

## Loads in hip disarticulation prostheses during normal daily use

M. NIETERT, N. ENGLISCH, P. KREIL and G. ALBA-LOPEZ

*Biomechanics Laboratory, Department of Hospital and Biomedical Engineering – Environmental and Biotechnology, Fachhochschule Giessen-Friedberg/University of Applied Sciences, Germany*

### Abstract

As a result of deficiency at birth, disease or trauma, there are people who have no limbs from the hip joint downwards. These people have no possibility of locomotion without the use of other devices such as wheelchairs or hip disarticulation prostheses.

As these prostheses are used by people of all ages, people who are different in their grade of physical activities and their weights, the prostheses are subject to different stresses related to these different circumstances.

The European Level 2 Draft Standard prEN 12523: 1966 "External limb prostheses and external orthoses - requirements and test methods" contains strength requirements for lower limb prostheses. These requirements shall be verified, where appropriate, by the application of the International Standard ISO 10328 "Prosthetics – Structural testing of lower limb prostheses" and ISO/FDIS 15032 "Prosthetics: Structural testing of hip prostheses".

In order to allow the prostheses to be tested to the stresses that are experienced in real life, it is necessary to measure the stress that is induced in the prostheses while the patient is in an everyday situation, such as walking on level floor, walking on grass and/or walking on an uneven surface.

This work is concerned with the acquisition of loads generated in hip units of hip disarticulation prostheses by amputees during various

activities. More than 30 patients were tested in Germany, France, and Belgium. The measurements were carried out with financial support from the European Commission and coordinated by the secretariat of CEN TC 293.

### Introduction

During walking both legs are alternately passing through two different phases: the stance phase (from the instant of heel contact to the instant of toe off) and the swing phase (from the instant of toe off to the next instant of heel contact).

The hip disarticulation prosthesis is aligned so that the load line always passes in front of the knee joint and behind the hip joint during the stance phase of walking, so that the joints are always kept in extension during load bearing and under stress.

The stress is caused by the resultant  $F$  of the gravitational force and those forces due to additional accelerations of the body and parts of it. Acting on a lever e.g.  $L_K$  or  $L_H$  (=perpendicular distance from load line to joint), this resultant creates the moment ( $M=F*L$ ) in the joint. The position of the load line (Fig. 1) changes during the stance phase due to the changing position of the points of load application and support. When using four-bar linkage designs the load line may pass behind the knee unit without losing knee stability as long as it still passes in front of the instantaneous centre of rotation.

### Nomenclature of forces and moments according to International Standards

The designation of the forces and moments generated in hip units has been carried out on the basis of ISO 10328-3:1996 although this

All correspondence to be addressed to Prof. Dr.-Ing. Manfred Nietert, Biomechanik-Laboratory, Fachhochschule Giessen-Friedberg, Wiesenstr. 14, D-35390 Giessen, Germany.  
Tel: (+49) 641 3092530. Fax: (+49) 641 3092914.  
E-mail: [manfred.niertert@tg.fh-giessen.de](mailto:manfred.niertert@tg.fh-giessen.de)

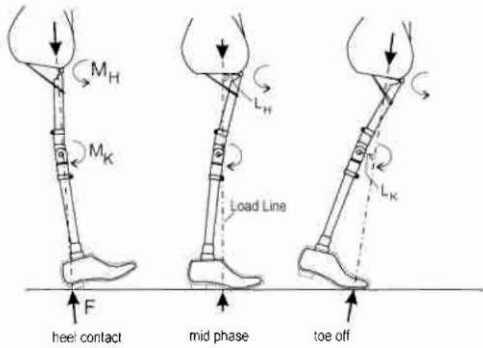


Fig. 1. Position of the load lines during the stance phase of walking.

standard excludes hip disarticulation prostheses for test purposes. In Figure 2 the application of a specific loading condition (forefoot loading) for a left-sided test sample is shown, presenting the coordinate system with  $u_B=0$ , with reference lines, reference points and components of internal loading generated by application of the resultant force  $F$ .

The load line passes through the knee and hip reference points  $P_K$  and  $P_H$  and the bottom and top load application points  $P_B$  and  $P_T$ . The  $u$ -axis is a line extending from the origin and passing through the effective ankle joint centre and the effective knee joint centre (ISO 10328-1:1996; ISO 10328-2:1996). Its positive direction is upwards (in the proximal direction).

Because the loading force and moments, which act in the joint centres, are vectors, these can be split into the directions  $f$ - $o$ - $u$  as partial vectors.

Figure 2 shows the coordinate system for a left leg, together with all positive directions of the axes, forces and moments. In order to get a

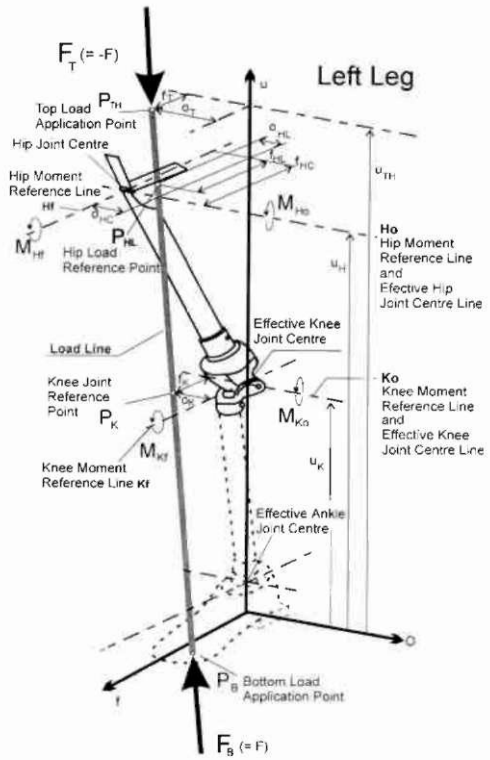


Fig. 2. Test loading condition corresponding to ISO 10328-3:1996 Annex A.

coordinate system for a right leg the system has to be reflected on the  $f$ - $u$  plane so that the  $o$ -axis shows opposite to the original direction (ISO 10328-1:1996). As a consequence the moments  $M_f$  and  $M_o$  also turn their directions but maintain their sign and value.

NOTE: In contrast to the ankle and knee moments the cumulative hip moment  $M_H$  does not act on the  $u$  axis.

Table 1. Positive internal forces and moments with descriptions of their effects corresponding to ISO/DIS 15032:1998, Prosthetics – Structural testing of hip units.

Internal load	Anatomical description	Alternative description
Positive load tends to		
Axial force	$F$	compress the thigh in its longitudinal direction
Knee moment	$M_{K_o'} = \overline{MKML}$	cause extension at the knee joint straighten the knee
Knee moment	$M_{K_f'} = \overline{MKAP}$	cause a lateral movement at the knee relative to the hip move the knee in an outward direction relative to the hip
Hip moment	$M_{H_o'} = \overline{MHML}$	cause flexion at the hip joint move the thigh in a forward direction
Hip moment	$M_{H_f'} = \overline{MHAP}$	cause adduction at the hip joint move the thigh in an inward direction
Twisting moment	$M_{o'} = \overline{MHK}$	cause internal rotation of the distal end of the thigh relative to the proximal end twist the thigh to turn the front side of the knee inwards

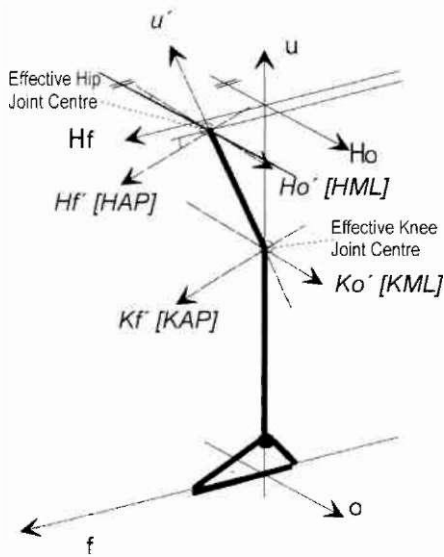


Fig. 3. Sketch of the coordinate system according to ISO/DIS 15032; f, o, u, are in accordance to ISO 10328.

