# THE FIRST STEPS TO THE DEVELOPMENT OF THE KNEE PROSTHESIS RATING METHOD

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**Abstract**
During prosthesis implantation, the surgeon can choose from replacements of a wide variety of manufacturers and sizes. So far, no specific coefficient has been introduced that determines the suitability, or goodness of these prostheses. In this paper an apparatus is presented for the qualification of knee prostheses. This apparatus is able to measure the rotation of any prosthesis, therefore the obtained results can be compared with the measured values on human cadaver knees. The prostheses are classified by the rate of their conformity. In addition, the first experimental results are reported as well.

**Keywords:** biomechanics, knee, prosthesis.

## Introduction: when is a prosthesis suitable?

Surgeons have a wide range of choice regarding the brands and sizes of knee replacements, although there are no specific numbers indicating the quality or goodness of the applicable prostheses. However, what factors determine the quality of prosthesis? Definitely not the similarity of the prosthesis surfaces compared to the physiological surfaces, but the ability of the replacement to ensure closely the same kinematics compared to the original, physiological knee joint.

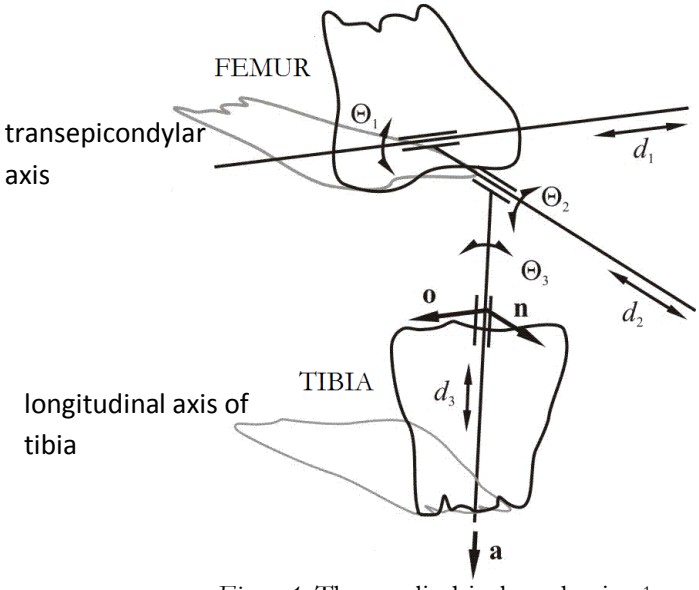


*Figure 1.* Three-cylindrical mechanism[1]

Naturally, the wear due to the sliding-rolling relationship[2] between the condyles along with the material properties of the prostheses are also essential, but this article deals exclusively with the

qualification of the reproduced movement. During the movement of the knee joint, the flexion can be controlled while the other movements (rotation, abduction, etc) *are constrained by the connection of the condyles*. Among the constrained movements the main emphasis is set on the magnitude and trend of the rotation, since its correspondence between the original and reproduced motion has the most importance.

**Methods and materials**

In order to estimate the goodness of the obtained rotation-functions regarding the prostheses, a basis rotation has to be defined. The research group carried out several experiments on cadavers in the past years. For these experiments, a special test rig has been designed[3] and manufactured which allows carrying out measurements on multiple kinematical quantities. Among others, the rotation of the tibia – carried out by its self-weight – was measured as a function of flexion angle. Taking into consideration the numerous measurements carried out on human cadavers and the results found in the literature[4] (with significant deviations), it has been concluded that the flexion-rotation functions depend on several parameters. They naturally depend on the investigated person (we examined in each case non-pathological knees), the type of the movement, the test rig, the examination method, the data acquisition system and significantly on the processing method. In case of the latest one, the positioning of the model and the reference system has crucial significance. The model was described by a three-cylindrical mechanism, with six degrees of freedom (*Figure 1*). In our case, the movements were related to an anatomical coordinate-system[4].

On the basis of our experiments, which were carried out on 28-60 years old male subjects according to the same protocol[5], an averaged flexion-rotation curve has been determined (*Figure 2*). The protocol included the processing method as well. This function was considered as a *reference function*. As it is seen in *Figure 2*, the function was approximated with a tri-linear function. The segments of the function – with moderate freedom – were determined based on the carried out movement. In the first 25° segment, the movement is constrained, while the following 25° segment is considered as a transition towards unconstrained rotation (presumed from the trend of the measurements), which is definitely possible above 50° of flexion angle.

