. One participant each was measured with the Orion or also VGK (on the second measurement day, without acclimatisation at home), for one participant Orion as well as VGK was measured a second time).
4 Results

Of the twenty-one participants two belonged to activity class 2, thirteen to activity class 3 and six to activity class 4. The following results will be displayed according to activity class. Table three shows an overview of previous fittings in relation to activity class (abbreviated K).

With fifteen out of twenty-one the C-Leg predominates clearly, four additional participants wear a different electronically controlled joint and two are mechanically fitted.

Table 3: frequency of previous fitting in relation to activity class

<table>
<thead>
<tr>
<th>Activity class</th>
<th>C-Leg</th>
<th>Rheo</th>
<th>Orion</th>
<th>Plié</th>
<th>Mech.</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>K2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>K3</td>
<td>9</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>K4</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Sum</td>
<td>15</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>21</td>
</tr>
</tbody>
</table>

4.1 Results in relation to “safety”

<table>
<thead>
<tr>
<th>Previous fitting</th>
<th>C-Leg</th>
<th>Rheo II</th>
<th>Orion</th>
<th>VGK</th>
<th>Plié 2.0</th>
<th>Mech.</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-Leg</td>
<td>10*</td>
<td>1</td>
<td>5*</td>
<td>16*</td>
<td>3</td>
<td>3</td>
<td>22*</td>
</tr>
<tr>
<td>Rheo</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Orion</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>VGK</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Plié 2.0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Mech.</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Sum</td>
<td>10*</td>
<td>3</td>
<td>3</td>
<td>5*</td>
<td>1</td>
<td>0</td>
<td>22*</td>
</tr>
</tbody>
</table>

Table 4: best result “safety”

*One participant previously fitted with the C-Leg shows equally good results with the C-Leg and VGK, due to the double result the sum is 22
Table 4 shows an overview of performance in relation to “safety” depending on previous the fitting. The correlation of best result with previous fitting is in bold; the last row states the number of best results per joint.

Of the twenty-one investigated participants, ten show the best results with the C-Leg, three with the Rheo, another three with the Orion, five with the VGK and one with the Plié knee. The matter of fact that someone fitted with VGK or C-Leg shows equally good results explains the sum of twenty-two ‘best’.

All ten participants showing the best result with C-Leg had it as their current fitting. The remaining six previously C-Leg fitted had the best results with the Orion (one participant) and the VGK (five participants).

Three of the five participants not previously fitted with the C-Leg performed best with the Rheo, two with the Orion and one with the Plié 2.0.

The fields with correlation of best result with previous fittings are in bold. This is the case thirteen times, nine times a different joint performs better, five times the VGK, two times the Orion and another two times the Rheo.

All five subjects who achieved the best result in regard of “safety” with the VGK had been previously fitted with the C-Leg (one of which had equally good results with C-Leg and VGK another with minimally better results for the VGK).

This points to the claimed similarity to the C-Leg as claimed by the manufacturer Orthomobility.

With previously mechanically fitted participants the Orion and the Rheo II are represented. This corresponds to results of Test Order 10 showing that previously mechanically fitted (participants) can benefit of the Rheo II even if (as in this case) in their advanced years and not belonging to a top activity class.

On the whole a predominance of electronically controlled knee fittings is clear, as they provided the best result in relation to “safety”, eighteen out of twenty-two times. The C-Leg dominates in particular, with ten out of twenty-two times best result; the frequency of previous fittings of C-Leg (fifteen out of twenty-one) favours that dominance.
4.2 Results in relation to “gait physiology”
Table 5 shows (with the same scheme as table 4) an overview of performance in relation to “gait physiology” depending on the previous fitting.

Table 5: best result “gait physiology”

<table>
<thead>
<tr>
<th>Previous fitting</th>
<th>C-Leg</th>
<th>Rheo II</th>
<th>Orion</th>
<th>VGK</th>
<th>Plié 2.0</th>
<th>Mech.</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-Leg</td>
<td>7</td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Rheo</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Orion</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>VGK</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Plié 2.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Mech.</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>21</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>2</td>
<td>6</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>21</td>
</tr>
</tbody>
</table>

For “gait physiology” only nine of the twenty-one participants performed best with the C-Leg, two with the Rheo, six with the Orion and four with the VGK. This confirms the property of the C-Leg, found in previous studies, offering a higher security but dynamic aspects could be enhanced. Here, the Orion and VGK are among the best, more frequently than the Rheo. This is however, irrelevant to participants of lower activity class if the safety lacks, since a better gait physiology is a sufficient criteria for a better prosthetic fitting but does not present a fitting alternative without meeting the necessary criteria of improvement of “safety” (for higher activity classes an at least equal safety level).