**Introduction of the coordinate system as specified in ISO/FDIS 15032:1998**

The development of the International Standard ISO 15032 by the Working Group WG 3 of the ISO Technical Committee TC 168, was based on a new coordinate system. As this work started during the data evaluation period, the measurements were done on the basis of the

coordinate system described in ISO 10328 (Fig 2). It is necessary to transfer the values of the measurement of the pylon before comparing them with the values measured in the coordinate system [f,o,u] and their transformation into the new coordinate system [f',o',u'] related to ISO/DIS 15032. The moments M within the [f,o,u] coordinate system are designated as  $M_{K_o'}$ ,  $M_{K_f'}$ , etc. (coordinate system according to ISO 10328). The designation of the moments in the ISO/DIS 15032 coordinate system are as follows: MHAP, MKML, etc. The related axes are designated as  $H_{f'}$  or HAP,  $H_{o'}$  or HML,  $K_{f'}$  or KAP,  $K_{o'}$  or KML,  $u'$  or HK. Figure 3 shows the relation between the two coordinate systems.

The internal forces and moments are indicated in Table 1 together with anatomical descriptions for their effects. It contains a list of these together with alternative descriptions for the movements which positive forces and moments tend to cause.

**Measuring principle**

The basis for the implemented measurements is the registration of bending moments, torsional moments, and forces by means of strain gauges. A strain gauge consists of a carrier on which there is a meandering resistance wire. If such strain gauges are glued to a bar and are wired in a Wheatstone's bridge then the detuning of the

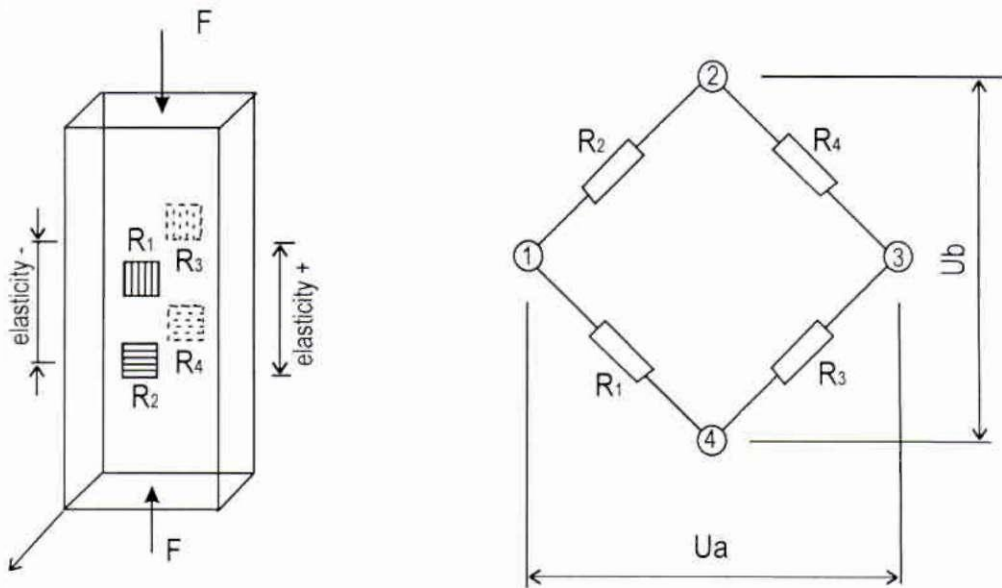


Fig. 4. Strain gauges on the bending rod and their wiring.

bridge ( $=\Delta U_a$ ) is proportional to the appearing bending moment.

The bridge stays balanced when the rod is loaded as in Figure 4 or when the force acts along the longitudinal axis of the rod. The reason for this is that the strain gauge is glued to the rod parallel to its neutral axis. The bridge detuning only appears when the affected levers are facing forward and are acted upon by a force. In that case the elongation in the front is negative and in the rear positive and  $U_a \neq 0$ . When additional strain gauges are glued to the sides in the same way, bending moments in frontal (AP) and lateral (ML) directions can be measured. This principle of strain gauge measuring technology is applied to the measurement system PoMeS II used for this work.

### Measuring system

The measuring system PoMeS II has been developed by the Biomechanics Laboratory of the Fachhochschule Giessen - Friedberg in collaboration with the company, Otto Bock. It consists of three basic components. The measuring pylon, the data acquisition and processing system, and the analysis software PoMGraph.

The measuring pylon consists of three parts, the basic body and two flanges a and b, which are attached to the basic body by screws (Fig. 5).

The basic pylon is equipped with strain gauges, where M1 and M2 are measuring the bending moments in the AP direction, and M4 and M6 the bending moments in the ML direction. The torsion is measured by M5 while the axial compression is measured by M3 at the measurement points.

When the bending moments are registered at the measurement points they can be converted from e.g. M1 and M2 to the bending moments at any points of the tube through application of the theorem of intersecting lines.

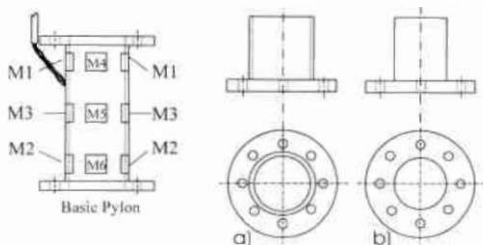


Fig. 5. Basic body of the measuring pylon and connecting flanges.

The measuring pylon can be mounted between the ankle-foot device and knee unit (Fig. 6) or between the knee and hip unit, as long as the connecting structural component between these components consists of tubes.

In order to insert the pylon into the prosthetic assembly it is necessary to shorten the tube which it will replace. The pylon is fastened by a flange (a) (Fig. 5) which is pushed over the tube and then fastened by a clamp collar or by a flange (b) which fits directly into a modular adapter and which is fastened with the clamp screw.

For the hip joint e.g. 7E7 from Otto Bock another flange had to be manufactured. This type looks like flange (b) but is specifically designed to house the extension assist mechanism of this hip unit which normally extends into the upper pylon.

The case of the portable data acquisition and processing system is fastened to the patient's body with a belt. The case of the data acquisition and processing system contains the measuring bridges to which the strain gauges of the measuring pylon are connected and also the integrated  $\mu$ -processor. The measuring pylon and the data acquisition and processing system are connected by a cable.

The signals which come from the measuring bridges are to be amplified, digitised, and stored in the RAM. After the measurements have been completed the data can be transferred into a computer via a RS 232 interface, and are then ready for further usage.

The analysis software PoMGraph is a programme which runs under DOS on a PC. It takes care of several functions. It allows the communication between the PC and the data acquisition and processing system. It is able to graph the measurement values and has analysing functions such as the search for the maximal value, step coverage, and transformation of the data into WKS format. The programme was used to exploit the measured data. For a more detailed description of the programme see Kreil (1995).

### Preparation of the measuring system

The calibration of the measuring pylon was checked and adjusted as needed before the measurements were started. For this purpose the measuring pylon was mounted in a calibration installation equipment.

Calibration was carried out in the AP and ML directions and also additionally in the longitudinal axis for measuring the torsional moment and the axial compression. To correct the cross-talk which occurs between the channels e.g. bending moments and axial force, it was necessary to find the correct mathematical correction factors. These were determined through calculation of the dependence of the measured value affected by the cross-talk and the value which is causing the disturbance. A 6x6 cross-sensitivity matrix was determined for each measuring pylon so that the influence of the cross-talk of the different loads to each channel could be eliminated through calculation (Nietert *et al.*, 1997).

The patients were checked with a LASAR measuring system of the Otto Bock Company to estimate the expected hip movements in the static alignment. This device is capable of localising the load line passing through the centre of gravity of the human body by means of a force plate and to project it on the body by means of a laser beam. Through automatically measured parallel shifting of the laser beam the perpendicular distance of any reference point from the load line and, hence, the effective lever arm by which the load is acting on any joint can be identified (Fig. 6). There has been a cover sheet drawn up for every utilised data set, containing images of a frontal and a lateral view of the patient's prosthesis, and its alignment with regard to the perpendicular distances (levers) of the joint from the load line passing through the centre of gravity recorded by the LASAR system.

The patient who was checked for the estimation was amputated on his right side and had a body mass of 65 kg. He stood with both feet on the force plate and was measured in both the frontal and lateral plane. The resulting lengths of the levers are shown in Figure 6.

