

SHORT THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY (PHD)

**DEVELOPMENT AND CLINICAL TRIALS OF DEVICES FOR THE
POSTOPERATIVE REHABILITATION OF THE KNEE JOINT**

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Development and clinical trials of devices for the postoperative rehabilitation of the knee joint

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1.INTRODUCTION

The number of different surgical techniques for the treatment of knee joint injuries is growing continuously. In cases of serious injuries or wear-and-tear of the joint the only solution is the total joint replacement, the so called total endoprosthesis. Total joint replacement surgery became a routine intervention in the 1960s at first for the hip joint, then for the knee joint a little more than 10 years later. According to the currently accepted predictions the number of primary hip prosthesis implantations is said to be increased by 30% until 2030, while the number of knee prosthesis implantations may quadruple. In addition to the growing number of joint replacement surgeries, postoperative rehabilitation has increasing importance, since the final outcome of the operation strongly depends on the successful implementation of the former. The main goal is to achieve the best possible range of motion upon the patient's discharge from the hospital. While the maximal flexion of the normal knee (approx. 150°) is beyond reach, apart from a really few exceptions, which is accepted both by the patients and the surgeons as well, reaching the full extension of the joint is essential as its absence – the flexion contracture – may lead to further problems. Despite the fact that full extension is reached during the surgery, the experience shows the development of flexion contracture in an overwhelming number of cases during the postoperative period. Based on literature data the incidence of extension deficit above 10° reaches 24% and 37% for women and men, respectively.

The most common underlying cause of the correctable full extension deficit is the protective reflex muscle spasm, triggered by pain, but inadequate cooperation of the patient may play an additional role in most of the cases as well. A flexion contracture of even a few degrees may cause fairly adverse biomechanical changes in the knee joint, since with full extension only minimal balancing muscle activity is needed from the muscles surrounding the knee, while in a semi flexion posture the flexor and extensor muscles are being forced to work continuously during standing position that leads to the early exhaustion and consequent permanent pain of the affected muscles. Additionally, as a result of the increased pressure between the

surfaces of the joint, the load on the patellofemoral joint increases significantly as well, while later, the broken balance of the soft tissues may lead to joint instability.

During the postoperative rehabilitation following total knee replacement, the so called *Continuous Passive Motion* (CPM) devices are used worldwide as an addition to physiotherapy. However, restoring the desired range of motion after the operation cannot be achieved in many cases due to the because of the muscular defence. These devices provide a significant aid during the rehabilitation period, but according to our everyday experience in our department the construction of these devices does not allow the full extension of the knee in all of the patients, thus preserving the state of flexion contracture.

Based on two findings of our own, i.e. 1) the CPM device does not provide for the full extension of the knee and 2) that periodic vibrational motion loosens the flexion contracture, we started the development of a complementary device-pair at the Department of Orthopaedic Surgery, University of Debrecen, which was proven to significantly decrease the extent of the flexion contracture. The first member of this pair is the so called *Elevated Heel Rest* (EHR), which is actually a milled-to-shape hard foam to support the heel. In addition to holding the lower extremity and the knee in an elevated position, its important feature is that it does not allow outward rotation so it only affects movements and knee joint components in the sagittal plane. Its significance lies in the fact that under physiological conditions a healthy individuals hold their lower extremity in a slightly outward rotated position while lying supine. Should we not prevent this outward rotation while having the heel elevated and the knee in the air, we would create a situation with a varisation tendency affecting the knee joint.

The other member of the device-pair, the *Heel Vibrating Device* (HVD) was developed to provide rhythmical vibration. As the first step the surgeons and physiotherapists of our department tested the device on themselves and it seemed to be really effective. The subjective and objective results of a pilot study conducted with the system after the addition of the EHR were promising as well. The clinical trial ended with favourable results, as the patients found the device to be well-tolerable

and they were keen to use it for better efficiency. Meanwhile, the further advancement of the device resulted in a bedside construction that does not require placing the patient on a separate bed, as it can be rolled beside any kind of bed and treatment may be started immediately.

During the development process of the EHR and the HVD and while assessing the efficiency of postoperative knee treatments, we repeatedly faced the essential question that how the flexion/extension angle of the knee can be measured with relatively high precision. In order to answer this question I carried out an extensive series of measurements when I assessed the precision and the applicability of an X-ray image-based measurement method.