For “gait physiology” the best result is only met with the previous fitting in nine out of twenty-one cases, seven of which with the C-Leg. Orion and VGK perform equally for previously C-Leg fitted participants (four out of twenty-one each), in total the Orion is in second place for the aspect of “gait physiology” followed by the VGK and the Rheo being only in fourth place.
4.3 Results of subjective evaluation

Table 6 shows (same scheme as table 4 and 5) an overview of the subjective performance depending on the previous fitting.

Table 6: best subjective results

<table>
<thead>
<tr>
<th>Previous fitting</th>
<th>C-Leg</th>
<th>Rheo II</th>
<th>Orion</th>
<th>VGK</th>
<th>Plié 2.0</th>
<th>Mec h.</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-Leg</td>
<td>10</td>
<td>2</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Rheo</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Orion</td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>VGK</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Plié 2.0</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Mech.</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Sum</td>
<td>11</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>21</td>
</tr>
</tbody>
</table>

The C-Leg is once again leading with eleven out of twenty-one, ten of the eleven favouring the C-Leg had it as their previous fitting, the eleventh had been fitted with the Orion but prefers the C-Leg. Of the remaining five previously fitted with the C-Leg two favour the Orion and three favour the VGK. A similar trend as for “safety” is identifiable.

The two participants not favouring their previous fitting had been previously fitted with the mechanically and both prefer the Rheo II.

4.4 Participants of K2

Both K2-participants had previously been fitted with the C-Leg, hence they were only measured with three different joints. In the questionnaire both participants prioritised their previous fitting followed by the VGK and the Orion joint ranked last.

For one of the participants the biomechanical Gaitrite and Vicon measurements in relation to “safety” had the best result with the previous fitting followed by Orion, for “gait physiology” however the Orion exhibited best values followed by the C-Leg. Because safety is of big importance in K2 the improved gait physiology at expense of safety (Orion) is no fitting alternative, confirmed in subjective evaluation of participant.
The second participant showed best values in “safety” as well “gait physiology” with the VGK which he however put in second place (his subjective evaluation).

4.5 Participants of K3

The participants of K3 are most strongly represented with n = 13. The previous fittings in this activity class are most scattered, even though electronic knee joints are strongly represented, however the two mechanically fitted participants of the study are both in K3.

Of the eleven previously electronically fitted, only six preferred their previous fitting; the five remaining favoured a different joint. Two participants previously fitted with the C-Leg preferred the Orion and another two preferred the VGK. One participant previously fitted with the Orion favoured the C-Leg. Both previously mechanically fitted participants favoured the Rheo II.

The two participants preferring the Orion (both previously fitted with the C-Leg) one only slightly prefers the Orion to the C-Leg, walking down stairs made the decision on the grounds of that the Orion’s tread point was not as narrow as with the C-Leg. The other one stated that the Orion gave a better sense of safety, since it dampened faster than the C-Leg, especially on slippery ground. Both named participants belonged to K3 but had a clear tendency to K4.

Of the two participants preferring the VGK (also both previously fitted with the C-Leg) one stated the electricity independency and the resulting ease of maintenance made the VGK pleasant. The other one explained that walking down stairs and ramps was easier with the VGK. Both participants also belonged to K3 with a tendency to K4. The participant previously fitted with the Orion preferred the C-Leg because according to him it had the best swing-through and walking down stairs leg over leg was better as well.

Of the two previously mechanically fitted participants one stated that the Rheo II came nearest to his previous fitting (OP5), whereas C-Leg and VGK had a worse safety standard. The second participant (previously fitted with the Teh-Lin) said that he nearly didn’t need any time to acclimatise to the Rheo II.