The following assumptions were made to estimate the range of the hip moments:

- the centre of gravity is located at the height of the navel;
- the centre of gravity stays the same in the one legged stance position, and the force vector runs through the centre of gravity and the foot (ground).

**Presentation of the data exploitation**

The data was utilised with the goal to determine the size of appearing moments and forces on hip and knee joints, required for the determination of the appropriate test load level(s) of ISO/DIS 15032 and ISO/AMD 15032. A prosthesis has to withstand these test loads for at least three million cycles without cracks and deformations, otherwise the prosthesis has failed the test and the component is declared as unsafe. The test load levels A100, A80 and A60 are recommended for a body mass of up to 100, 80 or 60 kg. In the standard ISO/DIS 15032 there is nothing said about activities to indicate that a person with only 60 kg body mass but, on the other hand, very active should be fitted with a prosthesis which was tested on a higher test load level e.g. A80.

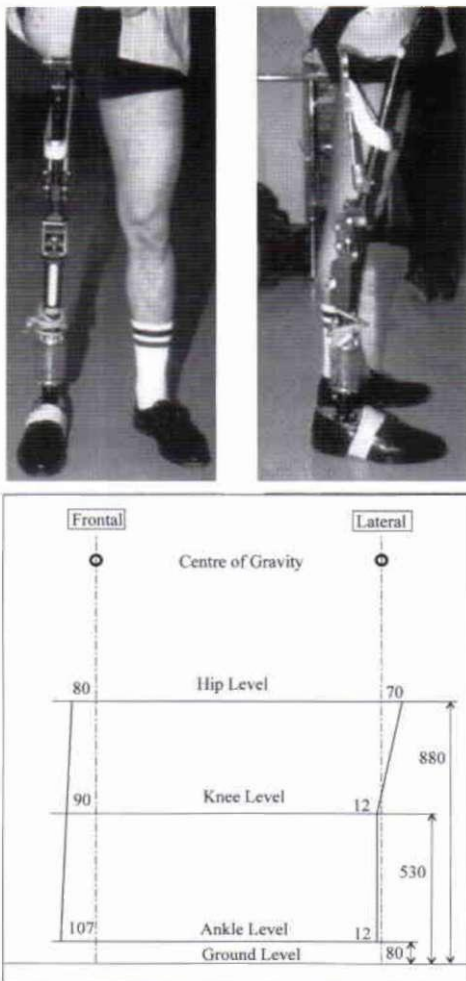


Fig. 6. Measuring pylon mounted between the ankle-foot device and knee unit and the location of the joints relative to the load line in upright stance.

Table 2. Values of knee and hip bending moments MK and MH and test force F for AP and ML test loading conditions corresponding to ISO/DIS 15032 Table B1, B2 and ISO/AMD 15032 Table 3.

		A100	A80	A60
MKAP= $M_{Kf}$	Nm	60	60	60
MHAP= $M_{Hf}$	Nm	110	95	75
MKML= $M_{Kof}$	Nm	80	80	65
MHML= $M_{Hof}$	Nm	-100	-100	-100
Axial torsion= $M_{Lj}$	Nm	30	30	30
Compression=F	N	1280	1050	900

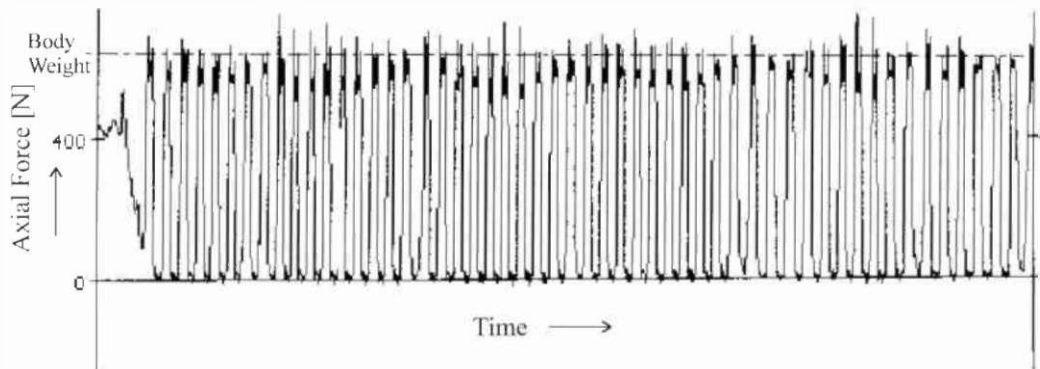


Fig. 7. Course of the axial force during normal walking.

The maximum of the different moments, the axial force and the resulting total force calculated from these were ascertained for each measurement. The steps have been superimposed and their mean with standard error was graphed, as the peak values are not representatives for all steps. The maximum moment and force have also been ascertained for the overlaying step.

The next procedure should be to look at the single steps on the screen, to register possible irregularities, as for example the application of the wrong side of amputation to the wrong side of the ML moments.

#### Visual control of the measured data

The whole file was checked for the maximum values by the programme, POMGRAPH with the special function "ANALYSIS of MAXIMA". When copying the indicated values it is necessary to make sure that the shown maximum is really part of a step, as there are often peak values appearing when the block measurement is switched off. They are to be found at the end of the file.

The graph in Figure 7 shows the axial force curve of the whole file of the patient during normal walking on level floor. The steps have

been superimposed as there were no identifiable runaways.

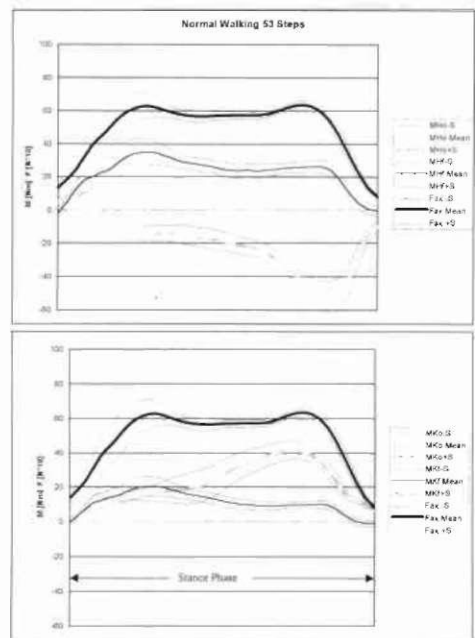


Fig. 8. Axial forces, hip and knee moments during normal walking.

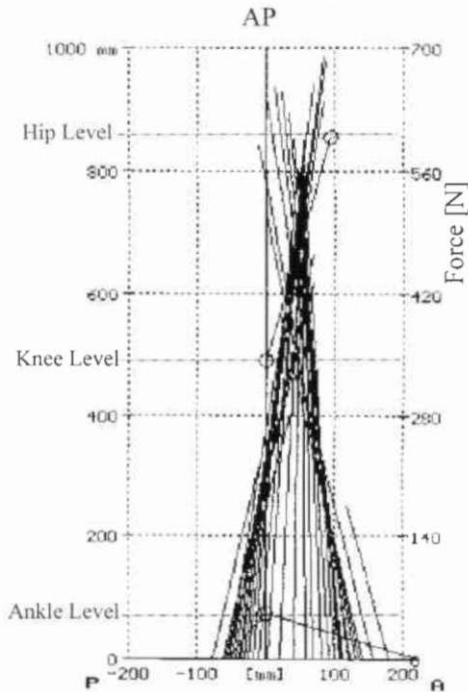


Fig. 9. Vector distribution in AP direction.

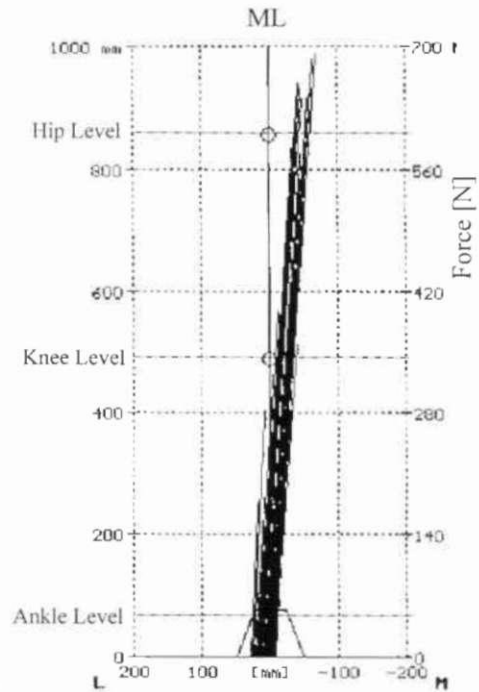


Fig. 10. Vector distribution in ML direction.

