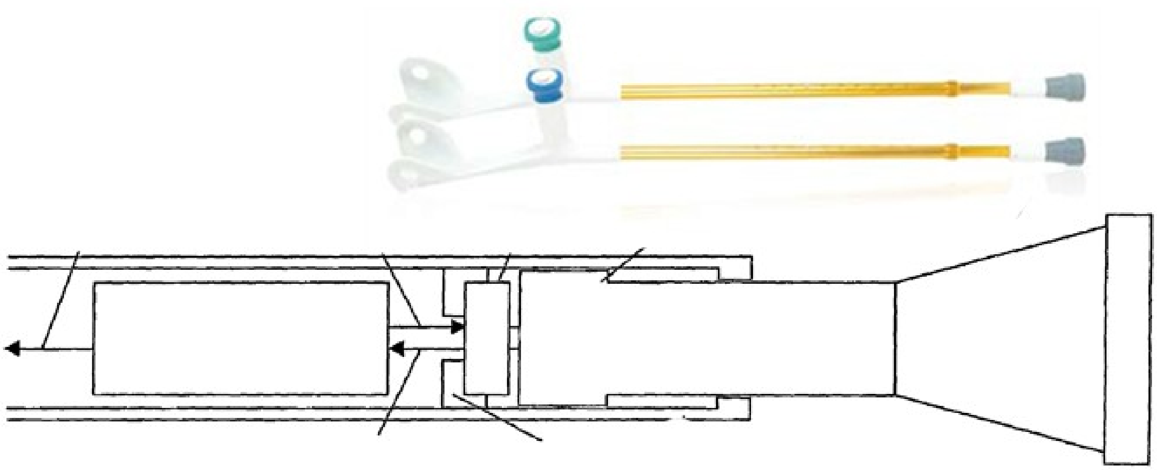
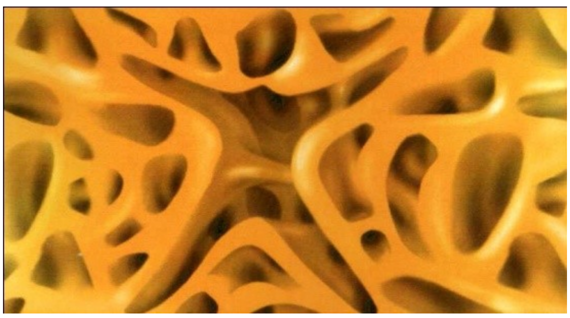
Medical University of Graz

Continuous Measurement and Monitoring of the Postoperative Remobilization after Primary TKA



Diploma-thesis of Wretschitsch Paul



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Diplomarbeit

Continuous Measurement and Monitoring of the Postoperative Remobilization after Primary TKA

(Kontinuierliche Messung und Überwachung der Teilbelastung in der postoperativen Remobilisationsphase nach primärer KTEP)

eingereicht von

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unter der Anleitung von

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Ort, Datum ………………………….. (Unterschrift)

Eidesstattliche Erklärung

Ich erkläre ehrenwörtlich, dass ich die vorliegende Arbeit selbstständig und ohne fremde Hilfe verfasst habe, andere als die angegebenen Quellen nicht verwendet habe und die den benutzten Quellen wörtlich oder inhaltlich entnommenen Stellen als solche kenntlich gemacht habe.

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Preface

When I started my studies in 2003, I soon began to focus my interests on the anatomic and biomechanics functionalities of the human body. Since I had a strong connection to sports, I was curious about surgeries of the musculoskeletal system.

For this reason, I have chosen an orthopaedic department as the focus for most of my internship. There, at a certain lecture about case reports by Professor Andreas Leithner, I pointed out my interests and got the chance to manage a project about a new aspiration-cytology-system and gained my first experience in science.

Priv. Doz. Dr. Heimo Clar holds a patent for a new gait analysis system, which is integrated in forearm crutches as a feedback device for patients who have to perform partial weight bearing of a lower extremity. This system was developed and implemented by Pierenkemper (Pierenkemper GmbH, Wetzlar, Germany). Trying to improve people's mobility and as result, their ability to live a self-determined healthier life by avoiding immobility as a co-factor for physical and psychic disease, made this project suitable as diploma thesis, meeting the general principal of the bio-psycho-social model of the Medical University of Graz.

The general part of the thesis is dedicated to the background of partial- weight bearing and modern devices for partial- weight bearing therapy. The second part is about our own study data concerning continuous monitoring of 31 patients who had to undergo partial weight bearing after primary total knee arthroplasty.

Acknowledgements

First I would especially like to thank Professor Andreas Leithner for introducing me to medical scientific research, giving me the possibility to get involved in different projects and supporting me in my first scientific oral presentations.

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Last but not least, I want to thank my girlfriend Katharina Bayer, B.Sc., for having supported me from the beginning, in between and up until the end of my studies.

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Abbreviations

Fig.	figure
Tab.	table
FWB	full weight bearing
PWB	partial weight bearing
NWB	non weight bearing
LE	lower extremity
TKA	total knee arthroplasty
ACT	autologous chondrocyte transplantation
CPM	continuous passive motion
MACI	Matrix-induced Autologous Chondrocyte Implant

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1 Abstract

Introduction: Partial weight bearing, as therapeutical prescription, can be used in the non operative rehabilitation following trauma or after surgical interventions at the lower extremity. Regarding the lower extremities, forearm crutches are the kind of assistive devices, which allow a necessary load-removal. In daily practice the patients learn to appraise their allowed load force of the lower extremity by using a common bathroom scale. As described in previous studies, this static training does not fulfill the requirements, which occur during a gait cycle under dynamic loads. According to literature, it is impossible for the physical therapist and medical doctor to determine whether the partial weight bearing is performed in a correct way. This inaccurate method holds insecurities for the rehabilitative therapy and can lead to a worse healing process or even an operation or reoperation.

Material and Methods:

With the aid of sensor-supported forearm crutches it is possible to inspect the "bathroom scale training" accurately and assess if patients keep the designated weight bearing. Thirty-one patients, who had undergone cemented primary total knee arthroplasty, were investigated. The postoperative rehabilitation was performed under standardized physico-therapeutical schemes for partial weight bearing using forearm crutches. The optional biofeedback mode was not activated in this study. The loads on the affected extremity were logged and evaluated by the sensor-crutches. Within this constant monitoring, it is possible to examine patients, according to their performance in weight-bearing.

Results:

31 patients (14 men and 17 women) were examined in total. The mean age was 66 years (48-84). The mean total body weight was 83 kg (51–125). Overall 34.652 gait cycles were analyzed, 1 117 steps per person on average. Thereof 269 steps (24%) per person were in the prescribed range (½ total bodyweight ±. 5kg). With a statistical spread of 35- 6251, the missteps (76%) were 848 on average. At the overload- steps (56%), 66% were between 5 kg and 15 kg over the area of tolerance. Thirteen percent were over 20 kg and 20% over 25 kg.

Conclusion:

On the basis of the evaluated data, we conclude that TKA-patients are not able to perform the prescribed partial weight bearing during their remobilization as prescribed. Although it has to be considered that the patients we included tended to reduce weight-bearing due to postoperative pain. Within this constant monitoring of a prescribed partial weight-bearing,

rehabilitation schemes and their indication could become better reproducible and researchable. Further research including the sensor crutches with constant feedback is in progress.

2 Zusammenfassung

Einleitung: Teilbelastung findet als therapeutische Verordnung sowohl in der postoperativen- als auch in der konservativen Rehabilitationsphase nach Verletzungen oder Operationen an der unteren Extremität ihre Anwendung. Die untere Extremität betreffend sind Unterarmgehstützen die Art von Gehilfen die eine notwendige Entlastung ermöglichen. In der Praxis lernen die Patienten unter Zuhilfenahme einer herkömmlichen Badezimmerwaage ihr erlaubtes Auftrittsgewicht abzuschätzen. Wie in mehreren Studien beschrieben erfüllt dieses statische Training jedoch nicht die Anforderungen, da beim menschlichen Gang signifikante dynamischen Gewichtsbelastungen auftreten.

Ob die Teilbelastung dann umgesetzt werden kann ist für den Patienten und den Physiotherapeuten bzw. Arzt laut gegebener Studienlage nicht überprüfbar. Diese inadäquate Methode der Teilbelastungsschulung birgt eine große Unsicherheit in der Therapie, die von einem schlechteren Heilungsverlauf bis hin zu einer Operation bzw. Reoperation reichen kann.

Material/Methoden:

Mithilfe sensorunterstützen Unterarmstützkrücken ist es möglich den Erfolg der "Waagen-Einschulung" genau zu untersuchen und festzustellen, ob die Patienten die gewünschte Teilbelastung erfüllen. Untersucht wurden 31 Patienten nach einer Primärimplantation einer zementierten Knietotalendoprothese. Die postoperative Rehabilitation wurde unter standardisiertem physiotherapeutischen Schema mit Teilbelastung und Unterarmstützkrücken durchgeführt. Die optionale Feedback- Funktion wurde dabei deaktiviert. Die Belastungen auf die betroffene Extremität wurden aufgezeichnet und ausgewertet. Durch diese kontinuierliche Messung ist es möglich, dass KTEP- Patienten hinsichtlich ihres Vermögens, die gewünschte Teilbelastung einzuhalten, untersucht werden.