Six of the previously electronically fitted participants prefer their previous fitting, the preference is confirmed within the objective data, two of the six
have best results for both “safety” and “gait physiology” with their previous fitting for three only with “safety” and one only with “gait physiology”. Five previously electronically fitted participants prefer a different fitting. Three of these participants show the best result of “safety” with the C-Leg (their previous fitting) one with the VGK and one with the Rheo II. The best results for “gait physiology” have been three times achieved with the VGK and two times with the Orion. For eight of the eleven previously electronically fitted, the C-Leg is the best joint concerning the aspect “safety” whereas VGK and Orion frequently perform best for the “gait physiology” aspect however at expense of “safety”. For those previously fitted with mechanical joints, the Rheo II stands first in line in the subjective evaluation followed by the respective previous fitting. The best results for biomechanical measurements with regard to “safety” were achieved by the Rheo in one case and by the Orion in the other. Concerning “gait physiology” the C-Leg was superior in both cases.

4.6 Subjects of K4
For four of the six participants, subjective evaluation and results of biomechanical measurements concerning “safety” and “gait physiology” was identical and resulted in the same winner, the winner being the previous fitting. One participant (previously fitted with the Orion) preferred the Orion and showed best results with it for “safety” whereas the best “gait physiology” results were achieved with the Rheo II which he only put in place two (subjective evaluation); the difference in objective measurements was only minor, the Orion joint was very close.

4.7 “Safety” and activity class
Diagram 11 illustrates the respective ‘best-safety joint’ in relation to activity class. As seen in table 3, two of the twenty-one participants belonged to K2, thirteen to K3 and six to K4. There are fourteen named best joints in K3 due to the previously mentioned (chapter 4.1, table 4) double mentioning of C-Leg and VGK. The C-Leg has the best safety results to (nearly) half of all activity classes. With decreasing activity class the VGK is roughly equally represented, whereas
it is not amongst the best in activity class 4. The Rheo having only been investigated on six participants, appears three times in higher activity classes as expected. The Orion only appears three times, was however tested on twenty-one participants. In contrast to the VGK it appears more often with increasing activity class. The Plié 2.0 appears once, for a participant who had it as his previous fitting.

Diagram 11: best “safety” joint in relation to activity class (n=22)

4.8 “Gait physiology” and activity class
Diagram 12 shows the best joints in relation to gait physiology. Here, a total of twenty-one participants and joints are present as there was no double mentioning.
The VGK and Orion are more common in the lower activity classes than the C-Leg. In activity class 2, VGK and Orion are exclusively amongst the best, in activity class 3 C-Leg and Orion appear five times each, the VGK three times. In activity class 4 the Rheo appears twice, the Plié 2.0 however is not represented at all.
4.9 Subjective evaluation and activity class

Diagram 13 shows the best joints in relation to subjective evaluation. Here, a total of twenty-one participants and joints are present as there was no double mentioning.

In activity class 2 the C-Leg is solely represented, in activity class 3 with six of thirteen and in activity class 4 with three of six (about half each). In activity classes 3 and 4 the Rheo, Orion and VGK are represented an equal amount (one or two appearances each) but it has to be mentioned that the Rheo was only tested on six participants whereas Orion and VGK on twenty-one. For all previously Plié fitted participants, the Plié is the subjectively best joint in activity class 3.
Diagram 13: best subjective joint in relation to activity class (n=21)

4.10 Results of maximum speeds
Diagram 14 shows the maximum speeds in relation to age. The best speeds reached are presented without regard to the respective joint. The youngest participant is on the left, the oldest on the right.

Speeds are between 92 and 231 cm/s. The maximal reachable speed decreases with increasing age.

For fifty to sixty year olds there is a wide spread between 130 and 230 cm/s.

In diagram 15 maximum speeds are written in order, shape of data points provides information of the joint with which the speed was reached.
The slowest participant reached a maximum speed of only 90 cm/s with the VGK. He had been previously fitted with the C-Leg with which he was even slower. The fastest participant was able to go 230 cm/s with the C-Leg (it also being his previous fitting); the fastest participant was also the youngest.

The C-Leg appears equally often over the whole range of variation, although the three slowest did not reach the top speed with the C-Leg, on the other hand the three fastest did. The Orion only appears three times, every time in the lower third. The previous mechanical fitting is only represented once, for the second slowest participant.