**Superimposed steps**

As the description of the superimposed steps with all the forces and moments and standard errors is too confusing, the knee and hip moments previously addressed have been depicted together with the related force curve and their standard deviations (Fig. 8).

**Description of vector distribution**

Figures 9 and 10 show the prosthesis (as a stick diagram) and the distribution of the curve

of the force vector over a step in AP and ML directions.

The density of the depicted vectors indicates that the duration of both the heel and forefoot loading by the patient is significant. The vector line is always passing in front of the knee joint and behind the hip joint so that both joints are always forced to keep their extended position during the stance phase of walking. The ML description indicates that the prosthesis is only loaded on the medial side during the step.

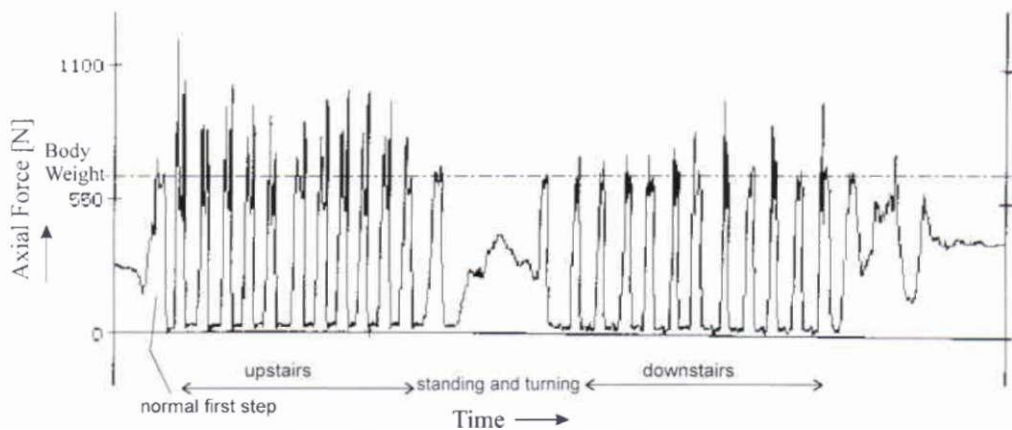


Fig. 11. Course of axial force while walking on stairs.

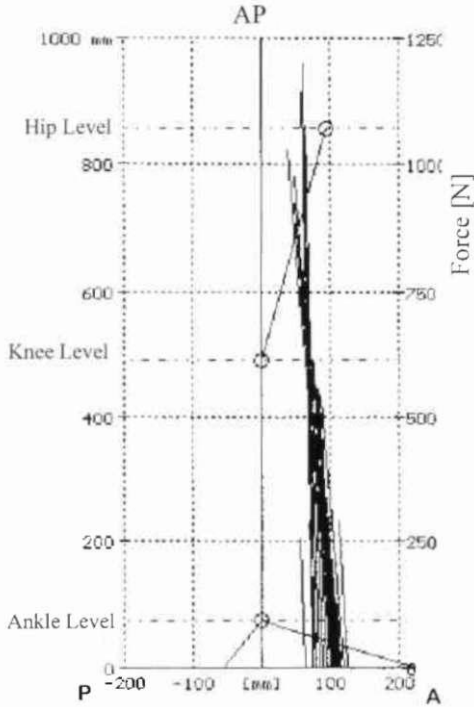


Fig. 12. Vector distribution while walking upstairs.

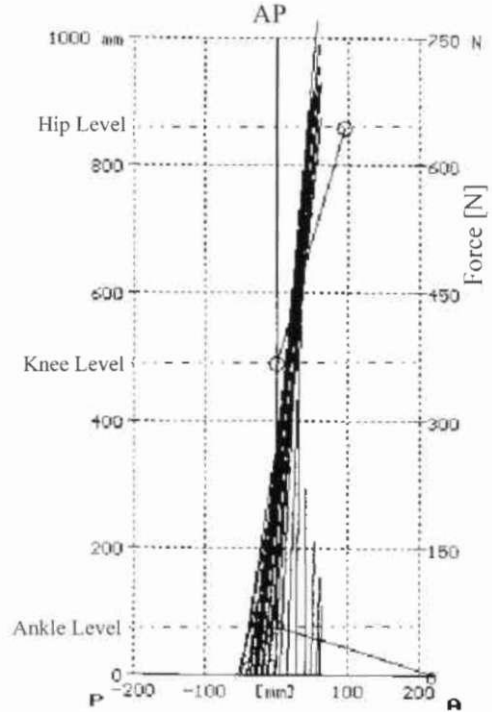


Fig. 13. Vector distribution while walking downstairs.

**Walking on stairs**

Figure 11 is related to walking on stairs. The first part of the curve shows the ascent and the second part the descent.

The first and second part of the file were marked to identify the maxima, and a maximum search was carried out in the 'marked region' thereafter. The steps out of the same marked regions were superimposed, graphed accordingly, and identified as 'upstairs' and 'downstairs'.

The vector distributions of 'upstairs' show that only the forefoot of the prosthesis is touching the stairs while walking upstairs and only the heel is touching the stairs while walking down.

**Walking on grass and walking over a grassy hill**

First the patient was walking across a meadow. Since the meadow was not very level the patient was unforeseeably/unintentionally stepping on hollows and bumps in the surface.

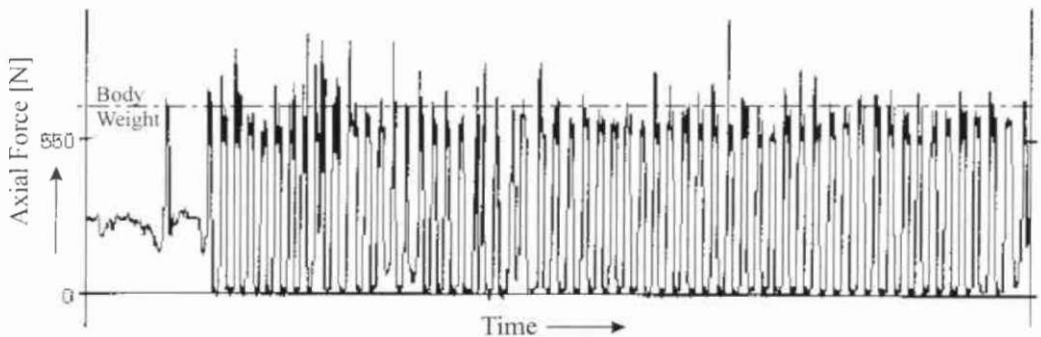


Fig. 14. Walking over a grassy hill.



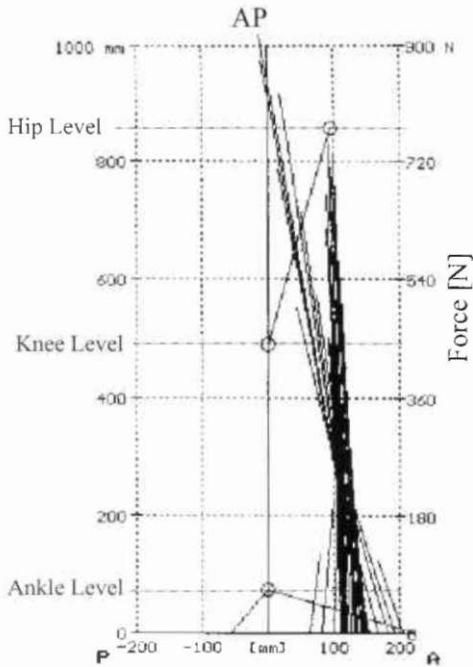


Fig. 15. Vector distribution while walking uphill.