2.OBJECTIVES

The objectives of my work were as follows:

A. Measurements

Evaluation of knee extension angles based on conventional X-ray images applying a new method and the determination of the accuracy of this new method. Development of the most suitable method of measurement.

B. Device development

Development of new devices for the prevention and treatment of postoperative knee flexion contracture.

- a. Development of a static device: the *Elevated Heel Rest (EHR)*;
- b. Construction of a dynamic device: the *Heel Vibrating Device (HVD)*;
- c. Development of the prototype of a combined equipment: the *Knee Moving Device (KMD)*

C. Clinical trials

Conducting clinical trials with the newly developed devices, summarising and statistically analysing the experience obtained during use.

3. MATERIALS AND METHODS

During the postoperative rehabilitation following total knee replacement surgery we try to achieve the *best possible* flexion, but full extension is also *essential*. Practically my research was based on the latter criterion and was realized in two main directions.

3.1. Measurement of knee extension angle based on X-ray images

Measurement of the flexion-extension angle of the knee seems to be a simple task, but using the traditional protractors and goniometers only approximated results may be obtained. In order to achieve appropriate precision we need to know the exact location and position of the bones, which determine the axis of the shin and the thigh. An evident solution may be provided by the analysis of routine lateral X-ray images, but we have to face two problems during assessment: (1) the X-ray images obtained according to international standards do not show either the entire *femur* or the entire *tibia* and (2) the X-ray image obtained from a direction other than the ideal lateral direction may result in distorted measurement of extension angles on the image.

In order to clear and eliminate the effects of the above mentioned factors, during the first part of my work I carried out a series of measurements that lead to the development of a precise method for the measurement of knee extension angle on X-ray images.

To clear and eliminate the effect of the above mentioned factors, during the first part of my work I executed a set of measurements that led to the development of a precise method to measure the knee extension angle based on X-ray images.

3.1.1. Evaluation of the virtual and the real lateral axes of the thigh and the shin

During our experiments we examined the difference between the real and the virtual X-ray based axes of the thigh and the shin when the direction of imaging devi-

ates from the ideal lateral direction. We took photos of 10 cleaned and boiled femurs and 10 tibia-fibula pairs from lateral direction and from a $\pm 30^\circ$ angle range with 2° steps using a stepping motor to rotate the bone around its longitudinal axis. Thus, we collected 30+1 photos of each femur and each tibia-fibula pair. Since there was no soft tissue, which would have interfered with the measurements we were could use a simple digital camera instead of X-ray. Using a vector graphics editing software we drew the following geometrical elements on the digital images:

1. the line between the centre of the greater *trochanter* and the centre of the *epicondyles* (*femoral axis*)
2. the half-line aligned to the anterior distal contour of the *femur*
3. the half-line aligned to the anterior proximal contour of the *tibia*
4. the half-line aligned to the posterior proximal contour of the *tibia*
5. the line segment between the head of the *fibula* and the *lateral malleolus*

In order to evaluate the precision at which the lines drawn on a normal X-ray image (No. 1, No. 2 and No. 3 half-lines) determine the axis of the *femur* and the *tibia*, we measured the angles between lines 1-2, 3-5 and 4-5 (angles α , β and γ , respectively). (The smaller the angle the determination of the axis of the femur or the shine is more precise by the corresponding half-line).

3.1.2. Measurement of knee flexion angle in different projections

While carrying out our series of measurements we sought answer to the question that how the known, pre-set flexion angles become distorted from different point of imaging. We applied the same set-up described previously with the stepping motor, but this time we used a plastic, full lower extremity for imaging. After pre-setting knee flexion angles of 6, 10, 13, 15 and 20° successively, we rotated the montage around its axis with steps of 2° in a range of $\pm 30^\circ$ and took photos of each state. On the digital photos taken from different points of view we drew the axis of the

femur and the tibia using the landmarks highlighted on the plastic bones (based on section 3.1.1. No. 2 and No. 5 lines), then we measured the virtual flexion angles with an image processing software on all of the images.