The VGK is five times amongst the fastest and also spread across the whole range. This means safety-needing amputees (only able to reach lower maximum speeds) as well as more dynamic amputees (able to reach higher speeds) reached best speed results with the VGK.
Diagram 15: maximum speeds – joints (n=21)

Diagram 16 shows the maximum speeds again as in diagram 8 this time however broken down according to previous fitting. The blue data points are speeds of participants reaching best results with their previous fitting, red marks participants having reached that top speed after only wearing the joint for a few hours.

Diagram 16: maximum speeds – previous fitting / study joints (n=21)
There is no visible effect of using a familiar or using a new joint in relation to maximum speed. For all those reaching their top speed with the C-Leg, the majority had however been previously fitted with the C-Leg.

4.11 Results of stump length
Diagram 17 show results in relation to “safety” regarding stump length. Displayed is the joint with which the participant achieved “safety” aspect result, the participant with the shortest stump is to the left and the participants with a long stump to the right. One participant performed equally with C-Leg and VGK (compare table 4) his data point is inserted twice.

Diagram 17: best “safety” results regarding stump length (n=21)

All joints with exception of the mechanical ones appear. Participants of all stump lengths exhibited best “safety” results, mostly so for knee disarticulated amputees. Individual participants with shorter stumps show best results with the VGK and Orion, multiple with the C-Leg and Rheo. Rheo does not achieve
best “safety” results for medium and long stumps. It was however only tested with six participants.
Diagram 18 displays the results just like in diagram 10, in this case referring to the “gait physiology”.

Here, only five different joints appear, mechanical joints and Plié 2.0 are not represented. In contrast to “safety” however, the Rheo appears with medium stump length and not only with short stumps.

Diagram 18: best “gait physiology” results regarding stump length (n=21)

Diagram 19 shows subjective results in regard to stump length. The best evaluated (by participants) joint is shown, participants with shortest stumps are on the left and long stumps are on the right.
In the subjective evaluation (similar to “safety”) all joints with exception of the mechanical ones are represented, the Rheo tends to appear for the shorter stumps.

**Diagram 19: best subjective result regarding stump length (n=21)**

4.12 Results of clinical tests
For the clinical tests timed-up-and-go-test, four-square-step-test, cone series and walking a spiral in this test report, only required time was analysed. The times only show mildly significant differences amongst the joints, however exclusively for C-Leg vs. Orion and C-Leg vs. VGK comparison which may be due to the high number of participants previously fitted with the C-Leg.

4.13 Results of reliability
The double measurements without acclimatisation period gave an irregular picture. For participants with two Orion measurements only minor deviations (from the first day) can be found. These show a very slight decline in “safety” for a very slight increase in “gait physiology”. This could be due to the participant getting to know the joint and being less wary.
The participant with double measurement, VGK demonstrated a strong but inconsistent deviation between the two measurements. In regard to “safety” it came to contradictory results resulting in a neutral result, “gait physiology” tended to worsen (on the second day). The VGK had, between the two measurement days however been fitted to a different participant so that the joint’s settings had been changed and had to be changed back to starting values. The VGK has limited reproducibility of patient-individual joint settings. The adjustment screws are not scaled; naturally digital programming options are missing, as it is a purely mechanical joint (see fig. 3). Found settings are not documentable and not exactly reproducible. This circumstance can explain the deviation.

One participant completed a double measurement with Orion and VGK. The Orion demonstrated a moderate “safety” improvement on the second day and a slight improvement of “gait physiology”. The VGK demonstrated a very slight decrease of “safety” and a slight improvement of “gait physiology”. The deviation of results with one certain joint at two different dates without acclimatisation period is partly bigger than that of the one with acclimatisation period (see below).

The possible difference in screw setting (at tube adapter on foot and pyramidal adapter on socket) when fitting one certain joint could explain this, this does however not apply when re-measuring with acclimatisation period.