Compared to walking on level floor the vector description shows a more even spread of the vectors over the whole foot. This more even

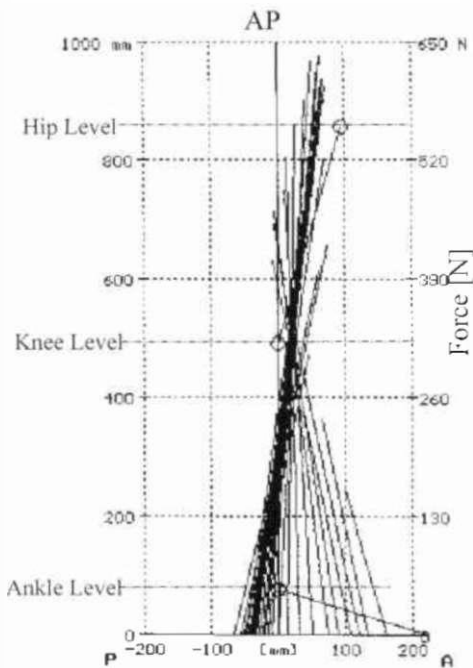


Fig. 16. Vector distribution while walking downhill.

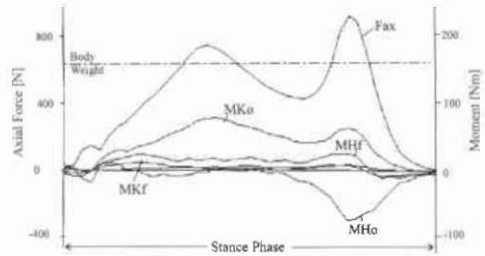


Fig. 17. Force and moments curves uphill.

spread of the vectors is (probably) related to a more careful and slower walking.

Figure 14 is representative of walking over a grassy hill which was located on the meadow used for measurements referred to in the preceding file. The steps or the procedures, respectively, are not very regular and the patient was not always walking straight up and down the hill, but instead, also ascended and descended the hill and on the meadow in a diagonal manner rather than in a straight manner. It is possible to identify the steps up and down the hill with the help of the vector description in Figures 15 and 16.

The vector distribution while walking uphill is similar to that of stair climbing. On the way up the hill only the forefoot of the prosthesis is loaded. In contrast to this, on the way down the hill mainly the heel is loaded.

The step up the hill is more distinctively powerful as can be seen on the well-defined double hump in Figure 17. In contrast to this is the step down the hill where there is almost no double hump distinguishable, because the patient has tried to load the prosthesis to the lowest possible level in order to avoid loss of stability by knee (and hip) flexion (Fig. 18).

### Walking on gravel and fast walking

While walking on gravel the distribution of the vectors is similar to that of normal walking on level floor. But the patient is always looking

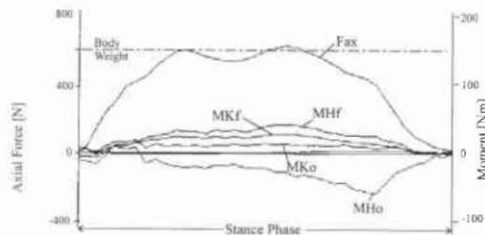


Fig. 18. Force and moments curves downhill.

for the best track. He takes the track with the least amount of stones, or tracks which have been rolled smooth by vehicles.

While walking fast the patient was running twice across a small gymnasium. When one looks at the top of the peaks, one can see a sinusoidal curve. The patient was starting slowly, accelerated then and finally decelerated at the end of the hall.

### Results of the measurements

Over 30 patients between the age of 22 to 50 have been measured. The data of at least 23 patients could be used for the evaluation. The lightest weighed 51 kg, the heaviest had a weight of 95 kg. The hip offset was, related to the ankle-knee axis, within a range of 55 and 105 mm in the frontal direction, and 0 mm in the medical direction.

During the measurements the patients had to walk on different floors and with different walking speeds: level floor (normal walking), upstairs, downstairs, grass, ramp, gravel, and fast walking.

By virtue of the local conditions and the weather it was not always possible to gather all the measurements, for example in the city there was no nearby meadow for the measurements. In addition, some specific measurements could not be taken because some patients could have walked faster than they actually did, others simply refused to walk on grass, with the justification that it was impossible. However, in general the patients have been very cooperative.

To build the pylon into the prosthesis it is necessary to disconnect the foot from the prosthesis and to remove the cosmetic foam cover of the prosthesis. A prosthetist generally does this. He should also be the one who reassembles the prosthesis afterwards. The pylon should already have been roughly calibrated in the workshop so that no major corrections need to be done when the patient is wearing the prosthesis. It has also proven very helpful to ensure that all screws of the prosthesis are tightened.

After having completed the preparation of the prosthesis for measurement, the patient should test the arrangements by walking around in order to recognise the adjustments. With the built-in pylon, it is not possible to maintain the alignment and functional characteristics of the original prosthesis. The patient has to get

accustomed to the fact that the lower leg swings with a different speed due to the removal of the foam cover. The patient also recognises differences in length even when they are only a few millimetres as well as the weight of the pylon.

As soon as the patient is managing with the modified prosthesis the pylon is eventually re-fixed (the pylon with the strain gauges is aligned frontal-medial), and the geometry of the prosthesis is recorded.

### Description of the force and moments generated by the body mass

The following diagrams show the forces and moments of all patients plotted against the body mass. In each diagram the maxima of the mean values of the superimposed peak values are registered, together with the peak values appearing in the related file. Since all patients did not walk on gravel, the values of walking on uneven ground, gravel and cobblestone pavement have been summarised.

### Mean values with two standard deviations and peak values measured in Europe and Japan during normal walking

The force typically occurs in a double hump as seen in Figure 8 and the moments are positive with exception of  $M_{HO}$ . In the frontal view, the force vector passes medially and in front of the knee unit and behind the hip joint seen in the side view. But on the other hand the course of the moments and force are also dependent on the prosthetic alignment or when the patient is walking with walking aids. In addition several measurements were also made in Japan (ISO TC 168WG3, 1996). These data are included into the diagrams where they have been available. The diagrams include peak values as occasional event, mean values and two standard deviations (2SD).

#### *Walking on stairs*

Typical patterns of force and moments also appear while walking on stairs. During stair climbing the patient is putting the healthy leg in front and is then pulling the prosthesis behind. Many of the patients take two stairs at a time and are always using the rail. The pattern of the force shows a very well-defined double hump. The step begins with the patient setting the prosthesis on the stair. Then the patient is pulling the healthy

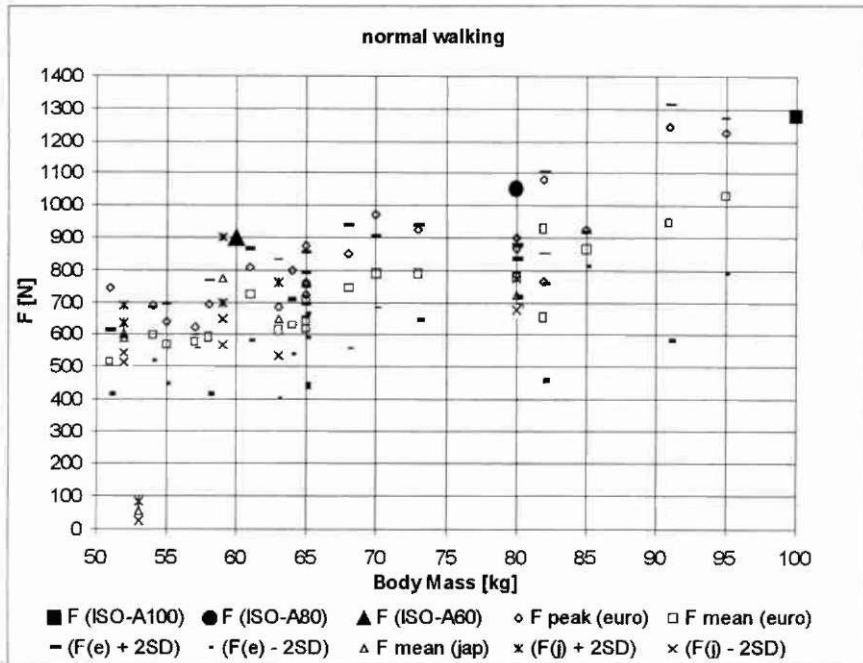


Diagram 1. Axial compression.

leg upwards to set it down one or two steps further above. The well-defined double hump is created through the swing of the leg being pulled

upwards, and the supporting pulling on the rail.