Ergebnisse:

Untersucht wurden 31 Patienten (14 Männer und 17 Frauen). Das durchschnittliche Alter betrug 66 Jahre (48- 84). Das Körpergewicht betrug im Mittel 83kg (51- 125). Insgesamt wurden 34652 Gangzyklen analysiert und im Mittel 1117 Schritte pro Person. Davon waren durchschnittlich 269 Schritte pro Person (24%) im verordneten Bereich (½ Körpergewicht ± 5 kg). Mit einer Streuung von 35-6 251 betrugen die Fehlschritte (76%) im Mittel 848 pro Person. Von den Überlastungen (56%) waren 66% zwischen 5 und 15 kg über dem Toleranzbereich. 13% lagen über 20 kg und 20% über 25 kg.

Schlussfolgerung:

Anhand der erhobenen Daten ergibt sich der Rückschluss dass KTEP-Patientinnen nicht in der Lage sind die verordnete Teilbelastung, die im Rahmen der physiotherapeutischen Remobilistation stattfindet korrekt durchzuführen. Dabei sollte berücksichtigt werden dass PatientInnen durch den postoperativen Schmerz bedingt weniger belasten. Durch konstantes Monitoring und eventuellem Feedback einer verordneten Teilbelastung können die Rehabilitationsschemata und deren klinische Indikation besser untersucht und nachvollzogen werden. Weitere Untersuchungen mittels sensorunterstützen Unterarmstützkrücken und kontinuierlichen Feedbacks sind daher momentan im Gange.

3 Introduction

"What goes on four feet in the morning, two feet at noon, and three feet in the evening?" is the riddle the Sphinx asks Oedipus. Oedipus answered "Man. As an infant, he crawls on all fours, as an adult, he walks on two legs and, in old age, he relies on a walking stick".[1,2]

Walking with a stick is a sign of getting old and frail. Walking and mobility itself are probably one of the main health issues from the very first hour. Evidence based medicine revealed immobility and therefore less physical activity is a wide spread co-factor for many forms of diseases such as, obesity, diabetes mellitus, depression, atherosclerosis and more[2]. In case of immobilization, we seem to be helpless and eventually might get the feeling of being dependent on others. Based on our autonomy, mobility allows us to practically fulfill our desires, which let us become individual and self-determinate people.

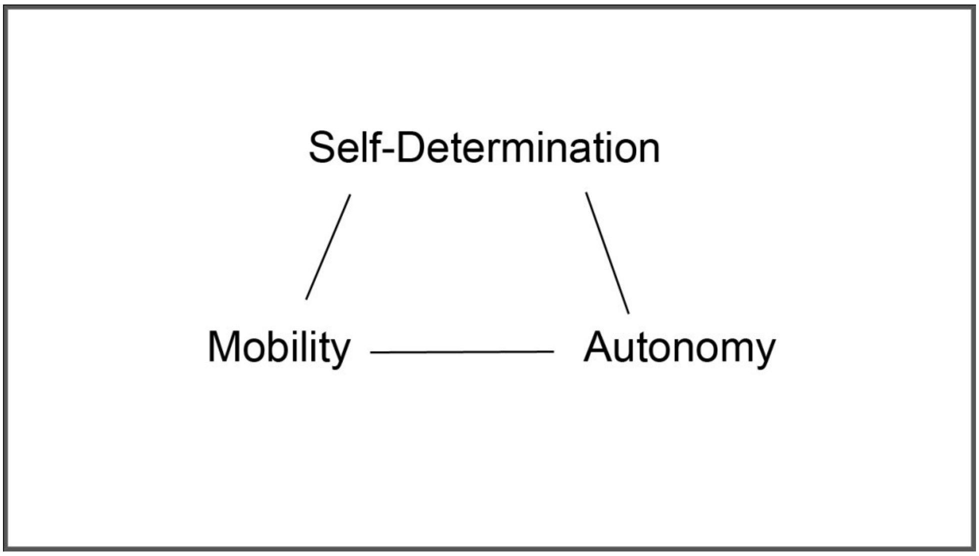


Fig. 1: *Self-determination, mobility, autonomy – directly depending on each other[3].*

A lack of self-determination itself can also be seen as a pathogenous factor, which has an effect on psychological and social problems in return. Therefore scientist, physicians and physical therapists always have to consider that reliable therapy schemes are not just important for curing their patient's acute problems. They are also important to prevent a loss in self-determination and its possible outcome in return.

The joint-replacement of the knee is a surgical routine procedure, which is generally preformed in centers of orthopaedic surgery. In Austria, in the year of 2009, more than 15400 total knee arthroplasties were implanted (ÖBIG). This high number implicates the importance of standardized high quality therapy regimes. The early mobilization after surgical intervention is a well understood principle of post-operative rehabilitation. On the one hand, the risk of general complications after surgery such as obstipation, pneumonia or thrombembolism[4] can be decreased; - on the other hand the therapeutic success of joint replacement is depending on appropriate mobilization[5]. The treating surgeon prescribes the algorithm of postoperative rehabilitation and weight bearing. There is a broad individual difference in the postoperative remobilization regimes. An early partial weight-bearing has a positive influence on implant-healing, whereas overloading can cause complications such as bursting of the implant or it can lead to early component luxation[6]. If an implant must not be loaded by 100% of the patient's bodyweight, physical therapists are confronted to teach patients extensively how to walk for example with two forearm-crutches while performing a partial weight-bearing. Unfortunately patients perform equally with supervision (verbal instruction, observation and bathroom scale method) as they do without.[7,8] Therefore, observation of such treatment schemes is mandatory and further justifies this investigation.

4 Weight Bearing & Fractional Load

In trauma and orthopaedic surgery, partial weight-bearing is the amount of weight-load, which is applied on the affected limb. The limit of weight is prescribed by the treating physician, and is given in percentage of body weight or in kilogram load. Depending on the therapy, different grades of PWB can be described:

- *Non-weight-bearing* (NWB): No bodyweight must be applied to the affected limb. The patient can use a wheelchair, jump on one leg or use crutches to move around.
- *Toe-touch weight-bearing:* The foot just touches the floor, not providing any weight-backup. Realistic applied loads can come up to approximately 5-10% of the total body weight. This regime is in standardized use as physiotherapeutic regime e.g. *c*hondrocytes-transplantation (ACT), acetabular fracture fixation, or plate fixation of displaced and unstable fractures of the tibia[9].
- *Partial weight-bearing (PWB):* Ranges from 10%- 90% of the bodyweight. Depending on the intensity, different mobility aids can support the patient to redirect weight away from the affected limb. A continuous probably ascending weight load will provide a consistent stimulus for bone growth and healing while preserving biomechanical overload which could affect the healing process.
- *Full weight-bearing (FWB):* 100% of the body weight can be applied. This corresponds to the physiological gait.

4.1 Domains of PWB

Partial weight bearing as „go easy on-"therapy finds its use in many different therapy regimes. Restoring the musculosceletal system to its postoperative performance and ensuring enough stimuli to generate a sufficient bone healing process are the two-pillars of this therapy strategy. Typical indications and the start for PWB are listed in table 1.

After total knee arthroplasties, remobilization starts from the first day after surgery with continuous passive motion (CMP) and the physical treatment,[10] including gait training for FWB or PWB. Therefore, the decision between FWB and PWB relies on the treating surgeons' prescription. In specific indications (table 1) the patients have to perform NWB initially, followed by PWB, commonly in the 2nd week after surgery. In these indications, the first phase of rehabilitation, loads on the operated limb have to be avoided. Within cartilage-plastics (MACI) for example, the knee must not take any loaded shear movements, because in the early stadium after implantation the tissue will not bear up against such strong forces.

Knee-close indications		*Indications for Partial Weight Bearing (Forearm-crutches, 3 Point- Gait)*
TKA (Total Knee Arthroplasty)	Controversial indication for FBW/PWB, prescribed of treating surgeon	
Medial slide prosthesis		*1st week*
Axis-free resurfacing		
Cement-free		*1st week*
Cemented		*1st week*
Axis-linked Alloplastic		*1st week*
TKA- Revision		*1st- 2nd week*
Corrective Osteotomy		
supracondylar		*2nd week*
infracondylar		
additive		*2nd week*
subtractive		*2nd week*
Cruciate ligament injuries		
conservative		*2nd week*
fresh operative reconstruction		*2nd week*
artificial ligament		*2nd week*

Cartilage-plastic's (femur's roll, patella, tibial plateau) *Abrasion* *Microfracturing* *Mosaic-Plastic* *Chondrocytes-Transplantation (MACI/ACT)*	 *1st week* *2nd week* *2nd week* *2nd week*
Tibial plateau fractures *Conservative* *Screwed osteosynthesis* *Plate osteosynthesis*	 *2nd-4th week* *2nd- 4th week* *2nd week*
Supracondylar femur fractures *Plate osteosynthesis* *Dynamic care*	 *2nd- 3rd week* *2nd week*

Table 1: Shows the start of PWB-Therapy after knee-close interventions[11,12] Mostly starting from the second postoperative week.

After advanced healing, it is generally recommended that the weight load should be increased continuously to FWB. Ascending stimuli of force and pressure are needed to keep the healing process continuing and regain a full-weight bearing end result.