4.14 Results of acclimatisation period
In three out of four cases, the investigation on acclimatisation period (one to three day long) of the Orion resulted in only slight changes tending to effect “safety” stronger (improvement to a minor extent) than “gait physiology” where results remained almost constant. One of the four participants (with an acclimatisation period of five days) showed strong improvements in regards to “safety” as well as “gait physiology”. Here, the parameters concerning “safety” react more sensitively than the ones concerning “gait physiology”.
With an acclimatisation period of several days the Orion achieves slight improvements in regards to “safety”, “gait physiology” only improves slightly or remains unchanged.
Concerning the VGK, two out of three participants showed changes, in one case a moderate decline of parameters concerning “safety” in conjunction
with a light improvement of parameters concerning “gait physiology” after a four day long acclimatisation period. In the other case an improvement of light to moderate extent in parameters concerning “safety” as well as “gait physiology”. The third participant had the VGK at home for a total of nine days; measurements were made after two and after nine days acclimatisation. There were no noteworthy changes on the second or on the ninth day.
5 Discussion

5.1 Measurement method
The question in this Test Order had multiple differences to that of previous commissions. For one, manufacturers postulate equal value or rather functional similarities of knee joints and secondly, recruited participants were content with their current fitting, 90 percent of which had an electronic knee joint. No participant came to the study thinking about refitting. This had been different with previous studies of knee joints. The age and activity structure of participants was different as well, in the past the majority of participants used to be of activity class 2 whereas in this study the majority belonged to activity class 3 (with a tendency to 4). That is why (previously) developed measurement methods - had to be revised partly. Proven investigation with Vicon-/Kistler remained part of the test course, for Gaitrite-recordings some of the tasks were substituted for new ones. Whilst walking with a weighted suitcase and walking on sideway slopes was left out, walking backwards, overcoming obstacles and walking in the dark was added.

Especially the evaluation matrix was changed. The old version firstly defined seven; later four criteria of functional gain, different amounts of data went into the criteria (but they were equally weighted). In addition, some data had been repeatedly evaluated and assigned to several criteria. To circumvent this, all data was evaluated only once and assigned to only one criterion (either “safety” or “gait physiology”).
In the evaluation it became clear that the subjective perception correlates more strongly with objective measurements of “safety” rather than those of “gait physiology”.

Overall a superiority of previous fitting became clear; the previous fitting consisted of the C-Leg for over half of the participants. The clinical tests timed-up-and-go-test, four-square-step-test, cone series and walking a spiral were used in this Test Order. However, it became clear that these tests did not suffice to strongly differentiate the tested knee joints. Presently, only required time was evaluated. In a current dissertation data of the ‘walking a spiral’ test (in relation to the trigger behaviour of each joint) is
being evaluated. Here, the tightest radius in which the respective joint can still trigger is of importance. Results show that joints can thereby be differentiated very well. First measurements with the Genium (not part of this Test Order) showed weaknesses for walking in a spiral as it stopped triggering when walking tight radiiuses.

For the double measurements testing reliability and acclimatisation period a bigger deviation than in previous studies regarding the C-Leg were found. Investigations concerning acclimatisation period could in a following Test Order be looked at in more detail.

5.2 Results
In this Test Order differently modern knee joints are compared with each other. Nowadays so many products of different manufacturers are available that an investigation of all respective knee joints would be impossible, considering current existing capacities. All presently introduced fully electronically controlled knee joints have a monocentric structure. Included are the C-Leg, the Rheo Knee II, the Orion as well as the Plié 2.0 but also older models like the Intelligent Knee and the Adaptive Knee as well as the – momentarily newest – Genium. There are also joints where functions are only partly electronically controlled like the C-Leg compact which has no electronic swing phase control or like the Intelligent Knee where only the swing phase is controlled electronically.
The Power Knee takes a special place, as it is an actively motorised joint.
The electronically controlled knee joints use either pneumatic or hydraulic dampening systems; the Orion and the Hybrid (Intelligent Knee) combine both techniques. There are also polycentric knee joints with pneumatic or hydraulic dampening techniques but none of these have an electronic stand phase safety. Both mechanical knee joints investigated in this study (OP 5 and TehLin-Knee) fall under this category. They were included as previous fittings for two participants in the measuring and comparing procedure. The knee joints Orion and VGK are technically and in comparison to the C-Leg, clearly differently constructed. The VGK is the only modern knee joint not electronically controlled and in terms of functionally it offers an equal value spectrum as electronically controlled knee joints.
These are – despite the similarity of principal construction as single-axle joint – quite different in regards to technical features and orientation. One reason for this is that manufacturers of technical orthopaedic components protect their own inventions and developments with patents. That is why knee joint systems of different technical approaches compete for equal or rather superior functional properties.