Likewise typical patterns of force and moments are found during the stair descending;

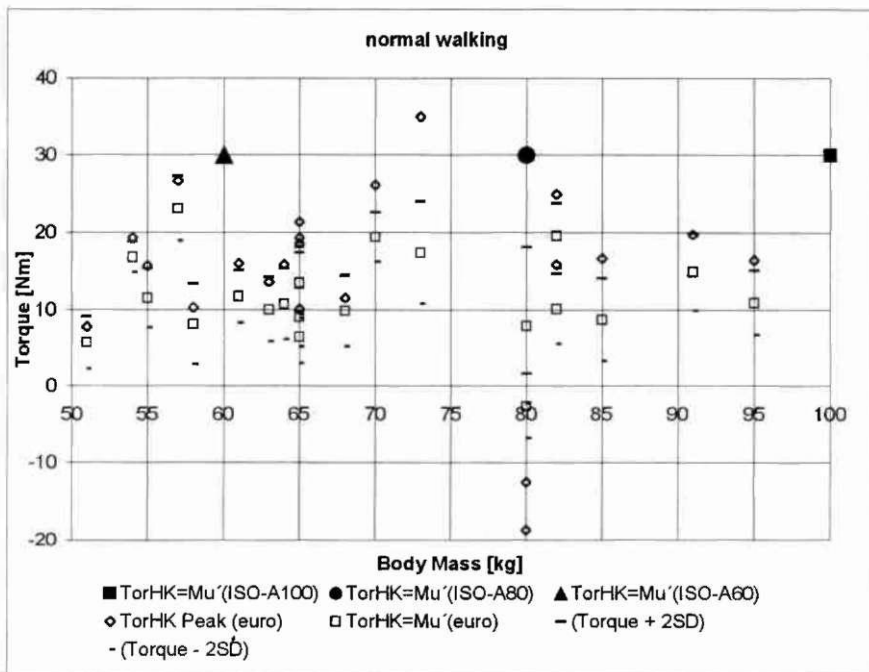


Diagram 2. Torque.

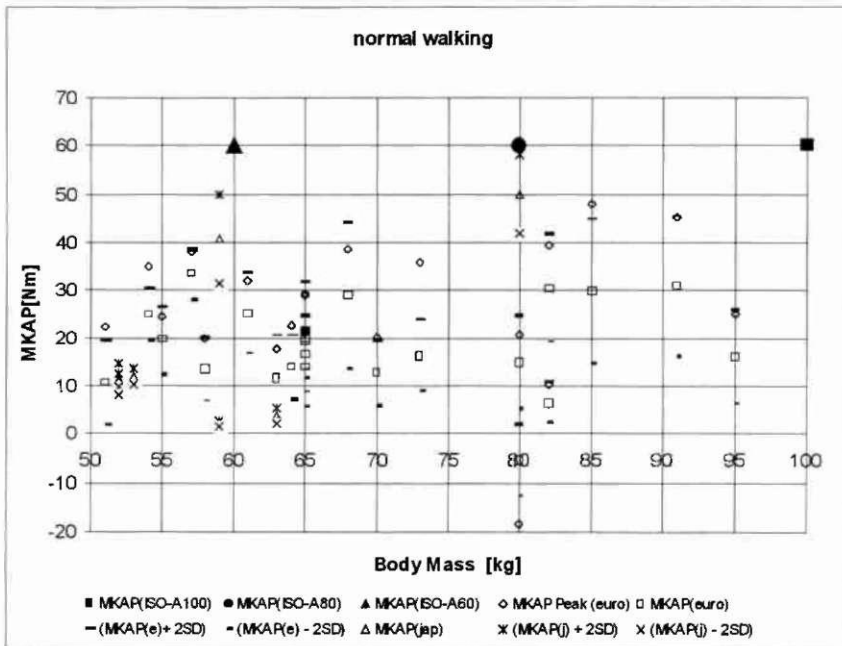


Diagram 3. Knee moments in the ML plane.

the patient first sets the prosthesis a step further down, and is then pulling the healthy leg behind. The pattern of the force shows a gradual rise without double hump. In contrast to the stair climbing here the patient is reassuring himself

through careful loading, to see the prosthesis is standing right and stable, in order to avoid tumbling.

This caution is not necessary for stair climbing since the patient is already standing securely

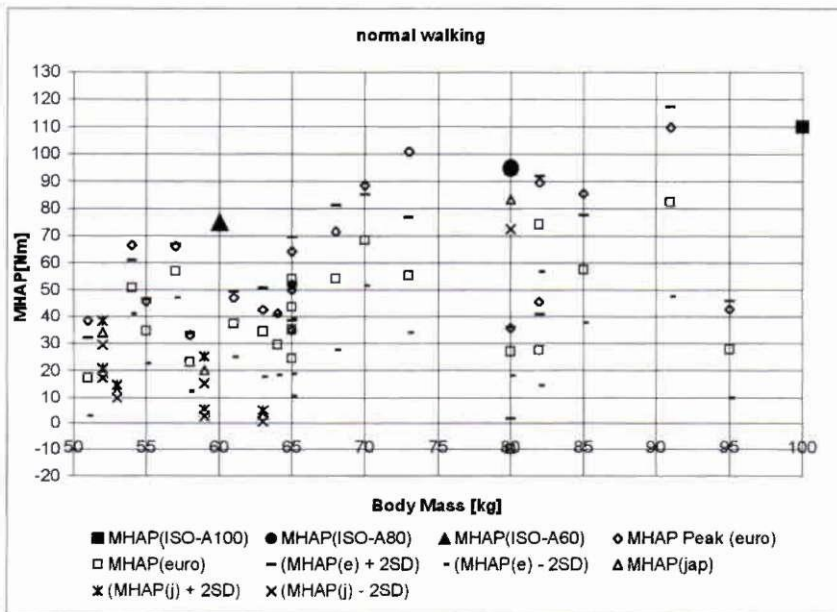


Diagram 4. Hip moments in the ML plane.

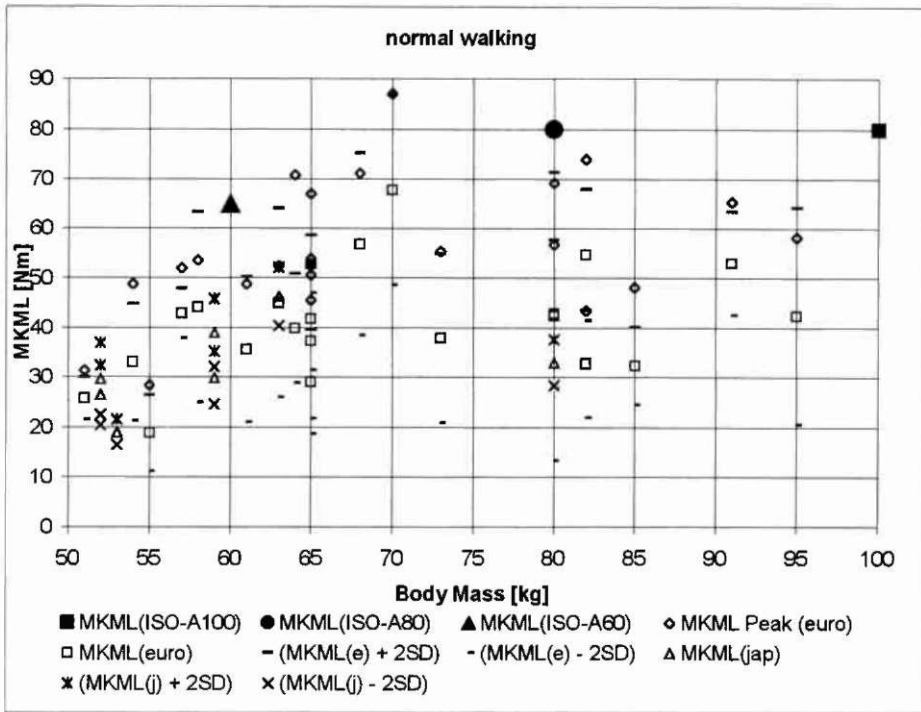


Diagram 5. Knee moments in the AP plane.