Nevertheless, not just the direct location of the intervention is affected by this therapy, as shoulders and arms might suffer from acute overload, since they need to take over the lower limbs bearing.

Problems of too long PWB with forearm crutches[13]:

- Atrophy of leg musculature
- Higher risk of deep venous thrombosis
- Shoulder pain due to overstraining
- Nerve compression syndromes of the hands

4.2 Assistive Devices for partial weight bearing

If you have a disability or injury, you may use a number of assistive devices. These are tools, products or types of equipment that help you perform tasks and activities. They may help you move around, see, communicate, eat, or get dressed. Some are high-tech tools, such as computers. Others are much simpler, like a "reacher" - a tool that helps you grab an object you can't reach (Medline Definition for Assistive Devices).[14]

The right choice of assistive devices and sufficient gait training are essential for a successful treatment. For the realization of a PWB therapy, different assistive devices, so called primarily mobility aids, exist. The usage of assistive devices, especially gait-assistive devices has a long history. When injury or illness made mobilization difficult or impossible, people had to find ways to get around. Prehistoric drawings that exist from ancient Egypt show Pharaohs using axillary crutches as they were visiting their medicine man, refer to fig. 2.[2]

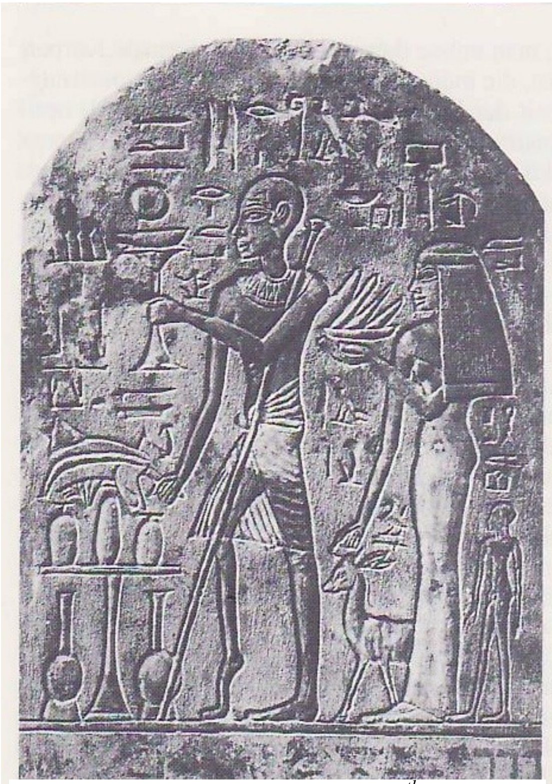


Fig. 2: *Egyptian man from the 18th Dynasty 1580-1350 B.C., using a stick as a walking-aid while visiting the medicine man.*[2] *This stele can be seen in the Carlsberg-Glyptotek in Copenhagen.*

Nowadays, a lot of different assistive devices are available. Mobility aids such as crutches, canes, walkers, wheelchairs and motorized scooters are helping to reduce ground force and unload an affected extremity. Depending on the needs of the individual user, different devices have their special advantages to maintain upright ambulation by providing any or all of the following criteria[15]:

- Supporting Balance

Walking aids provide a wider range of stable centre of gravity positioning by giving additional contact points to the floor.

- Reducing the load to one of the lower limbs

The walking-forces are bridged by the walking aid and not transmitted through the affected limb.

- Generating Movement

Walking aids support to move still dynamically around. The power of other muscle groups (e.g. the shoulder) will generate enough force to bear and accelerate.

- Transmitting Information

Sensory cues can be perceived through the hand and help to avoid obstacles.

Common assistive devices for a partial weight bearing gait are axillary crutches, forearm crutches, wheeled walkers and single-point canes.

4.2.1 Canes and Walkers

Walkers and canes are commonly used for geriatric patients in case of frailty. Patients are at risk of falling or suffering from fatigue or decreased endurance. The user has the possibility to lean on the cane quickly and get support finding the balance.

Fig.3: *4-Point-Cane and walker used to minimize the risk of falling. The walker has breaks to avoid unwanted acceleration.*[16]

Youdas et al[17] showed that the average load removal of canes (~25%) and wheeled walkers (~35%) is just little support for weight-bearing. Canes and walkers do not unload as much weight as crutches, but have the usability-advantage in that a cane might be used just 1 handed and walkers have a storage-box integrated. Nevertheless environmental considerations such as accessibility (i.e. tight rooms) have to be evaluated before.

4.2.2 Crutches

Crutches traditionally were made of hardwood, whereas nowadays anodized aluminum crutch-designs are the “crutch of choice” for many reasons. Three different types are known:

- Axillary crutches
- Forearm crutches (also known as Lofstrand)
- Platform crutches

Due the fact that axillary crutches provide stability with a padded piece, which is held between the lateral thorax wall and the upper arms, they seem to be more suitable for patients with weak arms or shoulder disorders. On the other hand, the use of forearm crutches is more feasible because it allows the client to use his hands without dropping the crutches.[18] Further, leaning on axillary crutches may cause neurological injury due to axillary nerve compression (i.e., crutch palsy).

Forearm crutches require resilience of the wrist joints and hands. To walk with crutches is a coordinative skill which not everyone is capable of. To ensure the therapeutical benefit, the use of crutches implies proper fitness like good upper extremity strength, joint integrity and enough range of motion.[19] Furthermore, shoulder flexors and depressors, elbow and wrist extensors, and finger flexors must have adequate strength (grade 4/5).[20] Additionally, the patient has to be able to keep his/her balance and should not use the crutches as a balance-tool. Another required ability is to erect the torso, because otherwise the balance of power between all the involved joints and muscles is not divided appropriately.

Typical indications for forearm-crutches after surgery of the lower limb: force-release of the lower extremity (full – partial) using 3 – or 4 –point –gait postoperatively, painful joint-affection, paralysis or after femoral- or lower leg amputation.

Platform crutches provide more areas of contact transmission for the load and should be an option for patients with limited capacity of their wrist and hand joints, like in cases of rheumatoid arthritis.[18] Straps, padded platforms and vertical handgrips should help patients with gripping limitations or problems bearing weight in the hand, wrist or forearm.

As shown in Fig 4, Youdas et al. described the differences between conventional assistive devices according to their quality of helping probands to achieve the target of a weight reduction of 50% on the right lower extremity[17]. Each of the investigated devices significantly reduced the vertical ground reaction force, but nevertheless, the target of 50% partial weight bearing was just achievable with axillary (50% reduction) and forearm (56% reduction) crutches *(fig.4)*. Hence in order to keep more than 50% body weight off the hips, knees, ankles or feet, crutches seem to be the assistive device of choice.

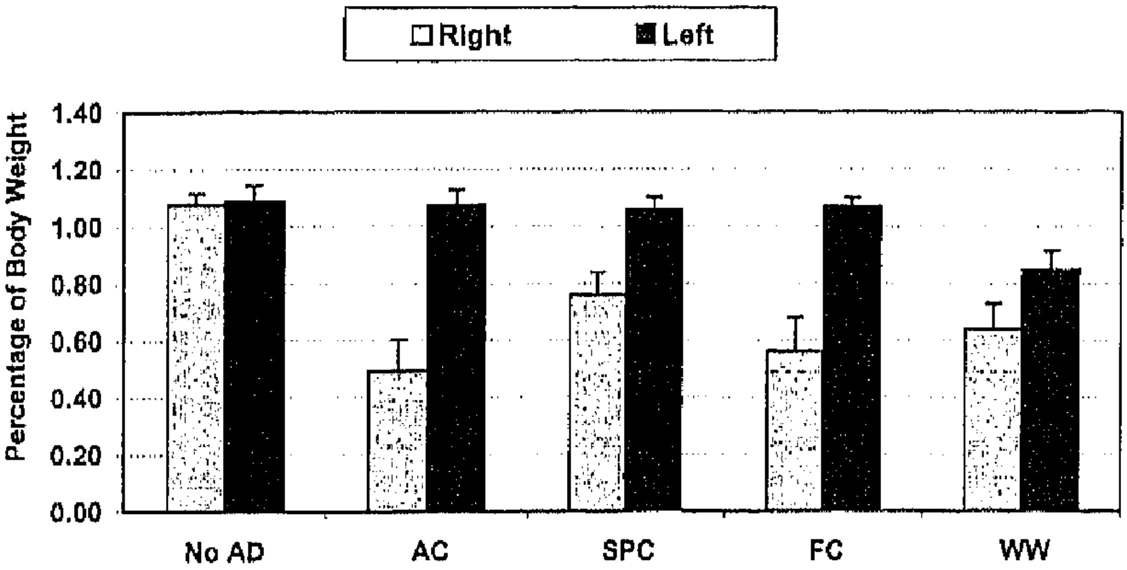


Fig. 4: *Shows the mean vertical ground reaction forces for different assistive devices, which were used to reduce the peak force on the right side. Abbreviations: No AD, no assistive device; AC, axillary crutches; FC, forearm crutches; SPC, single-point cane; WW, wheeled walker.*[17]

4.3 Gait Training

After trauma or surgery, physiotherapeutical gait training is needed, to regain the coordinative skills, for the gait process. Walking with crutches can be unfamiliar to patients and has to be trained. In cases of elective surgical interventions, it would be wise to practice walking with crutches before surgery. Particularly PWB has high demands on the patient's sensorimotor skills, since a certain ground reaction force should not be exceeded. According to this, side effects following surgery (e.g. adynamia, nausea, pain) can make learning to walk with crutches additionally difficult. Nevertheless, pre-interventional gait training seems not to be wide spread in clinical practice.