Even if – as shown – there are considerable differences of study joints in technical interior design as well as outer features, within the study, they were relatively easily exchangeable. By now, the modular construction of leg prosthesis is practically standardised without exception, and through use of pyramid adapters necessary adjustment in the frontal median is sparsely problematic. Occasionally, an adjustable adapter had to be inserted, multiple participants’ lower leg length was rather short but no participant had to excluded from the study due to technical incompatibility of fitting components. The knee joints were similar in assembly height, weight and outer dimensions. Within the study all measurements were completed without cosmetic cover as mechanical effects of rigidity of foam were not supposed to disturb measurements. The qualitative effects of cosmetic cover regarding mechanical function and heat dissipation from dampening systems is, for clinical research, rarely a considered area.

It can be noted that there is a tendency to build prosthesis without cosmetic cover. This does not fulfil all patients’ desire. For older patients (but also adolescent tumour patients) there is often a strong desire to cosmetically conceal the loss of limb (Wetz 1990).

The study has shown that the Orion and VGK are (for certain participants) subjectively as well as objectively the best functional combination. A continuous superiority of one of the installed knee joints was not found.

It would be ideal if a reproducible system for fitting selection could be derived from the measurements, the system would have to find the best-suited knee for easily determinable output parameters. From a clinical point of view, parameters such as age of participant, cause of amputation, length or performance of stump, activity level etc. are obvious and influential factors. Data from this study however does not give a clear possibility to differentiate an optimal fitting choice. It is however not admissible to conclude that all joints give equivalent results. On the contrary, there are participants in whom clearly differentiable functional results can be identified and the subjective evaluation was mostly very clear.
On the other hand there were participants in this study who, with their previous fitting (mostly C-Leg), after evaluation of the data had no equal or superior joint in both subjective and objective evaluation. Generally it was again shown that (often but not throughout) previous fittings performed the best. In the subjective evaluation thirteen out of twenty-one participants put their previous fitting as best, in the objective evaluation the previous fitting was thirteen times best for “safety” and nine times for “gait physiology”. This could either be due to the previous fitting being the optimal fitting in certain cases or it could be due to the big advantage of acclimatisation of a (virtually any) knee joint resulting in other knee joints being unable to compete. The following arguments speak against the last assumption: with multiple measurements at the clinical test centre concerning gain of the C-Leg, the C-Leg also prevailed against long accustomed mechanical knee joints. In Test Order 14 it has happened as well that a study joint has proven to be better than a long accustomed and subjectively quite satisfactory previous fitting.

Compared to previous studies in Test Order 14, a slightly differing formation has to be pointed out: in the past, participants’ dissatisfaction with their available previous fitting or rather wanting to have a new one, for example with the C-Leg, was their motive to part-take in the study or tests in the clinical test centre. For Test Order 14 no participant part-tok because he wanted to have the Orion or VGK. Multiple participants came to us wanting to have a Genium-fitting but part-tok in the complete study and got to know the Orion and VGK in direct comparison. Surrounding factors such as pending applications, legal disputes and appraisal orders inevitably influence the subjective evaluation of study joints.

If one looks at the ranking order given by each study participant and when given three points for “first place”, two for “second place” and one for “third place” over the total cohort following picture results: The summarily ranking of tested knee joints shows following subjective evaluation: C-Leg (74 P), VGK (32P) and Orion (28 P). The other joints only measured with a few participants are (previous fitting / alternative electronic joints for previously mechanically fitted) not presented. The same evaluation by means of the objective criteria “safety” and “gait physiology” gives the same picture qualitatively, quantitatively however, but differently weighted:
For the aspect “safety”: C-Leg (46 P), VGK (37 P) and Orion (30 P).
For the aspect “gait physiology”: C-Leg (44 P), VGK (37 P) and Orion (37 P).
The objective data of measurements register kinetic and kinematic gait parameters with high accuracy. For the total evaluation handed in by participants, other properties of knee joints could have a considerable impact. One question for example, whether and if how often the knee joints have to be charged up, not equally important or interesting for every prosthesis wearer. One study participant preferred the VGK because for him the complete independence of electronic components, compulsory rechargeable batteries and the lower moisture-sensitivity were highly outstanding features. Other participants explained that nightly charging of electronic knee joints was no burden on everyday life. Anyhow, the prosthesis leg is not worn in bed and other everyday life objects (mobile phone, electric tooth brush or razor) had to be regularly charged anyway making the nightly prosthesis charging no problem.