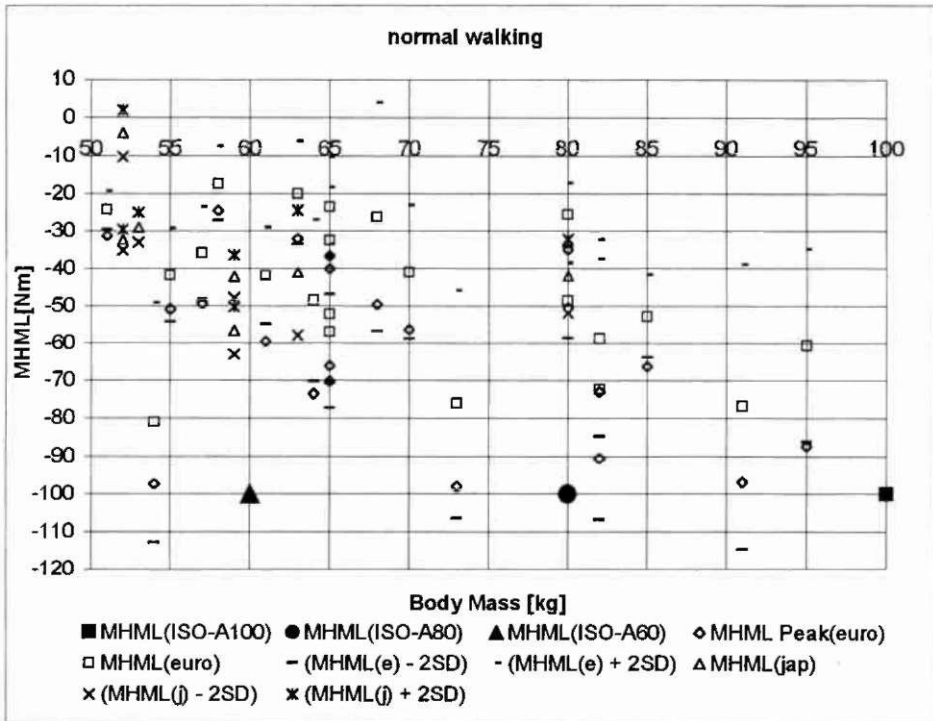


Diagram 6. Hip moments in the AP plane.

with the healthy leg, when the loading of the prosthesis begins.

There are often peaks noticeable at the beginning of the curve during stair descending. The patient is causing them through setting the prosthesis sideways on the stair while descending. As a consequence the moments in the result description are partly diverging from the expected values of these peaks.

*Walking on grass*

Raised first peaks in the pattern of the force are always essentially appearing while walking on grass. They are caused through the patient unintentionally stepping into hollows, which he did not recognise in the mown meadow.

The patterns of force and moments resemble those of walking on level ground, despite the raised peaks. Walking on wet grass probably would have lead to different results. However the risk of slipping on wet grass was too high for the patients.

*Walking on gravel*

The gravel paths used for the measurements had been rolled hard and almost even by vehicles

on the left and right. As the patients preferred to walk on the hardened ground although they had been asked to walk on gravel, there are no typical step characteristics visible. The pattern is like normal walking on level ground.

*Fast walking*

The values and vector patterns measured during fast walking are very similar to those of normal walking. The walking speed of the patient is limited by the minimum duration of the forward swing of the lower leg. The damping characteristics of the knee joint would have to be changed to reach maximum speed, but then the patient would have had trouble with normal walking.

**Superimposed values of all data**

The superimposed values of all data are shown in Figure 7 (axial compression), Figure 8 (torque), Figures 9 and 10 (knee moments), and Figures 11 and 12 (hip moments).

**Discussion**

Relations between the body mass and measured values of force and moment generated

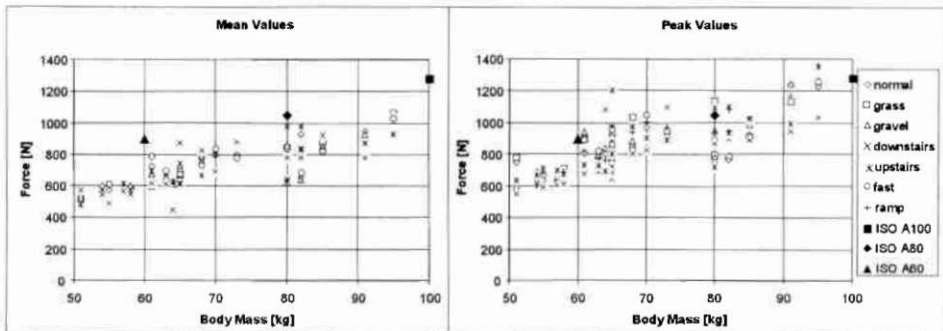


Diagram 7. Axial compression (mean and peak values) during different walking situations.

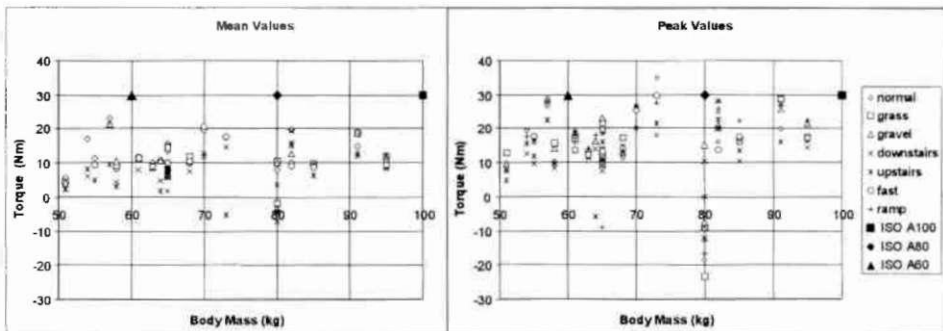


Diagram 8. Torque (mean and peak values) during different walking situations.

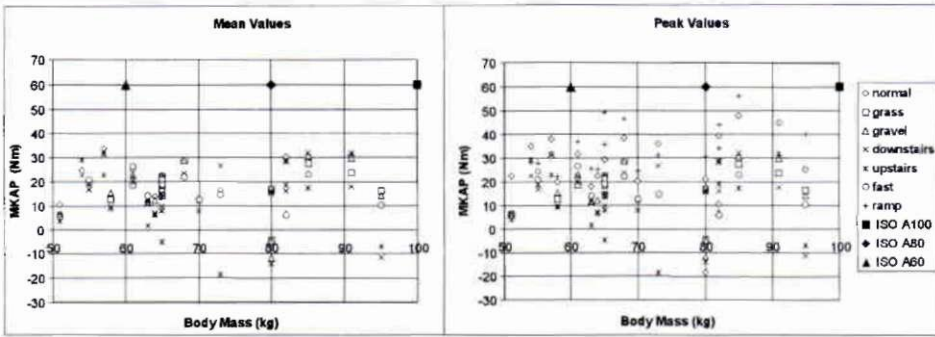


Diagram 9. Knee moment (mean and peak values) during different walking situations in ML plane.

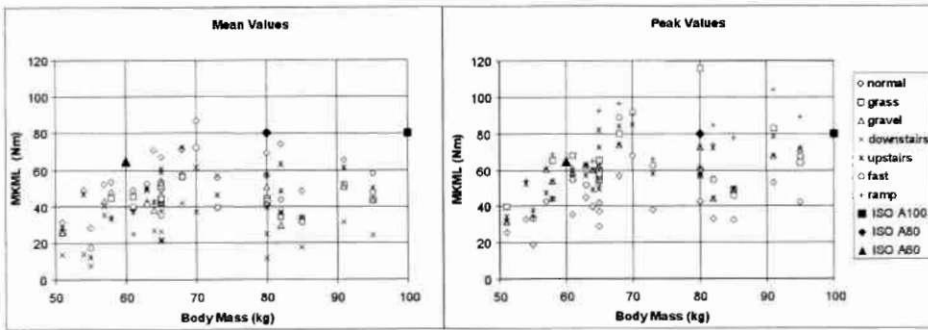


Diagram 10. Knee moment (mean and peak values) during different walking situations in AP plane.