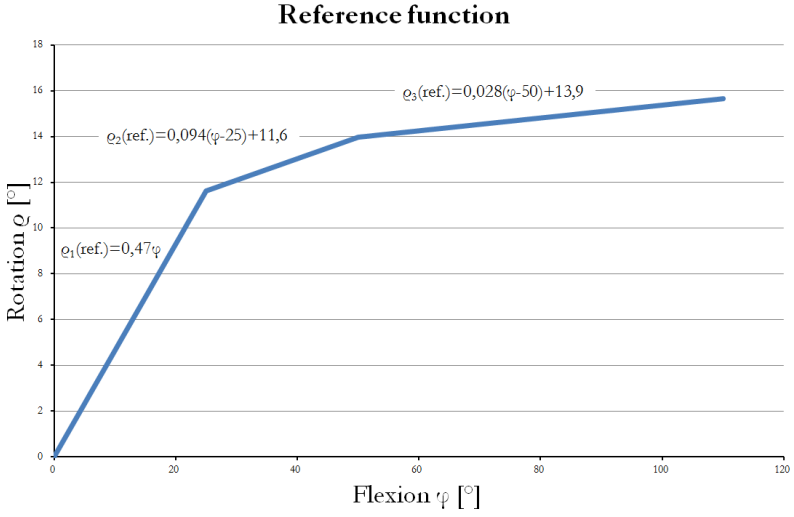


*Figure 2*. The reference function

The aim of the research is to create a test rig which is able to qualify the kinematics of prostheses, based on the above mentioned reference-function comparison. For this reason the concept of the design was carried out in a way that the test rig, together with the measuring – and processing method – for the sake of an adequate comparison – would be identical with the reference-function determined by cadaver and prosthesis experiments.

## Results and discussion

### Description of the test rig

The first condition is that the qualification device has to be the part of the test rig (*Figure 3*). This ensures that during the flexion of the knee joint, which is controlled by the quadriceps under the effect of self-weight, the same type of movement can be compared. The magnitude and the change of load (1) alongside with the bending mechanism of the joint is the same regarding the test rig for cadaver- or prosthesis measurements. The load is transmitted through a rubber-muscle model3, while the movement is exerted by a force applied on the end of the tibial bone. The test rig has been complemented by a stepper motor (2), which allows the knee to be flexed beyond 70-80o of flexion angle. The test rig is designed in a way that the tibial shaft (or cadaver) can carry out unconstrained movement. This feature is in essential since the movement has to be controlled only by the quadriceps, the self-weight and the condyle surfaces. The unconstrained movement was secured by the use of bushing- and planar bearings (3). The flexion was controlled by a curved rail (4) and the movement was performed along with it.