3.2. Development of rehabilitation devices for the treatment of flexion contracture

3.2.1. The *Elevated Heel Rest (EHR)*

As the first step of our device development sub-project we developed the details of the EHR that assists the static relaxation and extension. The EHR is a cube from hard foam that contains a vertical groove that supports and fixes the heel and the foreleg up to the lateral malleolus and assures that the lower limb elevates from the plane of the bed. As the axis of the leg is fixed in vertical position, it prevents the lateral rotation of the hip and assures the horizontal position of the cross axis of the knee joint, so the effect of the force of gravity clearly try to extend the knee. The real efficiency of the EHR could be experienced during long-time use or parallel application of the device described in the next sub-chapter.

3.2.2. The bed-dependent version of the *Heel Vibrating Device (HVD)*

This device is basically a mechanical construction connected to an extra-low voltage control unit that was developed based on the following requirements:

- the amplitude and the frequency of the vibration must be continuously adjustable (between 10-30 mm and 1-3 Hz, respectively)
- the device must be programmable
- the dimensions of the device must allow it to be positioned at the end of the patient bed

In order to demonstrate the efficiency of these newly developed EHR and HVD we conducted a randomized clinical trial involving 144 patients, who underwent primary total knee replacement surgery. During the trial we basically examined that what kind of extension results may be achieved with our new devices compared to

the cases, in which treatments were delivered without these therapeutic devices following surgery, during the rehabilitation period spent in our department (usually 7 days). Patients were randomly assigned to one of the two groups; either with the new types of treatment or to the one with the conventional treatment only.

All of the patients were treated by the usual, CPM based physiotherapy, while the test group got an additional HVD treatment for 10 minutes per day (frequency=2 Hz, amplitude=2 cm) and an EHR treatment for at least one hour per day.

We determined the extension angle before and after the treatment period based on lateral X-ray images using computer assisted measurements of the angles between the axes of the femur and the shin, determined by lines drawn between the specific anatomical landmarks described in sub-chapter 3.1. For the statistical analysis of the data collected a one-sided two-sample proportion test with a significance level of 5% was used.

3.2.3. The bedside version of the *Heel Vibrating Device* (HVD)

Based on the experiences gathered during clinical trial we attempted to further develop and advance the construction of the original HVD, therefore we compiled the following list with the new requirements and simplification principles:

- the device should not be stationary, it should be easily moved around (*bedside* design),
- the hardware components of the device should comprise a single unit (the original version was composed of a mechanical unit and two boxes with the electrical units),
- the alternating motion should be delivered through a bridge from above.

Using the new and advanced HVD prototype, we conducted another clinical trial involving 64 patients, using an updated investigation protocol with several basic and important changes. To avoid the bias arising from the manual physiotherapy related to the knee extension, the 7-day rehabilitation period was divided to two

periods. During the first 5 days the activities were almost the same as in the previous trial, so both group of patients received the usual CPM treatment plus physiotherapy and the subjects of test group received an additional treatment for 2x10 minutes with the new HVD. The only difference was skipping the passive physiotherapy in both groups. During the second period of the treatment (after 5 days) passive physiotherapy was applied as needed, in order to avoid extension deficits, but the treatment according to the first period was carried on.

The differences between the test and the control groups were evaluated using the flexion contracture angles measured on the X-ray images taken on days 1 and 5, i.e. the last day without optional passive physiotherapy. By using this method we determined the improvement in the extension angle among the patients of the test and control groups. The data gathered during trial was analyzed using a two-sample t-test with a significance level of 5%.

3.2.4. The *Knee Moving Device* (KMD)

Meanwhile, based on the original conception we took a different direction and initiated another device development process. We started to design a device that is able to move the knee in its full range of motion, while including the vibrating function of the HVD.

4. RESULTS

4.1. Measurement of knee extension angle based on X-ray images

4.1.1. Evaluation of the virtual and the real lateral axes of the thigh and the shin

The calculations were based on the mean values measured on all the 10 femurs and tibia-fibula pairs. Regarding the femur we saw that the angle between the line defined by the anterior contour of the bone and the greater trochanter - epicondylus line is between 1.4° and 2.5° (min = 1.39° ; max = 2.48° ; mean = 1.71° ; SD = 0.36°), depending on the point of view.