Basic conditions for walking with complete load-removal or PWB are compensating due to enough strength of the shoulder girdle and arms, a minimum coordinative skill as well as a minimum of motoric-force expansion.

Generally, different gait patterns can be performed. After total knee arthroplasty, locomotion considering PWB is best with forearm crutches using the 3-point-gait.

Fig. 5: *To reduce the load on the right leg, the foot has to be put between the two crutches. While the weight is shifted from the healthy leg onto the affected side, the arms can intercept the vertical ground force.*[33]

With the 3-point gait, an affected leg can be unloaded fully- or regulated. The patients can lean on and release force from the leg, which is put between the crutches. Depending on how much ground-pressure the foot percepts and on the walking experience, the patient stops shifting more weight on the affected leg and intercepts the rest with the crutches.

The physical training requires further intellectual skills and awareness as well, which might be difficult for some patients due to, the patient's postoperative constitution. Elderly or overweight people may not have enough muscular strength in their arms to distribute bodyweight from a leg to their arms.[21,22]

Additionally many patients may suffer from an unfavorable technique when using the crutches. This results in an overload shortly after the heel strike or shortly before the end of the stance phase.[21]

Patients need to be informed about the direct influences according to their weight-loading performance. Risks like loosening of the implant and bone-healing disorders with all their consequences (revision, reoperation, wound healing disorders, danger of thrombosis, bone-healing disorders etc.) might give some motivation to practice with a focus on the gait training in an appropriate way.[13,23]

4.3.1 Gait Training & PWB

Current methods of PWB gait training are mainly subjective and depend on the experience and skills of the treating physical therapist. To train a patient in PWB, the following methods are described.[24]

- Hand under foot

The therapist puts his/her hand under the involved lower extremity of the patient, trying to appraise the correct force-level the patients puts on the involved limb.[25]

- Bathroom scale

The patient should learn to internalize the feeling of a certain PWB by a visual control through a bathroom scale.[26]

- Full-length mirror

The patient gets visual support by observing himself/herself using a full-length mirror. This can help to adopt a correct position.

- Video-based instructions

A video shows and describes a certain exercise. Different angels and detailed demonstration should help to understand the exercise.

- Verbal instructions

The patient gets only a verbal instruction.

All of these methods seem to be rather inaccurate, [7,22,25,36] because using these methods, PWB is more a guessed, than a measured factor. Another disadvantage is that these methods are preformed in a more or less static setting and do not reflect the dynamic forces during a gait cycle. The sensomotor system with its proprioceptive abilities does not provide a quick and efficient short-term memory which would allow learning such a complex exercise in a short time. Therefore the reproducibility of a practiced PWB may differ during a dynamic activity such as gait.[17]

4.4 Gait Analysis:

Within gait analysis, the applied loads, which take an impact on our body can be determined. Measuring elements define mechanic influence of forces, like distortion, elongation, or direct electronic voltage fluctuations. Through the applied forces, tension- and compression stresses one's bones, sinews, muscles and even ligaments can be interpreted. Nowadays electronic measurement-systems directly display measurements in form of native data or graphical diagrams. These mechanoelectric transducers are termed force-sensors and can be subdivided in two modes:

- **Strain Gauge Pressure Transducer:**
  Acquisition of stretching/compression distortion; A light distortion already leads to a change of the electric resistance. Stretching leads to increase-, whereas compression to decrease of the resistance.

- **Piezoelectric Pressure Transducer:**
  The piezoelectric effect results from the effect that special quartz crystals produce electric voltage if they are deformed. With sensitive charge amplifiers, applied forces can be transcribed into proportional voltage (e.g. Kristler-Plate).

If more force-sensors are arranged, vectors can be measured. Multicomponent force-plates can be used to measure ground reaction forces (refer to figure) and are widely spread especially in gait-analysis–facilities.

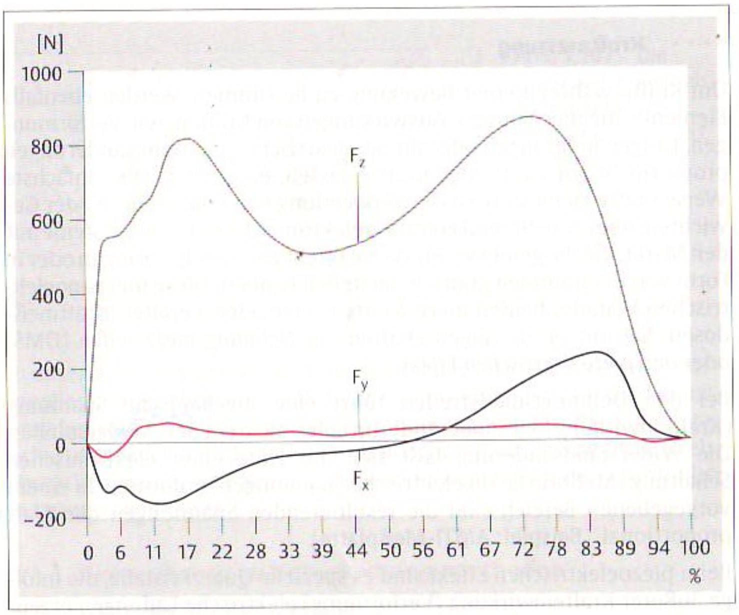


Fig. 6: *Ground reaction forces during mainstay-phase (Kristlerplate). The first peak of F_z indicates the touch-down-, the second peak the push-off of the foot.*[27]

The image shows the measured forces and can be interpreted as followed: $F_{z,}$ the vertical force component, shows a typical M-shaped process. The first peak represents the touch of the heel and the second peak the repulsion of the toes. F_x shows the horizontal force components, which are the opposite forces in the phases of touch and push off. F_y shows lateral impulses, which are typically small, but can be expected in the case of instable collateral ligaments.[27]

The vertical ground reaction force is of course the most interesting factor for PWB, since this force directly corresponds with the load the limbs have to bear. But gait analysis facilities are rare, expensive and they have limited capacities. Therefore modern assistive devices were designed, which support physically, but also measure and monitor your activity.

5 Modern Devices for PWB

Modern Devices for PWB are high technology supportive devices, which are able to measure and control the weight-bearing forces (directly or indirectly). These devices for PWB need to fulfill different demands for patients and therapists:

- Measurement Accuracy
- Ability of Monitoring
- Programmability/Customization
- Transmission/Saving of Measurements
- Emission of Alarm Signals/Biofeedback

The measurement accuracy may be limited if the devices are not used in a designated setting (walking stairs, running). The ability of monitoring is the main component, which offers more possibilities if implemented. First, it gives therapists the possibility to analyze the patients' performance and walking-habits. Every step can be measured and stored if the patient is practicing on his/her own. In the follow up period the treating physician or therapist can check the latest progress and get an objective evaluation. This might be advantageous when used as a treatment control. Within programmability, the devices measurements can be processed further and be adapted to the patients allowed step-weight. Due to an instant processing of measured data, the device should be able to send any kinds of alarm signals in real time when a wrong step is recognized.

Learning how to walk while keeping one leg just loaded with the half of the total body-weight can be a tough skill to learn without constant support. Winstein et al described that verbal feedback as "postresponse feedback" does not help for immediate performance, but concurrent biofeedback mechanisms can be used to teach a patient until he/she automatized the therapeutic gait.[26] Sensors detect the overload/underload via direct or indirect measures and return this information to the patient in form of signals (acoustic, visual, kinesthetic). This option allows a controlled gait training, which gives patients the opportunity of real-time-correction of their gait, as well as the assurance that they are walking correctly. Various studies have already shown, that just by using biofeedback, prescribed weight-bearing can be reached during ambulation and gait training will be shorter and more efficient than compared for example to the bathroom scale method.[24,28,29]

5.1 *In-Shoe Systems:*

In-Shoe-Systems are devices for measuring the weight force exerted on the foot when a patient is walking or standing. The sole includes pressure- sensitive sensors and produces an electrical signal. This is directly related to the applied force on the operated limb and is being processed to alert the wearer when the maximum force is exceeded. The measured data can be recorded and exported for further analysis.[28]

Fig. 7: *In-shoe systems for real-time measurement of applied vertical ground forces. The storage and accumulator have to be carried on a belt or in a bag.*[30]

A clear advantage of such a system is the direct measurement of where the vertical force takes place. Counterpoints of this system are that the data storage has to always be carried in a vest or on a belt and that the reuse is unlikely because of involved orthopaedic cobbling and hygienic issues. Furthermore, the patient always has to wear shoes – which might not be a convenient solution for home usage or in summer.