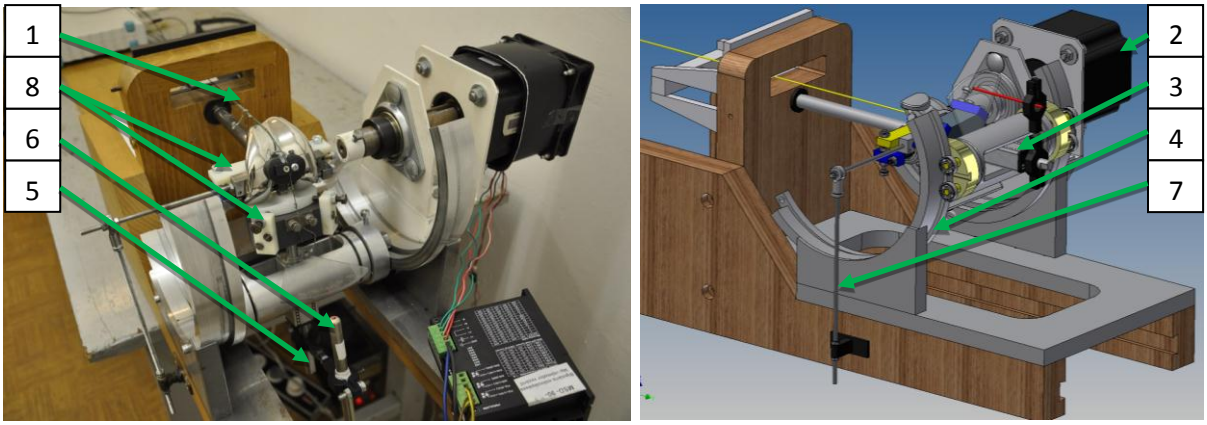


*Figure 3.* Test rig for prosthesis qualification

In order to make a fair comparison between the cadaver and prosthesis movement, the measuring device and the processing method has to be identical respectively to the aims. The rotation was directly measured on the test rig by a laser (6). The tibia plateau part of the prosthesis was attached to the tibial model (5), which represents the direction of the medullary cavity or canal (contains bone marrow). In the interest of having identical rotation measurements with respect to the cadaver results, the reference-system has to be also identical in both cases. The anatomical coordinate system can only be determined in case of cadavers by a rather complex method5. With regard to prostheses, the surgeon performs the prosthesis implantation in way that the replacement condyles would precisely connect to the patient's anatomical system. This process is supported by certain assisting tools and a strict protocol. Based on the analysis of this certain protocol, and the consultation of Dr. Kristóf Andrónyi surgeon, the prostheses were

inserted into the test rig that their „condyles" would be correctly positioned with respect to the anatomical coordinate-system. This ability of the test rig is provided by a special fixture system (8), which ensures the upcoming new conditions during the insertion as well (*Figure 4*).

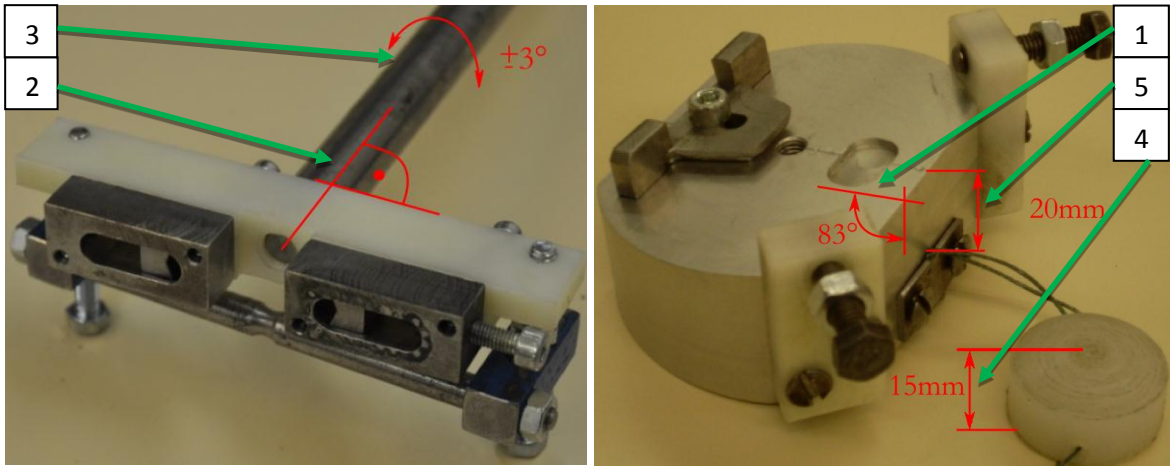


*Figure 4.* The special fixture system

During our investigations, a condition-system had to be fulfilled which was pre-defined during the insertion of the prosthesis. This process was ensured by a universal fixture system (*Figure 4*) and the correctly set test rig, as follows:

- Tilt of tibia plateau to 7° (*Figure 4*) (1). This is secured by the tibial fixture of the test rig,
- The femoral component of the prosthesis fixed into the test rig is at a 90° angle relative to the axis of femur (*Figure 4*) (2), therefore the anatomical angle is ensured. As the prosthesis is inserted into the test rig, the femur is adjusted from the mechanical axis to the anatomical axis by performing 5° of tilt and creating perpendicularity between the femoral component and the anatomical axis,
- Setting the adequate rotation (*Figure 4*) (3). 3° of femoral component tilt in the lateral direction respectively to the left or right leg.

Additional settings on the test rig with regard to the anatomy of the leg:

- The point of action of the quadriceps force is approximatelly situated at 15 mm (4) of height (*Figure 4*),
- Line of action of quadriceps: the line of action has 5° of lateral difference compared to the femoral axis with regard to a right-legged or left-legged prosthesis (*Figure 3*) (1),
- Quadriceps tendon attachement on the tibia is situated 20 mm away from the resection (*Figure 4*) (5).

An additional calibrating device (*Figure 3*) (7) had to be designed and manufactured as well, to adjust the rotation to zero with the use of a hinge-type, „cylindrical" prosthesis.