Regarding the shin our measurements demonstrated that the angle between the real axis of the shin and the line defined by the anterior cortical of the tibia is not really affected by the point of view. This angle remained $4 \pm 0.5^\circ$ (min = 3.8° ; max = 4.89° ; average = 4.36° ; SD = 0.19°) throughout our measurement. At the same time, the angle between the axis of the shin and the line defined by the posterior cortical of the tibia was much smaller, as measured between 0.5° and 2° (min = 0.53° ; max = 1.98° ; average = 1.11° ; SD = 0.35°) and the effect of the point of view was not clearly substantial in this case as well.

4.1.2. Measurement of knee flexion angle in different projections

During our investigations of the knee angles using the plastic lower limb bone model we found that the difference between the real and the virtual angles (so the error) and the deviation from the ideal lateral direction may be described with a quadratic function as the function representation results in a parabola. Our measurements demonstrated that the bigger the flexion angle the larger deviation from the correct value when determining the flexion angle on the images not taken from the ideal lateral direction. At the same time we may conclude that the extent of the measurement error is at a maximum of 2.5° when the flexion angle is 20° and the deviation from the ideal point of view is 30° .

4.2. Development of rehabilitation devices for the treatment of flexion contracture

4.2.1. The Elevated Heel Rest (EHR)

Based on the preliminary conception, we made the EHR from hard foam with a faux leather cover. This unit then was applied concomitantly with the HVD treatments for at least one hour a day and as a heel support during X-ray imaging.

According to our experience this device is excellently suited for supporting the transverse axis of the knee in a horizontal position and in addition to its therapeutic functions it is an effective instrument for positioning the knee during X-ray imaging.

4.2.2. The bed-dependent version of the Heel Vibrating Device (HVD)

After a treatment period of one week we compared the full extension angles measured in the group that only received the usual CPM treatment and in the group that received additional HVD and EHR treatment. During analysis we rated the angles measured according to the practice in our department. Accordingly, we rated the post-treatment result as satisfactory when the extension angle was in the range of $\pm 5^\circ$ compared to the ideal 0° . The null hypothesis, which assumed an extension angle of $0^\circ \pm 5^\circ$ upon discharge in a similar number of patients in both groups, was rejected using a one-sided two-sample proportion test with a significance level of 5% ($p=0.0355$). Therefore, there was a significant difference between the two procedures: the proportion of patients with satisfactory angle results was significantly higher in the group receiving CPM plus HVD plus EHR treatment.

4.2.3. The bedside version of the Heel Vibrating Device (HVD)

As a result of the development process we constructed a prototype of the device. During the construction we successfully achieved our revised objectives and the device works according to our expectations without any problem.

During the analysis of the data gathered in the clinical trial involving 64 patients and conducted with the advanced version of the HVD, having an extension arm console over the bed, we focused on the changes in the extension angles during the treatment period. Accordingly, we analysed the differences between the extension angles measured at the beginning of the treatment and after the fifth day, i.e. we considered the improvement or worsening of the extension angles. In order to evaluate the efficiency of flexion contracture treatment we examined the effectiveness of treatment in both groups of patients with contracture (whose extension angle was larger than 0 on the first day of treatment). According to the overall results in the control group (CPM only treatment) the angle of flexion contracture increased i.e. worsened by 0.85° , while in the test group with additional treatment with the new HVD, the angle of the flexion contracture was decreased i.e. improved by a mean of 2.4° . There was a significant difference (two-sided; level of significance=5%; $p=0.0033$) between the results of the two groups, so the improvement regarding the extension angle of the knee in the test group was significantly larger.

4.2.4. The Knee Moving Device (KMD)

Based on the initial aspects and the experience with the two HVD versions, the construction of a KMD prototype (an extended HVD version) is in its final stage. The computer-controlled system is capable of moving the knee in its full range of motion, while including the shaking-vibrating function from the previous two constructions as well.

5. DISCUSSION

5.1. Measurement of knee extension angle based on X-ray images

5.1.1. Evaluation of the virtual and the real lateral axes of the thigh and the shin

During our experiments our fundamental concept was to verify and evaluate the effect of deviation from the ideal lateral direction during X-ray imaging on the difference between the real axes and the reconstructed lines based on the anatomical landmarks visible on the X-ray images. Based on the results of our measurements we may conclude that in cases of X-ray/digital images showing only the distal part of the femur we should use a line aligned to the anterior cortical as the axis of the bone. This line provides an accuracy of 2.5° when the deviation of the point of view during imaging from the lateral direction is 30° .