5.2 Sensor Crutches (Pierenstep)

The sensor-crutches-system Pierenstep (Pierenkemper GmbH, Wetzlar, Germany) is designed for measuring and monitoring the fractional load of orthopaedic and surgical patients through an indirect determination of the weight load of a lower extremity. Furthermore this device is equipped with an alarm transmitter which emits an acoustical and/or a vibration alarm when an adjustable load fails a defined programmed range.[31]

These crutches (Fig.8), each with ~0.6 kg weight, contain 4 Mega Byte Flash memory and are running through a 2,4 V (2 x 1,2 V) accumulator. Each of the crutches has a power absorber which measures the actual weight load on the crutch. This measured analogue signal, which is directly proportional to the weight load on the same crutch, will be fed into a digital evaluation circuit.

Fig. 8: *The sensor-crutches „Pierenstep" are able to provide biofeedback if the prescribed limit is exceeded.*[33]

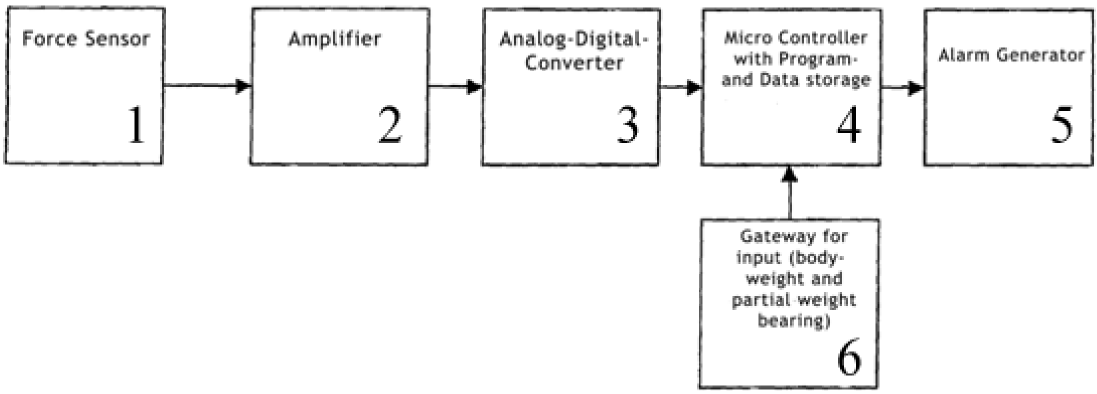


Fig. 9: *The Illustration of an appropriate electronic evaluation circuit.*[32]

The input from the force sensor (1) is sent to an amplifier (2). This signal is getting converted into a digital signal (3).

The crutches are divided into a master- and slave crutch. The first crutch (master) constantly measures the weight loading and sends its measurements to the second crutch. The second crutch (slave) receives this data and adds it with its own measurement. This result corresponds directly to the known total body weight minus the weight the affected leg is bearing. This sum is permanently processed in the slave crutch by a microcontroller (4), which is able to perform an algorithm to conclude the estimated bearing with or without dynamic enhancement.

$$weight_{limb} = weight_{body} - (weight_{crutch\,1} - weight_{crutch\,2})$$

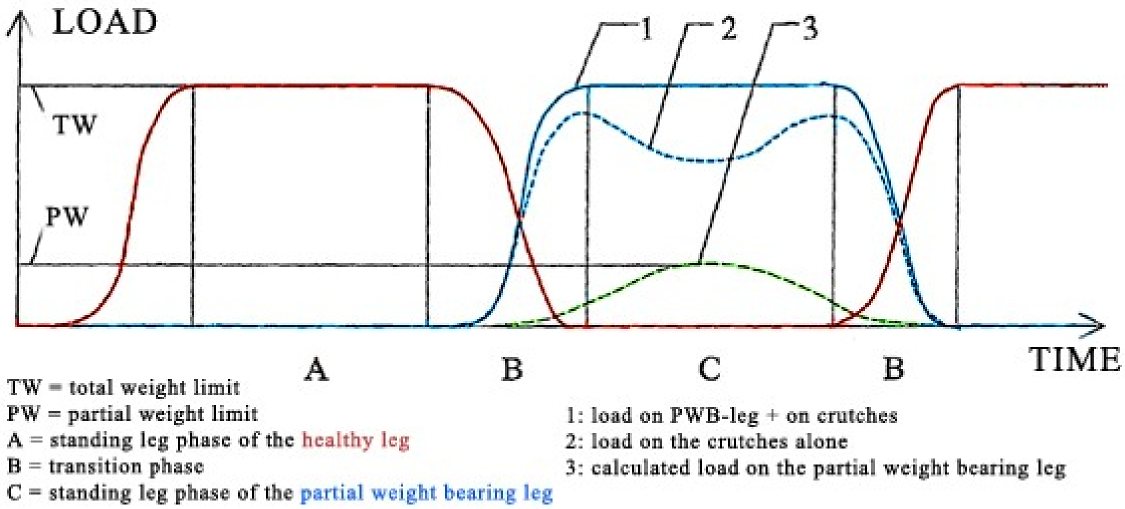


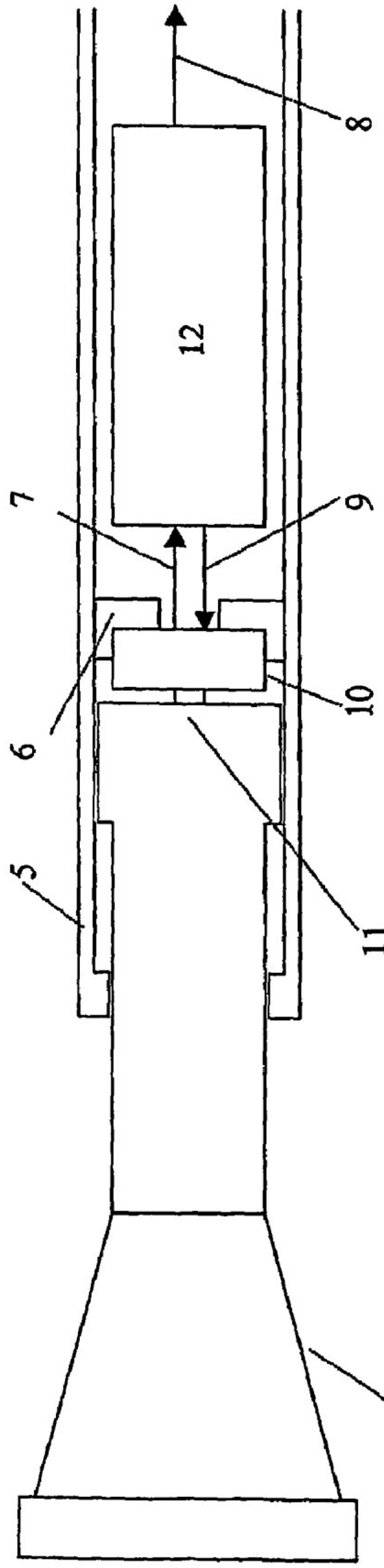
Fig. 10: *A graph demonstrating the weight bearing conditions prevailing when walking with crutches and practicing partial weight bearing under "ideal" static conditions.*[32]

If the weight-bearing is over or below the allowed load, a signal tone or vibration-motor can be activated by the alarm generator (5). This mechanism is used to give possible instant feedback to the practicing patient, if desired.

Every step and its measured weight-bearing will be stored at a memory device seated inside the crutch. All measured results are stored and can be analyzed by addressing different parameters; for example the number of wrong- loaded steps, how much overload was put onto a leg (< 5 kg, >5 kg, >10 kg, etc), or how many steps were made per day.

Due to the system’s gateway (6), information can be sent to a computer via cable/wireless connection, where software can then process it further. When setting up a new pair of crutches, this software is also needed to set the total body weight and the allowed partial weight bearing limits. Besides the upper limit of weight-bearing, a lower limit can be defined. This opportunity allows constant securing of the requested load on the affected limb.

The software also provides different settings for alarms (sounds, vibrating) which can be assigned to a certain limit or turned off if desired. Additionally, the collected patient’s data can be exported into Microsoft Word (Microsoft Corp., Redmond U.S.) and Microsoft Excel (Microsoft Corp.) documents for further analysis or as patient-handouts.