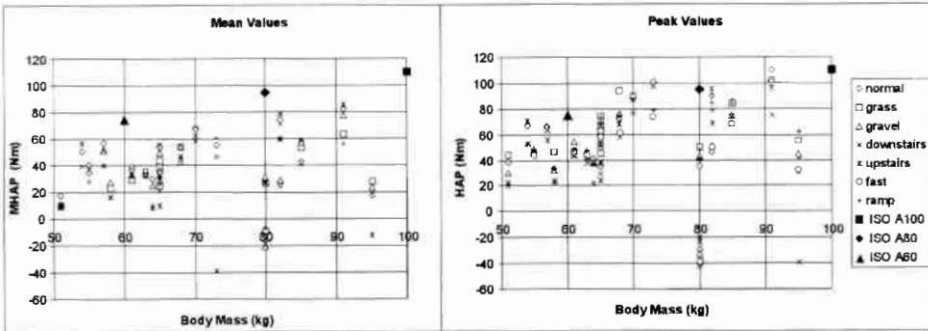


Diagram 11. Hip moment (mean and peak values) during different walking situations in ML plane.

in the prosthesis can be established considering the force  $F$ . An unambiguous linearity is not to be expected, since the measured force is not only dependent on the body mass of the patient but also on the dynamics of the gait which is different from patient to patient. The combination of the individual dynamics of the gait and the individual structure of the prosthesis is the cause that values of the moments in relation to the body mass are widely spread.

Due to the fact that the values of the moments have to be calculated from the measured data it

is necessary to consider the following comments.

None of the measured patients reached the body mass of 100 kg estimated for the standard. The patients furthermore explained that the stress on the prosthesis was very much dependent on the use during their working days. A farmer used his prosthesis for all jobs on the farm. Others indicated that they were hiking in the mountains with their prosthesis.

Most of the patients confirmed that they only leave level ground with their prosthesis when

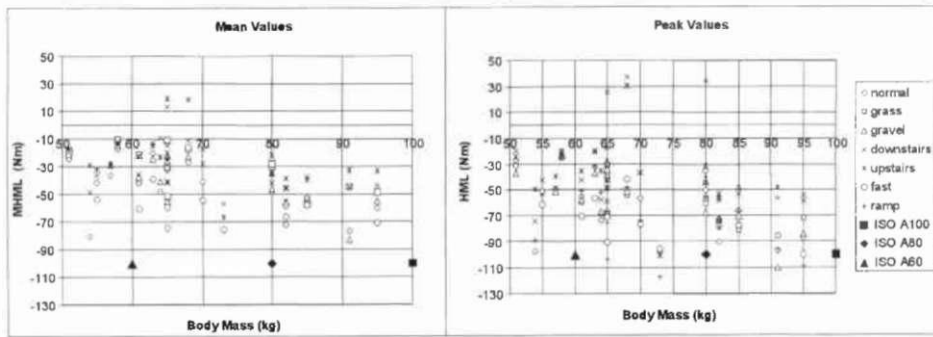


Diagram 12. Hip moment (mean and peak values) during different walking situations in AP plane.

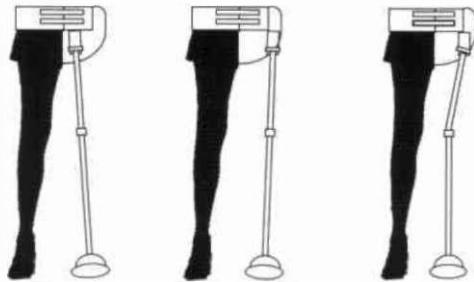


Fig. 19. Examples of prosthetic alignment.

there is no way to avoid it. This was clearly visible in their behaviour on a gravel path on which they were always looking for smooth tracks along the way. Having the alternative to walk on stairs or to take the elevator, preference was given to the latter possibility.

Another significant influence on the stress of a

prosthesis is given by the alignment of its structure.

As illustrated in Figure 19, there are different possibilities of aligning the prosthetic structure. The stresses of the single components/segments are obviously changed according to the structural alignment.

Table 3 lists the absolute ultimate mean and peak values ever reached by all patients while walking on level ground, as well as the maxima of the superimposed steps, of all patients considering all surfaces and activities. The right column contains the values of the ISO/DIS 15032 and ISO/AMD 15032.

In some cases the peak values actually appeared only once, but nevertheless they indicate that values higher than the draft values of standard for torsion, MKML, and MHML do occur. The value of the force of 1350 N is not the

Table 3. Absolute ultimate values measured with patients in comparing to the test loads of ISO/DIS 15032. Table B1, B2 and ISO/AMD 15032 Table 3.

	Normal walking on level ground			All activities		ISO/DIS 15032:1998		
	Mean values	Mean values +2SD	Peak values	Mean values	Peak values	A100	A80	A60
MKAP Nm	34 (50 jap*)	45 (58 jap*)	48	34 (normal)	57 (ramp)	60	60	60
MHAP Nm	82 (84 jap*)	117	110	83 (downstairs)	110 (normal)	110	95	75
MKML Nm	68	87	87	68 (normal)	116 (grass)	80	80	65
MHML Nm	-81	-115	-98	-82 (gravel)	-118 (ramp)	-100	-100	-100
Torsion Nm	23	27	35	23 (normal)	35 (normal)	30	30	30
Compression N	1030	1312	1243	1050 (grass)	1350 (grass)	1280	1050	900

\*1 Japanese data (ISO/TL 168, 1996)



true value, as the amplifier of the measurement system went into overload by this patient (95 kg). The value was reached while walking on grass and downstairs by a patient whose body weight was 68 kg and whose prosthesis had no lateral offset.

### Conclusions

The data clearly indicates that the determination of test values cannot be based on the supposition that the heaviest patient will automatically generate the highest stress is the prosthesis. Many factors which are dependent on the individual habit of each patient and therefore not predictable have an effect on the stress level and, hence on the lifetime of a prosthesis.

Of significant influence is the personal attitude of the patient to her/his prosthesis. Does she/he see it as an aid for locomotion or as a cosmetic device just contributing to less conspicuous appearance.

On one side it would be advisable to determine a standard alignment for the prosthesis, but on the other side it should be the goal to adapt the prosthesis optimally to the patient and not the other way round.

### REFERENCES

KREIL P, (1995) Erstellung einer Software, inklusive Bedienungsanleitung zur Visualisierung und Analyse der biomechanischen Meßdaten des Meßsystems PoMes II im Hinblick auf die zu erstellende ISO-Norm 15032 zur Prüfung von Hüftprothesen. Diplomarbeit (Thesis) Fachhochschule Gießen-Friedberg.

ENGLISH N, (1996). Messungen von Kräften und Momenten an Hüftexartikulationsprothesen zur Erstellung einer internationalen Prüfnorm (ISO). Diplomarbeit (Thesis). Fachhochschule Gießen-Friedberg.

ISO 10328-1:1996. Prosthetics Structural testing of lower-limb prostheses, Part 1: Test configurations.

ISO 10328-2:1996. Prosthetics Structural testing of lower-limb prostheses, Part 2: Test samples.

ISO 10328-1:1996. Prosthetics Structural testing of lower-limb prostheses, Part 3: Principal structural tests.

ISO/DIS 15032:1998. Prosthetics – Structural testing of hip units (draft document).

ISO/AMD 15032:1998. Prosthetics – Structural testing of hip units (amendment).

ISO/TC 168/WG3 (1996). Limb load exerted on the hip and knee joints of hip disarticulation prostheses in Japan. N202 (technical draft).

prEN 12523:1997. External limb prostheses and external orthoses – requirements and test methods.

NIERT M, ENGLISH N, KREIL P, ALBA-LOPEZ G (1997). International Study on the Acquisition of Loads in Hip Disarticulation Prosthesis. Published in ISO/TC 168/WG3 "Testing" N216 and CEN/TC 293/WG5 N53b: Final Report of laboratory tests in support of the European Standard EN 12523, External limb prostheses and external limb orthoses – Requirements and test methods (WI 00293-20 and WI 00293-21). p1-113

Note: Standards designated ISO are published by International Standard Organisation, Geneva. Standards designated EN are published by CEN (Centre Européen de Normalisation), Brussels.