Regarding the shin we examined two cases because of the inconsistencies in the related literature. We examined the precision of the determination of the axis of the shin via the lines aligned to both the anterior and posterior cortical of the tibia and similarly to the femur, we measured the distortion effect of the deviation from the ideal lateral direction of imaging. Our results demonstrated that the estimation of the axis of the shin should be based on the line aligned to the posterior cortical of the tibia (accuracy = 2°) instead of the anterior cortical (accuracy = 5°) as the former provides greater accuracy.

Furthermore, we established that the deviation from the ideal lateral direction during X-ray imaging does not significantly affect the angle and position of the construction lines of the axes of the femur and the tibia, since the maximum deviation of the reconstructed line was only 2.5° with a lateral deviation of 30° during imaging.

5.1.2. Measurement of knee flexion angle in different projections

In this sub-project our objective was to determine the level of distortion caused by the deviation from the ideal lateral point of view during X-ray imaging regarding

the pre-set knee flexion angle, thus determining the difference between the known pre-set angle and the virtual angle reconstructed by the construction lines drawn on the X-ray images. The importance of this experiment lies in the fact that it is essential to know the objectivity and precision of the X-ray image-based measurement values in patients with significant flexion contracture occurring directly even in the postoperative period or later (which is sometimes a true issue in the clinical practice, whatever the underlying cause might be).

After processing the data we may draw similar conclusion as in the previously described experiment, i.e. if we consider the knee as a system and we examine the full lower extremity, the significance of deviation from the ideal lateral direction during X-ray imaging – while staying within a relatively normal range - is less than we anticipated. The error in angle estimation in relatively extreme conditions (flexion contracture of 20° with a deviation of 30° from the lateral direction during imaging) was only 2.5° , which is negligible in the clinical practice. Nevertheless, according to our experience, the increase in the flexion angle of the knee causes an exponential elevation of the error in axis determination, even with lateral deviations of $10-20^{\circ}$ during imaging.

Based on our experiments we may conclude that using lateral X-ray images for the measurement of knee extension angles, more accurate values may be achieved during imaging with knee being extended and with a heel support in use, which also ensures that the opposite knee will be outside of the image. In these instances the X-ray cassettes may be positioned directly next to the extremity to be assessed, onto the bed, or on a console placed beside the bed.

Using this set-up we suggest taking lateral X-ray images in order not to miss any important details, but at the same time to get the images from a fairly important position suitable for measuring the full extension angle.

Based on our measurements we concluded that while the accuracy of other knee angle measurement methods are questionable regarding the measurement taken

in full extension, lateral X-ray images taken in fully extended position provide accurate and reliable measurement results.

It should be noted that our measurement method can be applied for knees with normal anatomy only, thus this procedure may not be suitable in certain cases (near knee fractures, osteotomies, exostoses).

5.2. Development of rehabilitation devices for the treatment of flexion contracture

The ‘gold-standard’ in the postoperative rehabilitation of total knee replacement has been the CPM treatment for decades. The favourable effect of the system on knee flexion was examined and demonstrated in several publications, but its effect on extension is questionable at least, predominantly because – according to our own experience as well – the extension angle set on the device is far off from the real extension angle.

Our primary objective was to develop a device that can be applied in the early postoperative rehabilitation period after primary total knee replacement surgery. Applying a vibrating motion to the heel (relatively rapid and rhythmic upwards and downwards moving i.e. vibration), the inertial forces in addition to the mass of the full lower extremity help the extension of the knee and the relaxation/extension of the posterior soft tissues, thereby preventing the development of an extension deficit. Applying this device concomitantly with a CMP machine provides the necessary effect for knee flexion as well.

The first phase of the development process resulted in the construction of the first, bed-dependent version of the Heel Vibration Device. The working principle of the device is that the machine force the heel of the affected lower extremity to vibrate with an adjustable amplitude and frequency, while the patella and the transverse axis of the knee remain horizontal. This way, the inertia and the mass of the lower extremity exert a passive extension effect at the bottom end-point of the movement on the posterior structures of the knee joint, which in turn helps it to reach the fullest extension possible.