The test rig is able to qualify prostheses in different size, brand, independently from additional features such as cruciate-retaining (CR) or posterior-stabilizer (PS). As initial steps in this research, measurements were performed on seven prostheses of different size, brand and type (*Figure 5*).

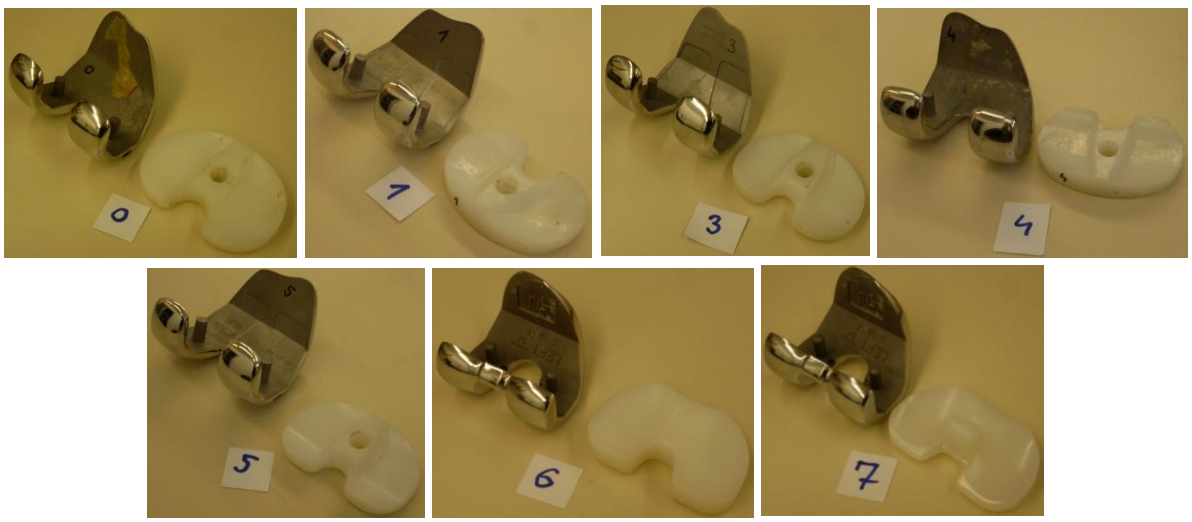


*Figure 5.* Examined prostheses

*Table 1* includes the parameters of the examined prostheses. Prostheses of four different designs from three different manufacturers were investigated: left, right, cruciate-retaining and posterior-stabilizer.

| Number | Manufacturer | Femur size | Tibia size | Femur Ref. num. | Tibia Ref. num. | Leg | Type |
|---|---|---|---|---|---|---|---|
| 0 | Unknown | L-L ARGE | XLGE 12 | KA 0017 12-00-74 | - | Left | CR |
| 1 | Biotech | Medium Right B140 | B105 M10 | 051-1311-3070 | - | Right | CR |
| 3 | Biotech | B102 XL-L | B106 L10 | 051-1712-5078 | - | Left | CR |
| 4 | Unknown | M-L ARGE | MED 10 | KA 0432 12-00-70 | - | Left | CR |
| 5 | Biotech | Medium Right B146 | B104 S10 | 051-1311-3070 | - | Right | CR |
| 6 | Sanatmetal | „D” | GRN-17PE | - | (z) 60158134 | Left | CR |
| 7 | Sanatmetal | „D” | EF 5-6 10 PE | - | (z) FE 61878361 | Left | PS |

*Table 1.* Examined prostheses

**First experimental results, qualification method**

When the prosthesis was secured in the test rig, the rotation was measured as a function of flexion angle (*Figure 6*). Each prosthesis was measured six times, and the average of these six measurements are plotted in the diagram. Prostheses – selected for qualification – were removed from patients due to the need of new replacements. In *Figure 6*, all the measured average values are plotted together with the reference-function. The difference between the measured and the reference values is quite significant.

In order to qualify the movement, carried out by the prostheses, a *goodness-function* has been introduced ($\kappa$), which provides a percentile value about the performed prosthesis rotation compared to the reference-function:

$$\kappa(\varphi) = \frac{\rho_{pr}(\varphi)}{\rho_{ref}(\varphi)} 100 \tag{1}$$

where:

$\rho_{pr}(\varphi)$: rotation of the prosthesis as a function of flexion angle,

$\rho_{ref}(\varphi)$: reference-function of the cadaver knee joint as a function of flexion angle.