4 - crutch foot of rubber
5 - crutch tube
6 - means for mounting the load cell
7 - analog output signal
8 - line to the signal generator
9 - power supply for the load cell
10 - load cell
11 - plunger for transfering the weight load to the load cell

12 - electronic evaluation circuit (Fig.9)

Fig. 11: *Embodiment of the Pierenstep-System.*[32]

Within the live- mode, therapists are able to follow every step in real-time and therefore the gait and PWB can be observed and corrected step by step. This might be helpful during practice sessions, where the patient has to learn the 3-point gait for example. For every step, measured results can be displayed instantly. The characteristics of the measured curve can be interpreted as the following examples illustrate (Fig 12 -14):[33]

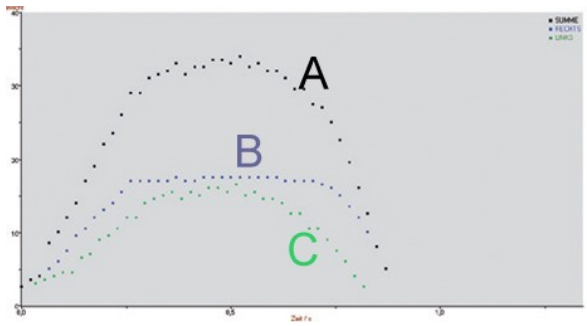


Fig. 12: *Too much PWB, symmetric curve, constant input;* **A**: *Sum of the vertical force on both crutches.* **B**: *Vertical force on the right crutch.* **C**: *Vertical force on the left crutch.*

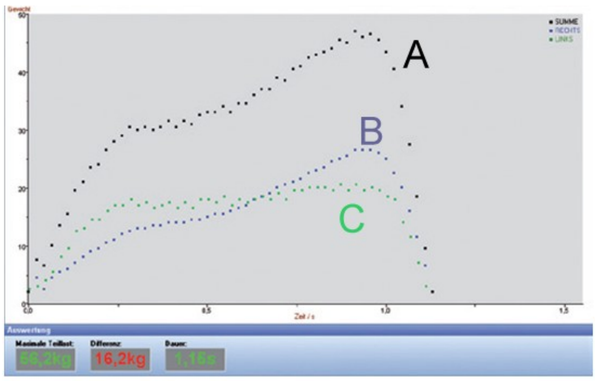


Fig. 13: *Asymmetric curve, no constant input, dynamic peek at "heel push-up";* **A**: *Sum of the vertical force on both crutches.* **B**: *Vertical force on the right crutch.* **C**: *Vertical force on the left crutch.*

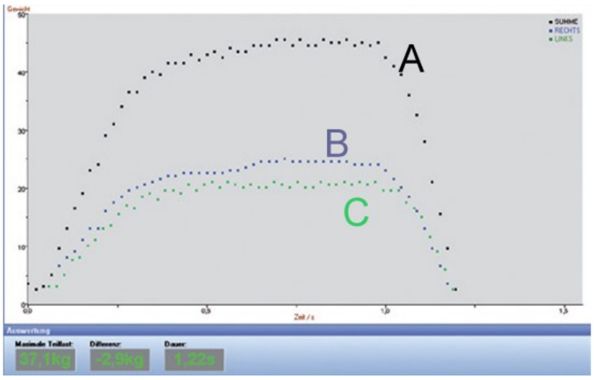


Fig. 14: *Ideal curve, symmetric, constant input, correct PWB;* **A**: *Sum of the vertical force on both crutches.* **B**: *Vertical force on the right crutch.* **C**: *Vertical force on the left crutch.*

The accumulated data can be stored externally at the therapist's room and can be compared to evaluate the course of practice of the gait training.

6 Special Part: Results of a Partial- Weight Bearing-Monitoring of 31 Patients with a Primarily TKA.

6.1 Introduction

At the Department of Orthopaedics and Orthopaedic Surgery at the Medical University of Graz, Austria, 31 patients were monitored respectively to their ability of performing a partial weight bearing 3-point-gait. The study did not address the clinical effect of PWB, but challenged the patients' ability to weight bear partially after practicing with a bathroom scale under supervised conditions. Every step the patient made with the sensor-crutches, during his/her residence, was monitored and analyzed. The main parameters where: correct steps, incorrect steps and by how much the limit was exceeded or deceeded.

7 Material and Methods

7.1 Participants

All participants were asked if they would join this clinical study but were not informed about the concrete meaning of the measurements in advance to avoid a possible performance bias. 31 patients (14 men, 17 women) were investigated. Everyone had an indication for a primary total knee replacement. Their details are shown in Table 2. The average age was 66 years with a range from 48 to 84 years and the median weight was 83 kg, with a range from 51 to 125 kg.

All patients had unilateral knee surgery (TKA) and were recruited before the operation. Patients with walking problems or more affected joints especially of the lower extremity were excluded. To ensure the cognitive skill which is necessary to use assistive devices for remobilization and follow the therapist's instructions, a mini-mental state examination (MMSE) was preformed and only patients with a score >25 where included.[34] All data for the participants were treated with confidentiality.

Patients characteristics	
Male	14
Female	17
Mean Age (years, range)	66,(48-84)
Median age (years)	67
Median weight (kg)	83
Range weight (kg)	51-125

Tab. 2: *Patients characteristics*

7.2 Instrumentation

The partial weight bearing analysis (overload, underload, and step-amount) was obtained by an "intelligent" forearm crutch system for the determination of weight bearing (Pieren-Step, Pierenkemper GmbH). Since the aim of this trial was to determine the ability of patients to perform partial weight bearing during their routine residence, the additional features of this system (alarms for biofeedback) were disabled. Compared to other patients, the study-participants had to use different colored forearm crutches.

7.3 Procedures

After the patient's acceptance, the crutches were configured individually for each patient. The total body weight was measured and subsequently half of the total body weight was applied to the crutches configuration as the desired value for the partial weight bearing (e.g. 90 kg total weight =.45 kg partial weight bearing).

At the first postoperative day the patients were remobilized with the aid of a physical therapist, including a tutorial on 3-point walking with forearm crutches. To learn partial weight bearing, the bathroom scale-method was used.[26] While bearing weight only on the healthy lower extremity, the patients have to shift their weight gradually to the opposite site until the numbers on the bathroom scale reach 50% of their body weight. Patients were told to remember this “50%-feeling” on their affected side when walking with their forearm crutches.

The patients were in possession of the “intelligent” forearm crutches during their clinical stay and were discharged from the hospital with conventional forearm crutches.

After the patient’s clinical stay, the data which was stored on the crutches memory was collected and exported into a spreadsheet program for further analysis.

8 Results

All in all, 34 652 steps were recognized and scaled by their accuracy hitting the ±. 5 kg zone of 50% of the total body weight. The overall percentage of correct steps was 24% (8364) and 76% incorrect steps (26 288). The majority of incorrect steps (74%) were steps which exceeded the prescribed limit.

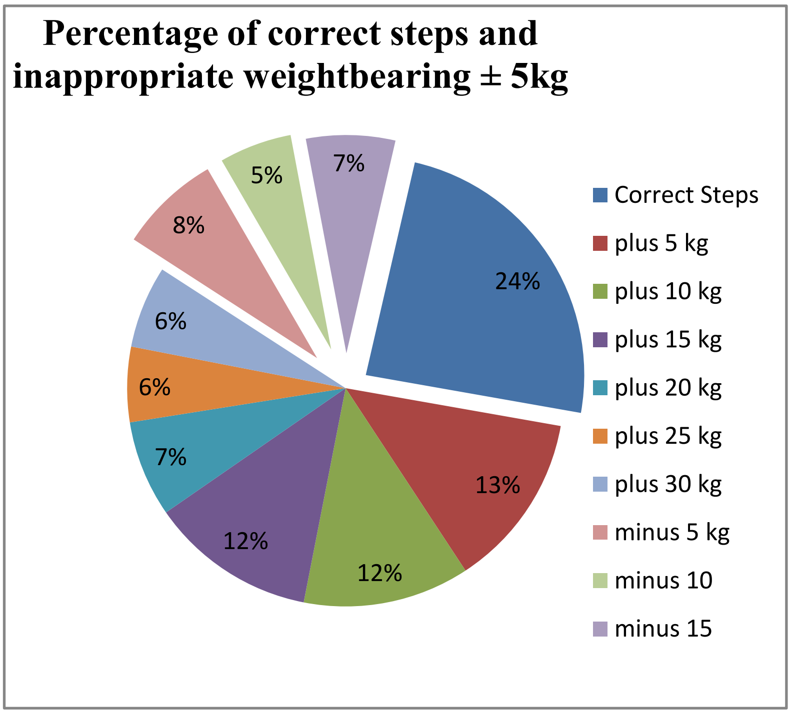


Fig. 15: *shows the percentage of correct steps (24%), and incorrect steps (underload/overload) of all measured steps.*

The results of overall overload-steps (19 509, mean 629) show that 23% of these were over 5 kilos exceeding, 22% were over 10 kg and 22% over 15 kg. Another 12% were over 20 kg, 10% over 25 kg and 10% more than 30 kg overloaded.
All steps which were under the prescribed limit (6737, mean 217) could be divided into, 39% minus 5 kg, 28% under 10 kg and 33% less than 15 kg.

Figure 16 and 17 show the mean overloaded and underloaded steps related to their deviation of the prescribed limit. Within overloaded steps, twice as much steps where made between +5 kg to +15 kg overload (13 007), than from +20 to +30 (6 502). The underloaded steps had a constant distribution between -5 kg to -15 kg. The positive error bars are raised because of two patients (See Fig. 18, Subject 7 & 17) with a massive higher step count compared to average patients. With 48 and 57 years of age, both belong to the younger age of participants. Further, Fig. 18 describes the individual performance, comparing correct versus incorrect steps. It is remarkable that 9 patients (No.: 2, 4, 5, 6, 9, 22, 23, 25, 31) had no correct step at all. Patient No. 7 was the only one who had more correct (2092) than incorrect (1871) steps. As mentioned above, Patient No. 7 was the youngest (47a) and additionally the most lightweight one with 54 kg.