After eliminating the problems and the ‘unease-of-use’ of the first version, we developed a new, bedside, rolling, thus much more mobile design of the HVD that can be easily positioned. In this construction the heel of the patient is placed in a belt that provides a certain level of self-adjustment for the operated lower extremity during therapy, since it sets the margins of the foot in vertical position. The device can be controlled very easily, even by the patient, furthermore, the treatment does not have any special requirements, as it can be carried out on any regular hospital bed. After starting the device, the treatment does not require supervision by the physiotherapist, therefore, in addition to its outstanding efficiency the device saves significant human resources as well. Considering the fact that we achieved fairly reliable results with very short-duration treatments, later on we plan to extend the duration of the treatments and exploit the efficiency of the device even more. According to our experience, patients tolerate the treatment for a duration of 10 minutes, but as soon as we have more of these devices, we strongly recommend to repeat the treatment more times per day.

Randomized prospective clinical trials were conducted for the evaluation of the efficiency of both devices.

The trial results with the original HVD demonstrated that the number of patients in the satisfactory extension category of $0^{\circ} \pm 5^{\circ}$ was higher by 25% in the group treated with HVD compared to the control group treated with CPM only.

The currently on-going clinical trial with the improved, bedside version of the HVD has a slightly revised protocol for the better detection of the effect of the device on the flexion contracture. Accordingly, the analysis focused on the data of patients with pre-existing flexion contracture. The results demonstrated that the extent of flexion contracture improvement was much higher among patients using the HVD compared to the group of patients, who were treated with CPM only (improvement of 2.4° vs -0.9°).

Corresponding to the general practice in Hungary we did not employ any knee score systems during the evaluation of our results. Detailed case histories were

taken and thorough physical examinations were carried out before surgery, furthermore we used visual analogue scale for the better assessment of the subjective aspects of our results.

There were no complications at all during the clinical application of the device and the patients tolerated the treatment exceptionally well and there was not single case where the discontinuation of the 7-day long treatment became necessary on the patient's request. Sometimes the patients did not want to use the device for the full 10 minutes during the first therapeutic session, but the necessary tolerance was reached at the next or at the third session at the latest.

The application of the HVD is on-going within the framework of the clinical trial and in the clinical practice as well, but not according to the assignment determined during randomization. We use it primarily in difficult cases after total knee replacement and for patients who are susceptible to the development of flexion contracture due to their preoperative deformity or extension deficit or even due to an abnormal gait or posture.

In summary, we may conclude that we successfully developed and introduced a device to clinical practice, which can be applied for the prevention and treatment of postoperative flexion contractures during the early postoperative period with promising results, primarily in cases of total knee replacement, but it can be used in conditions with similarly decreased ranges of motion but with variable underlying cause.

The application of our HVD and EHR during the postoperative rehabilitation period was proven to significantly decrease the occurrence of flexion contractures, so the continuous application of these devices is reasonable and strongly recommended. The results of our development were published in peer-reviewed journals in order to maintain our role as the proprietors of this invention.

After the development of the bedside HVD a reasonable need was considered, namely to merge the advantages of the CPM and the HVD in a single device. In order to accomplish this challenge we started to construct a new device (Knee Moving

Device, KMD), which currently is in the final stage of development. The computer-controlled KMD is able to move the knee in its full range of motion according to the installed treatment programs and is capable of applying the vibrating function of the HVD at angled positions and in full extension as well. According to our plans the final version would include a force measurement system built into the heel support, which would provide feedback to the system and therefore would allow a new, force-based control mode as well, so the target value of the moving could be a force instead of an angle or even the combination of these. Thus, for example we may set a force limit for the extension moving, but the angle position of the extension would be different treatment-by-treatment or even in each moving cycle.

6. SUMMARY

The issue of knee flexion contracture after total knee replacement surgery appears to occur relatively often. It may cause problems in one-third or quarter of the patients, and may either manifest as a limitation of the ROM or as an increased load of the surrounding muscles and the joint surfaces.

In the first part of my work I focused on the measurement of flexion contracture. I tried to find a reliable measurement method that can be used to precisely determine the angle of the contracture and the extension. The results demonstrated that an X-ray image-based angle measurement provides high accuracy even with short films and even when the direction of the X-ray imaging is not exactly lateral.

After analysing the measurement method of the knee flexion-extension angle, a new device has been developed during second part of my work – the Heel Vibrating Device – for the treatment of flexion contracture. This device significantly and effectively decreases the angle and the incidence of flexion contractures as an addition to the CPM compared to the CPM used alone.