Different solutions are provided for different models. For the C-Leg, Rheo II and the Orion the whole prosthesis leg has to be charged via a recharger cable, whereas the Plié 2.0 and the Power Knee batteries can be changed individually allowing continuous use only interrupted by battery change. A knee like the VGK functioning completely without batteries completely relieves the user of any charge-time-planning or attention to battery level of knee joint.

The question with regards to moisture plays a similarly different important role for participants. A very active life-style with outdoor activities including sporting activities such as cycle tours, hikes etc. has a much higher risk of exposure to weather conditioned moisture than everyday life without these events. Depending on individual disposition a more or less strict demand to protect the joint from moisture can result in bigger or smaller loss of use. In case of doubt, the less sensitive component is the more robust, less susceptible and thereby the preferable joint. Within a scientific discourse, discussion comparing published study data or similar questions is relevant in order to critically classify and assess own results.

Studies comparing multiple electronically controlled knee joints intra-individually are rare. Furthermore, such publications coming directly from the research and development laboratories of manufacturers are somewhat critical concerning the aspect of industry independency. Studies comparing mechanically controlled with electronically controlled knee joints (i.e. Segal et
al. 2006, Greitemann et al. 2011) are not very significant, concerning the current question of comparison between different electronically controlled knees, the same applies to the comparison of C-Leg and Genium (Bellmann et al. 2012) which was not part of the test section at hand. Bellmann et al. (2010) investigated the intra-individual comparison of the C-Leg, Hybrid Knee, Rheo Knee and Adaptive Knee on nine participants. It was found that the metabolic energy cost differentiated so little that this parameter was an unsuitable distinguishing feature. Due to the vast technical cost for measurement with grave interpretation difficulty of the results, the clinical test centre did not strive (in earlier Test Orders as well) for this type of investigation. In this respect consensus with the literature exists. The other results from work of Bellmann et al. are not comparable as other study joints were used. The reported properties of investigated joints naturally show similarities but represent the precursors of the currently offered products.

In previous Test Orders, the clinical test centre compared electronic knee joints with one another. The results are recorded in the test reports partly published separately (Veltmann et al. 2007, Wühr et al. 2008, Schüling 2011). In Test Order 10, we reported no improvement for a previously electronically fitted participant, when changing to a different electronic knee joint. This was different for the current study: six of the nineteen previously electronically fitted, therefore almost a third, preferred a different tested knee joint. This is to be interpreted as evidence that the functional performances of the competing products are very close and disproves the theses that one model is clearly superior in every respect.
5.3 Final evaluation of the study hypotheses

- The clinically relevant effects on gait dynamic and stance safety by use of the VGK or Orion are not equivalent to those of the C-Leg
  - The study hypothesis is disproved. Both the Orion as well as the VGK showed equivalent functions in regard to gait dynamic and stance safety compared to the electronic fitting.
- The functional differences between VGK or Orion and electronically controlled joints will be more significant in higher activity classes
  - The study hypothesis is disproved. Multiple participants of higher activity class show equal and superior results with the test joints VGK and Orion.
- For transfemoral amputees of lower activity classes, the VGK and Orion present a provision without significant disadvantages compared to the C-Leg
  - The study hypothesis was largely confirmed. Participants of lower activity class had results with the test joints VGK and Orion not significantly worse than the electronic fittings. The number of participants belonging to K2 is too small to make more differentiated statements.