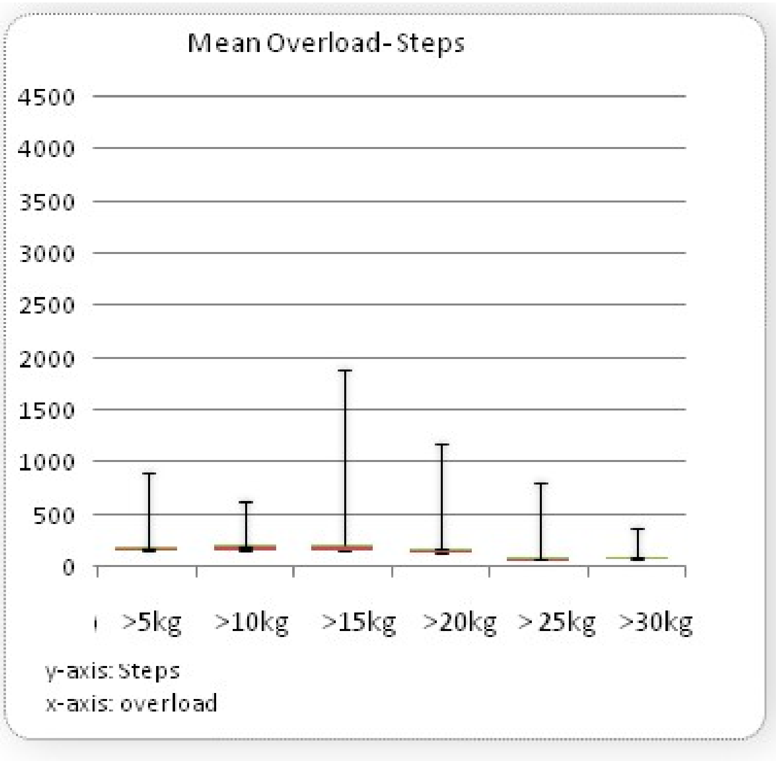


Fig. 16: *The diagram shows the mean overload-steps per patient. The error bars are raised because of two patients with a massively higher step count.*

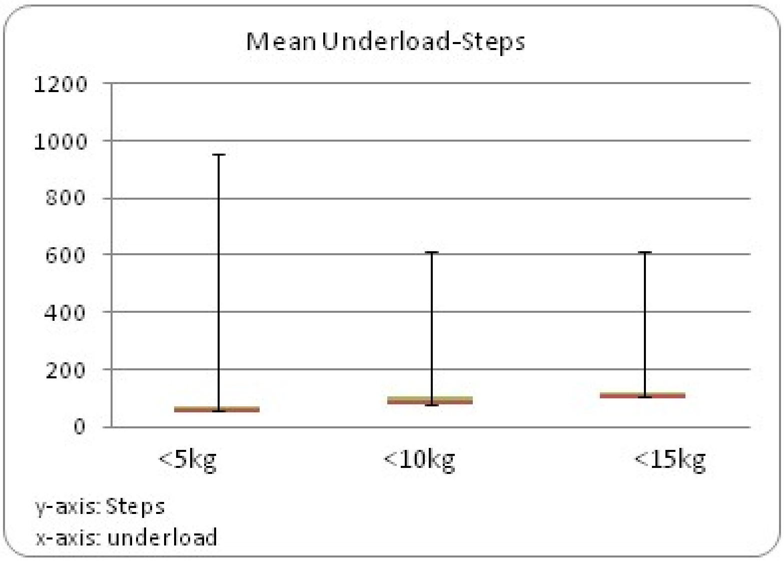


Fig. 17: *The diagram shows the mean underload –steps. Again, the error bars are raised because of two patients who made significantly more steps.*

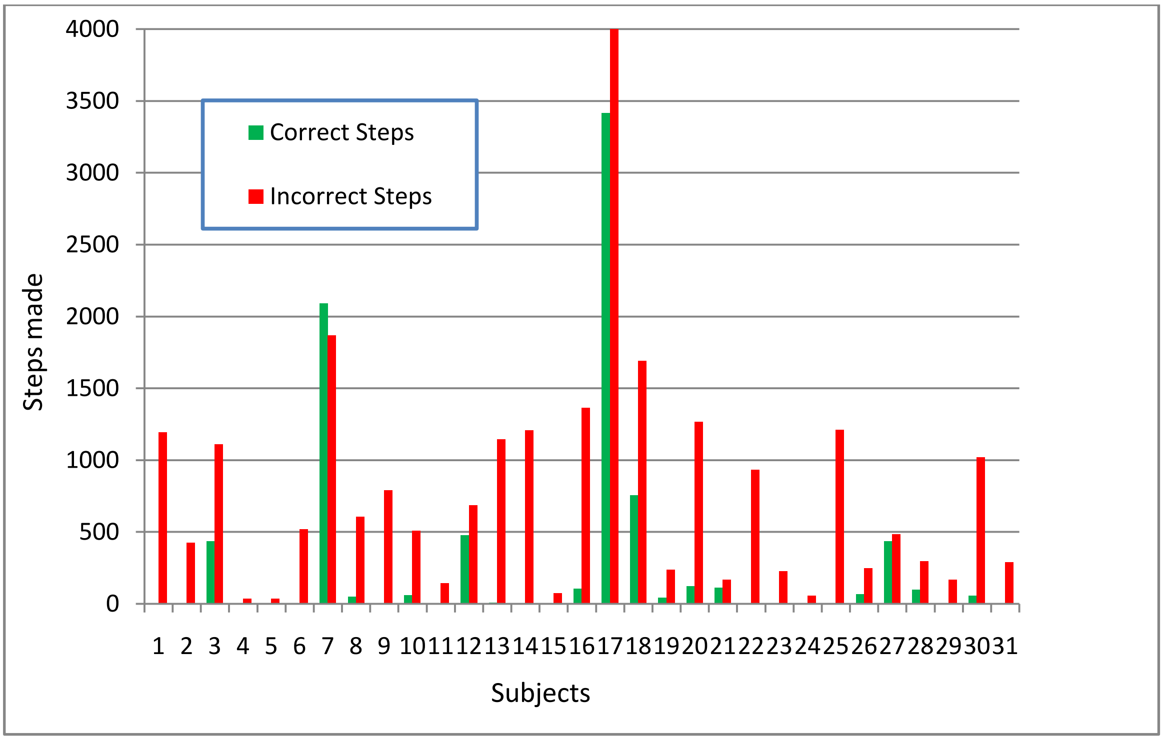


Fig. 18: *A bar diagram was used to compare correct versus incorrect steps. A massively higher step count was recognized in Subjects 7 and 17. Subject 7 was the only one with more correct than incorrect steps.*

The findings of this experiment definitely indicate the lack of the patient's ability to perform a 3-point gait, while bearing not more than 50% of the total bodyweight on the affected limb.

9 Discussion

Meeting our expectations, the patients were not able to keep the prescribed weight-bearing limit using forearm crutches. This result correlates with published data of previous studies.[9,21,22,28,35,36,37,38,39] Table 3 shows comparable results of previous studies.

First, an important reason might be that using a bathroom scale or auditory feedback, which are probably the most common methods, does not lead to satisfying results in teaching patients how to perform partial weight bearing.[21,35] The sole of a human foot just can not store and reproduce a weight bearing "feeling". While auditory feedback has to be at least a minor support, the bathroom scale seems to act as an extra challenge for the patient and is learned under static conditions. This might lead to overloading during real gait dynamics.

Author	Comparable results of PWB-performance
Guy Rubin	22%-50% success rate 20% +9 kg overload, 64% +14 kg overload
Tveit M.	Aim-weight was 30% BW; Average weight bearing was 63%-80% BW
Dabake H.V	Exerted by mean of 35.3% BW
Vasarhelyi A	186-194 N difference than prescribed
Stangl R.	Aim-weight was 20 kg; 64% overload steps/pers. Reduced ~34% overload steps after feedback-training with insoles
Ebert J.	Aim 20% BW. Patients exerted a mean of 15.8% BW more. Aim 40% BW. Patients exerted a mean of 8.3% BW more. Aim 60% BW. Patients exerted a mean of 11.9% BW more. Aim 80% BW. Patients exerted a mean of 1.2% BW less. No improvement between immediate performance and 7 day retention (for the groups of 40%-., 60%- and 80% BW-PWB)

Tab. 3: *This table shows comparable results of different authors, researching the patients' ability to achieve a prescribed PWB.*

A study by Malviya A. suggests using a bathroom scale for the PWB training,[40] but because of the very low amount of patients (n=12) and their young average age (28-42yrs), the results have to be doubted in comparison to results of the majority of previous studies.