The results of the clinical trial with the first version of the device involving 144 patients were favourable and the further advanced design proved to be even more promising. The partial results from the currently on-going clinical trial show that the application of the device leads to significant improvements in the prevention and the treatment of flexion contracture ($p=0.0033$) compared to a conventional CPM device.

The results of the overall work consist of an angle measurement method based on X-ray images, developed for the accurate determination of knee extension angle and supported by several hundred measurements, furthermore, a rehabilitation device that can be applied effectively for the prevention and treatment of flexion contracture as it was demonstrated in clinical trials.

7. NEW RESULTS

A. Measurements

- a. Using a new method developed by me and using conventional lateral X-ray images I determined
 - i. the axis of the femur is practically parallel with the anterior cortical;
 - ii. the posterior cortical of tibia is the most suitable line for the determination of the axis of the shin.
- b. I proved that during the evaluation of the flexion-extension angle of the knee, the distortion effect of the lateral deviation of imaging is minimal: within the realistic $\pm 30^\circ$ range it is below 2.5° .

B. Device development

- a) We developed a relatively simple static aid for the support of the heel, called the *Elevated Heel Rest*, which was applied as a really useful accessory both during the postoperative rehabilitation and during obtaining the lateral X-ray images as well.
- b) We developed an original then an advanced version of a device, called the *Heel Vibrating Device* for the prevention and treatment of postoperative knee flexion contractures.
- c) We constructed the prototype of an instrument (the *Knee Moving Device*) that combines the moving functions of the current CPM devices and the new vibrating function of the HVD as well. We anticipate further efficiency improvement from this device compared to the HVD but its clinical introduction will take place in 2016.

C. Clinical trials

We conducted clinical trials with the newly developed HVD and EHR prototypes that demonstrated the efficiency of the devices. Based on the results we demonstrated that the application of both version of the HVD in addition to the EHR leads to significantly more favourable results compared to the CPM in decreasing knee extension deficits.

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Ph.D. List of Publications

Candidate: Sándor Manó
Neptun ID: M9BSIL
Doctoral School: Doctoral School of Clinical Medicine
MTMT ID: 10036683

List of publications related to the dissertation

1. **Manó, S.**, Pálincás, J., Szabó, J., Nagy, J.T., Bakó, K., Csernátó, Z.: Application of a vibrating device for the prevention of flexion contracture after total knee arthroplasty.
Eur. J. Orthop. Surg. Traumatol. 25 (1), 167-172, 2015.
DOI: <http://dx.doi.org/10.1007/s00590-014-1466-4>
IF:0.181* (2012)
2. **Manó, S.**, Pálincás, J., Kiss, L., Csernátó, Z.: The influence of lateral knee X-ray positioning on the accuracy of full extension level measurements: An in vitro study.
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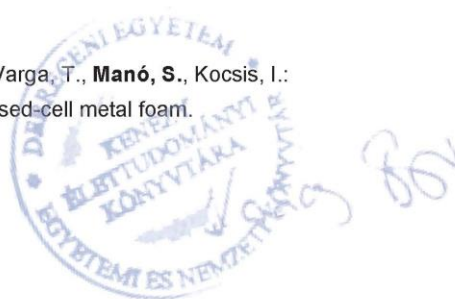


*The Doctoral Council allowed the use of the 2012 Impact Factor for this publication.



List of other publications

4. Varga T.A., Mankovits T., Kocsis I., Budai I., Balogh G., Gábora A., Kozma I., **Manó S.**: Fémhabok struktúrájának elemzése és modellezése =Structural Analysis and Modelling of Metal Foams. In: A XX. Fiatal műszakiak tudományos ülésének előadásai = Proceedings of the XX-th International Scientific Conference of Young Engineers. Szerk.: Bitay Enikő, Erdélyi Múzeum-Egyesület, Kolozsvár, 331-334, 2015.
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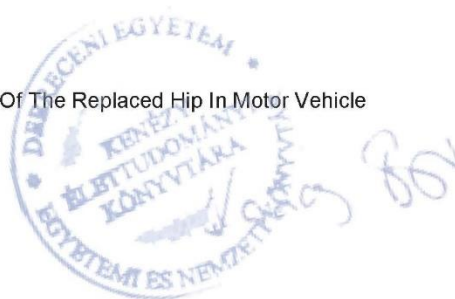
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