5.4 Outlook

The extensive measurements of Test Order 14 showed that there is an interesting increase of alternative technical solutions in the field of electronically controlled knee joints, which has different technical equipment and can definitely compete. Important functional properties are realised equivalently without showing a clear ranking that would validly address all prosthesis wearers. The continuously seen fact that all used measurement methods show only minor differences between the joints leads to the conclusion that they really perform very similarly in terms of function. Individually a relatively short-term trial – a few ours up to a few days – can ascertain which joint is preferred subjectively. Combined with clinical measurements, to some extent with relatively simple clinical tests such as
cone series or walking in a spiral, results in a good basis for an individual
decision regarding a fitting.
On the basis of the presented results, rehabilitation centres can document
their evaluation, over time making a bigger collective study possible which can
ultimately produce a comparison of study results with user data and everyday
health care.
The question of acclimatisation period with a new knee joint is a very
important problem appearing in connection with test observations of modern
knee joints. The smaller the actual differences of various knee joints are, the
more important is the acclimatisation to the fitting. A new, previously
disregarded factor is (for some electronic controls) the learning function of the
control algorithm. This function adapts to the individual needs of prosthesis
wearer with automatic procedures within the component or via computer
supported radio control, allowing direct control for the prosthesis wearer
himself. Knee joint systems only reaching a constant control setting (as
planned and intended) after a few days, cannot be investigated with the thus
far reliable study designs.
The detailed evaluation of repeated and double measurements executed after
varying acclimatisation period, is an important duty of the clinical test centre.
Likewise, investigations concerning new or rather not yet systematically
investigated fittings are due.
In any case, in regard to functional properties there are a number of new
products, not yet investigated as part of an intra-individual crossover study of
industry-independent side, to be investigated. Especially the Genium of the
Otto Bock Company has to be mentioned, as well as offered fitting
combinations of knee and foot fitting (from other manufacturers) for which
very good functional properties by means of specific interaction between
prosthetic knee and prosthetic foot is postulated.
Everyday health care will bring us further doubt and conflict cases in which
the scientifically proven evaluations of an independent party is required. Every
individual assessment has to be based on scientific groundwork and
understandably applicable to individual cases. Formulating such criteria will
continue to be necessary for innovations and further development.
6 Summary

In a prospective intra-individual cross-over study the functional effects of the provision of different modern knee joints to 23 unilateral transfemoral amputees, all experienced in prosthetic walking were examined by means of gait analytical and clinical measurements. Measured data of twenty-one participants went into final evaluation.

The participants were predominantly male (nineteen men, two women), the age varied between 18 and 69 years with a mean age of approximately 51 years. The amputation causes: trauma (thirteen out of twenty-one) prior vascular disease (three out of twenty-one), tumour (three out of twenty-one) and osteomyelitis and congenital malformation (one out of twenty-one each).

In total there were: one short stump (femur length under a third of the length on the sound side), nine medium-length stumps (femur length up to two thirds), five long stumps (femur amputated in the distal third) as well as five knee disarticulated amputations and a Gritti-Stoke stump with full femur length compared to the sound side.

The participants were assigned to the activity classes K2 (two out of twenty-one), K3 (thirteen out of twenty-one) and K4 (six out of twenty-one).

Depending on previous fitting, three, four or five different knee joints were fitted in the existing prosthesis while retaining the other components but with all necessary corrections in construction to ensure a bench alignment corresponding to the manufacturers specifications. For twenty-two of twenty-three participants the C-Leg, Orion and VGK joints were tested, in one case Rheo, Orion and VGK. Participants with a current fitting of different electronic or mechanic joints were tested with their previous fitting and the Rheo Knee II.

The evaluation of the 84 complete measurement procedures shows a mixed picture with ultimately rather small differences in the functional effects of the tested knee joints. Both in the subjective ratings of the participants and the objective data that were evaluated according to the criteria “safety” and “gait
"physiology" the C-Leg performed the best. Orion and VGK were close to each other and only slightly behind the C-Leg. Even for the participants normally using the C-Leg, one of the other test joints proved superior several times.

In functional terms, the tested knee joints offer quite interesting alternatives to the established electronically controlled knee joints C-Leg and Rheo Knee. A clear indication of suitability according to criteria like stump length, cause of amputation, activity class or age of participant could not be detected. The subjective evaluation is influenced by features not having immediate impact on the measurements like dependency for a power supply or the (not tested) different splash-water-vulnerability. These properties affect the individual context factors of the prosthesis wearer and have to be considered when deciding for a fitting.
7 Literatur


Wetz HH: Stigmatisierungsprozesse in der Orthopädie oder Techniken der Bewältigung beschädigter Identität. Med Orth Tech 110, 1990, 8-12


Herstellerinformationen zum VGK: http://disano-gmbh.plentymarket.net/kniegelenke/

Wissenschaftliche Veröffentlichungen zu den Studienkniegelenken waren nicht zu finden.

Einzelne Anwenderberichte finden sich hier:


VGK: http://www.compare-prosthetic-legs.info/