Another factor for bad PWB skills might be that patients in general start to practice the 3-point gait using crutches postoperatively. Disregarding the postoperative pain, partial weight bearing can be a very demanding skill, which requires practice and the patient's compliance. To ensure a therapeutical effect, a certain sensory skill as well as muscular arm power and endurance are basic requirements. This might be a disadvantageous factor especially for elderly patients, since the physical constitutions tend to decrease with age. In this context, Vasarhelyi et al. showed, that if 200 N are prescribed, younger patients, they loaded their affected limb in the mean with 315 N, whereas elderly patients had an average of 430 N.[22] Additionally, neither healthy volunteers nor patients were able to perform the prescribed partial weight bearing and no discernable learning effect was visible during 3 test days. In our results, 9 of 31 patients (29%) had no correct step at all. This means no correct step was recorded, not even during the supervised training sessions. This phenomenon, that supervision has no influence on the PWB performance was described in previous studies.[7,8]

This divergence between subscriptions and performances may indicate the necessity to develop more sufficient practice sessions for the patient. For some indications patients may have to learn this probable new skill. Apart from the quality of the gait training, the quantity of sessions could also be an important factor, because some patients might not be strong enough to carry e.g. 50% of their total bodyweight or they might suffer from a lack of endurance. Therefore, it can take weeks to months to build-up these basic motor skills. Although we found no significant difference in gender-related weight bearing performance, Hurkmans H. stated that women tend to load the leg more than men after a total hip arthroplasty, because of less upper arm strength.[23]

While postoperative pain is mainly an undesired effect of the surgical intervention, patients who have more pain would unload their effected lower limb more than with less or no pain.[23] This may seem controversial, because the already high error rate (mainly overload) in PWB performance might worsen by a better pain treatment. This hypothesis might be underlined by results of Vasarhelyi who showed that young patients tend to load more if pain was less.[22]

Rubin et al. showed that there might be a difference in performance success between a kilogram- or body weight percentage definition. Although not significant, the body weight percentage regime leads to a lesser deviation from the prescribed weight limit than with an absolute amount of kilograms.[9] According to this, Li et al. showed that volunteers had more problems to keep a partial weight bearing instruction with 10% (and 90%) than with 50%.[41]

Postoperatively, patients recover mostly at home for several weeks and just stay in the hospital for a short time (5-7 days). At home, the patients are not under supervised conditions anymore. Helpful support through a physical therapist or nurse is not easy available. Additionally, the patients could be distracted from handling the walking aid correctly while doing more things alone at home.[42]

With the help of modern assistive devices for PWB, continuous feedback of the patients' performance could lead to a successful strategy to upgrade the gait training. Furthermore, the results of gentle techniques like minimal invasive osteosynthesis implants, micro fracture technique or matrix assisted chondrocyte implantation (MACI) might strongly depend on the patients performance; keeping in mind that one overload can irreversibly harm the surgical result. The indication for such a system could be made easier if postoperative monitoring and feedback gave enough therapeutically security. The sensuousness of rehabilitation regimes could be critically questioned as well as improved and further developed.

10 Conclusion

Different studies already demonstrated the limitations of partial weight bearing-prescriptions and the inefficiency of these methods. Nevertheless, the bathroom scale is still an established method and in clinical use. Especially weak and elderly patients need support before surgical interventions take place, due to the fact, that PWB is currently not comprehensible, in his/her remobilization-phase. The sensor crutches with an integrated feedback-system might allow patients to learn preoperatively PWB, independent from a therapist. Therapists can concentrate on functional therapy of affected joint and gait analysis. Therefore further studies are in current progress at the Department of Orthopaedics and Orthopaedic Surgery at the Medical University of Graz, Austria. Decreasing the insecurity of patients when it comes to weight bearing using crutches would give gentle techniques a possibility to go on their edges and might help more people to preserve their quality of life.

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12 Appendix

Mini Mental State Examination Test

Geriatrisches Assessment

Mini Mental State (MMS)

I. Orientierung

1.1. Den Wievielten haben wir heute?	*Tag*	✿
1.2.	*Jahr*	✿
1.3.	*Monat*	✿
1.4. Welcher Wochentag ist heute?		✿
1.5. Welche Jahreszeit haben wir nun?		✿
1.6. Könne Sie mir den Namen eines Arztes hier, oder Ihres Hausarztes nennen?		✿
1.7. In welchem Stockwerk befinden wir uns?		✿
1.8. In welchem Krankenhaus sind Sie hier?		✿
1.9. In welcher Stadt ist dieses Krankenhaus?		✿
1.10. In welchem Land befinden wir uns hier?		✿

Score (max.10):........

II. Kurzzeitgedächtnis

Fragen Sie den Patienten, ob Sie sein Gedächtnis testen dürfen.	*Buch*	✿
Dann sagen Sie langsam und deutlich „Buch", „Haus", „Blume"	*Haus*	✿
(jedes Wort in etwa einer Sekunde). Nachdem Sie alle drei Worte	*Blume*	✿

gesagt haben, bitten Sie den Patienten, die Worte zu wiederholen.
Diese erste Wiederholung bestimmt seinen Score. Fahren Sie jedoch fort (bis zu sechs Wiederholungen), die drei Worte zu sagen, bis er alle drei Worte wiederholen kann.

Score (max.3):..........

III. Aufmerksamkeit und Rechnen

Bitten Sie den Patienten, bei 100 beginnend, fortlaufend 7 abzuziehen. Hören Sie nach fünf Subtraktionen auf (93, 86, 79, 72, 65). Bewerten Sie die Anzahl der richtigen Subtraktionen.

✿
✿
✿
✿
✿

....ODER...

Wenn der Patient den „Reihensubtraktionstest" nicht ausführen will	E	✿
oder kann, bitten Sie ihn, das Wort „WOCHE" rückwärts zu	H	✿
buchstabieren. Der Score ist die Anzahl der Buchstaben	C	✿
in korrekter (verkehrter) Reihenfolge.	E	✿
	W	✿

Score(max.5): ....

Fortsetzung umseitig

IV. Gedächtnis

Bitten Sie den Patienten, die drei Worte, die Sie ihm zuvor nannten (II), noch einmal zu wiederholen.

Buch ✿
Haus ✿
Blume ✿

Score (max. 3):...........

V. Sprache

Benennen: Zeigen Sie dem Patienten eine Armbanduhr bzw. einen Bleistift und fragen Sie ihn, was das sei. *Uhr* ✿ *Bleistift* ✿

Wiederholung: Lassen Sie den Patienten wiederholen: „Keine Wenns, Unds oder Abers". *korrekte Wiederholung* ✿

Dreistufenbefehl: Geben Sie dem Patienten ein glattes, leeres Blatt Papier und sagen Sie:"Nehmen Sie das Blatt Papier in Ihre rechte Hand, falten Sie es halb und legen Sie es auf den Boden!" *nimmt es in die rechte Hand* ✿ ✿ *faltet es halb,* ✿ *legt es auf den Boden* ✿

Lesen: Lassen Sie den in großer Druckschrift geschriebenen Text „Schließen Sie Ihre Augen"lesen und bitten Sie den Patienten, dem Geschriebenen Folge zu leisten. Eine Antwort ist nur richtig, wenn der Patient die Augen wirklich schließt *schließt die Augen* ✿

Schreiben: Geben Sie dem Patienten ein leeres Blatt Papier und bitten Sie ihn, einen Satz zu schreiben. Dieses soll spontan geschrieben werden. Er muss ein Substantiv und ein Verb enthalten und sinnvoll sein. Grammatik und Interpunktion brauchen nicht korrekt zu sein. *schreibt einen Satz* ✿

Score (max.8):..........

VI.Kopieren

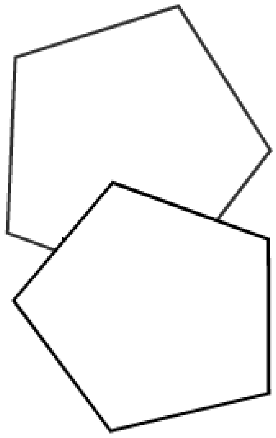
Zeigen Sie dem Patienten die Zeichnung mit den beiden sich überschneidenden Fünfecken und bitten Sie ihn, diese genau zu kopieren. Alle zehn Ecken müssen erkennbar sein, und die Figuren müssen sich überschneiden. Tremor und Drehungen werden ignoriert. *zeichnet richtig* ✿

Addieren Sie die erreichten Punkte der Einzelaufgaben.
Der maximale Score in diesem Test beträgt 30 Punkte.

Gesamtpunkte: ....

(nach Folstein M.F., 1975)

Schließen Sie jetzt bitte Ihre Augen.



13 CURRICULUM VITAE

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■ Education

1990 – 1994	Elementary School VS Hart
1994 – 1998	Secondary General School HS Hart
1999 – 2002	High School Hohenauerstraße, Focus on sportive education. Degree: Matura
2002 – 2003	alternative civil service, gynecological hospital Linz
2003 – 2010	Human Medicine, Medical University Graz
2009 –2010	Informatics, Technical University Graz

■ Internship

1998 (Ferial)	Technical Service Ars Electronica Center Linz
2004 – 2009	10 weeks Internship at Institute of Orthopaedic Surgery, University Graz
2007 – 2010	Scientific assistance at the Orthopaedic Surgery, University Graz

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Mathias Glehr, Gerald Gruber, Andreas Leithner,*Paul Wretschitsch*, Maximilian Zacherl, Thomas Kroneis, Franz Quehenberger, and Reinhard Windhager; A New Fine-NeedleAspiration System. Published in "Surgical Innovation" Journal. 17(2) 136–141; 2010 [Journal]

2008:

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Wretschitsch, P; Glehr, M; Kroneis, T; Leithner, A; Windhager, R Evaluation of a new needle for thyroid fine needle aspiration biopsy
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■ Other Qualifications

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Other:	Extra Courses in: Topographical Anatomy of the Extremities, Manual Therapy; Anthroposophical Medicine Basic Skills in: HTML, CSS, SQL, MS Office, C Interests: Sports, Music, Traveling