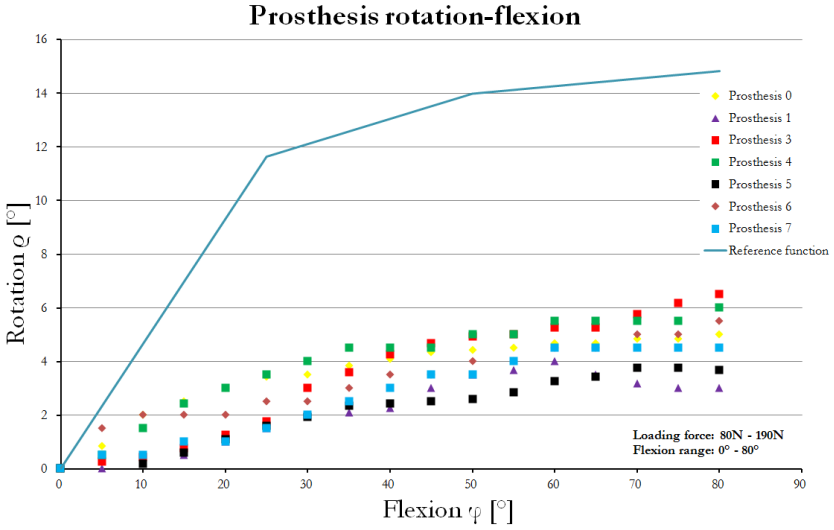


*Figure 6.* Rotational function on prostheses

Since the reference-function (the averaged change of rotation as a function of flexion angle) was approximated by tri-linear function, the same function was fitted on the measured prosthesis rotations as well. The equations of the fitted approximation-function on each segment:

$$\rho_{1pr} = a_1 \varphi \quad [°] \tag{2}$$

$$\rho_{2pr} = a_2(\varphi - 25) + \rho_{10} \quad [°] \tag{3}$$

$$\rho_{3pr} = a_3(\varphi - 50) + \rho_{20} \quad [°] \tag{4}$$

The constants were summarized in *Table 2*, along with the values of the goodness-function, obtained in the boundary points. In *Figure 7*, the change of the goodness-grade of the seven prostheses is plotted as a function of flexion angle.

| *i* | $a_1$ [-] | $a_2$ [-] | $a_3$ [-] | $\varrho_{10}$ [°] | $\varrho_{20}$ [°] | $\varrho_{3(\varphi=80°)}$ [°] | $\varkappa(25°)$ [%] | $\varkappa(50°)$ [%] | $\varkappa(80°)$ [%] |
|---|---|---|---|---|---|---|---|---|---|
| Pr. 0 | 0,1506 | 0,02311 | 0,02227 | 3,765 | 4,342 | 5,01 | **32,4** | **31,1** | **34,1** |
| Pr. 1 | 0,0509 | 0,08482 | -0,00753 | 1,272 | 3,393 | 3,167 | **10,9** | **24,3** | **21,6** |
| Pr. 3 | 0,06212 | 0,15589 | 0,02115 | 1,553 | 5,450 | 6,085 | **13,3** | **39** | **41,3** |
| Pr. 4 | 0,14636 | 0,05314 | 0,02914 | 3,659 | 4,98 | 5,861 | **31,5** | **35,7** | **39,9** |
| Pr.5 | 0,0509 | 0,06422 | 0,03273 | 1,272 | 2,878 | 3,86 | **10,9** | **20,6** | **26,2** |
| Pr.6 | 0,11575 | 0,04192 | 0,04792 | 2,893 | 3,941 | 5,379 | **24,9** | **28,2** | **36,6** |
| Pr. 7 | 0,05818 | 0,09339 | 0,03024 | 1,454 | 3,789 | 4,696 | **12,5** | **27,1** | **31,9** |
| Ref. | 0,47 | 0,094 | 0,028 | 11,6 | 13,9 | 14,7 | - | - | - |

*Table 2.* Fitting parameters of the experiment


*Figure 7.* Goodness function of different prostheses

## Conclusion

As a summary, we can conclude that:

- A test rig has been designed and assembled which is a capable to measure and qualify the performed rotation of any prosthesis,
- A qualification-method has been elaborated,
- Measurements were carried out on seven commercial prostheses. The results showed that the prostheses can only achieve the 10-30% of the appointed rotation.

Our investigations with respect to the qualification of prostheses are followed by the examination of factors and their effect on the rotation.

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