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Proof of Effectiveness of a Valgising Gonarthrosis Orthosis by means of Biomechanical Analyses

The biomechanical effectiveness of the "Genu Arthro" gonarthrosis orthosis was studied on 16 patients with varus gonarthrosis. The time of therapy with the orthosis had been at least four weeks at the time of the study. In addition to the well-known parameters of instrumented gait analysis (Vicon System, Kistler force plates), the deformation of the orthosis was measured while walking. Furthermore, for every individual orthosis the relation of deformation and orthotic moment was determined by means of an especially developed calibrating device. Computation of these orthotic data against those of the gait analysis reveals an average reduction of the varus moment on the knee of about nine per cent, which could explain the significant reduction of pain observed in clinical studies.

Introduction

Joint deterioration (arthrosis) takes an important place among joint disorders that cause pain. Hip joints and knee joints are affected particularly often. In terms of incidence, gonarthrosis significantly increases from the third decade of life. Epidemiological studies arrive at the conclusion that, all in all, about five to six per cent of the population is affected more or less severely [2]. Treatment concepts can basically be divided into surgical and non-surgical methods. In the field of surgical methods, joint replacement and osteotomy techniques are often applied in addition to arthroscopic methods. Non-surgical treatment, which is used in minor and moderate cases of arthrosis as well as in cases where surgical methods are not applicable, mainly comprises medication, physiotherapeutic measures and fittings with orthopaedic appliances (walking aids, insoles, shoe sole elevations, knee orthoses).

Despite clearly proven clinical effectiveness of gonarthrosis orthoses [1, 7, 9], these orthopaedic appliances are still not mentioned in the current guidelines of orthopaedics issued by the German Society for Orthopaedics and Orthopaedic Surgery (DGOOC). It is therefore not surprising that according to the latest surveys, less than one per cent of all gonarthrosis patients are treated with a knee orthosis [8]. Insufficient availability of objective, measurable proof of effectiveness may be one reason for this.

Directly measuring the torsional moment generated by a gonarthrosis orthosis provides proof of effectiveness. Orthoses for the treatment of varus gonarthroses generate a valgising moment counteracting the external varising torsional moment that is naturally present during maximum load in the stance phase. This compensating function of the appliance may lead to an explanation of the pain relieving and function improving effect. Until now, direct measurements of orthotic moment were only taken with instrumented test orthoses [12]. This contribution describes how the knee relieving torsional moment is measured with the individual orthosis of the patient without modifying the orthosis with additional measuring instruments. Biomechanical/gait-analytical diagnostics and an especially developed calibration procedure for individually adapted orthoses provide the basis for this.

Methods

Patients

16 patients (eight of them male, eight female) with medial gonarthrosis, diagnosed by orthopaedic physicians, participated in the study. Exclusion criteria comprised recent injuries, skin diseases, varicosis and diseases influencing the gait pattern except gonarthrosis. With the arthrosis classification according to WIRTH and on the basis of x-ray images the patients had brought with them, one patient was to be assigned to degree 1, five patients to degree 2, seven patients to degree 3 and three patients to degree 4. All patients had been using a Genu Arthro knee orthosis on one side for at least four weeks. The examinations were also carried out with this orthosis (Fig. 1). Important patient data are contained in Table 1.

	Age [Years]	Height [cm]	Mass [kg]	Period of application [weeks]	Duration of use [hours/day]	Walking distance [km/day]
Mean value	56	172	83	22	9.6	5.3
Variance	10	9	7	41	3.5	2.2
Minimum	41	158	57	4	2	1
Maximum	67	192	100	164	12	8.5

***Table 1** Data of the examined patients.*

***Fig. 1** Patient with the knee orthosis mentioned in the article.*

Determination of the Valgising Moment of the Orthosis

The knee relieving function of the above-mentioned orthosis results from the classical three-point principle. A thigh module and a lower leg module are connected to each other with a single-axis joint. The restoring forces required for an orthotic moment with valgising effect result from the deformation force that is needed for fixing the thigh module to the thigh starting from a variably adjustable initial position (Fig. 2). The basic idea for determining the orthotic moment is to deduce the moment from the restoring force and the effective lever arm, mainly determined by the length of the thigh module. For this purpose, it was necessary to first determine the correlation between the restoring force and path for every individual orthosis using a special force measuring device. The restoring force corresponding to a defined deformation was measured using a resilience force meter (Fig. 3). After measuring 15 to 18 value pairs per orthosis, the linear correlation

$$F_{Orth} = C_{Orth} * (X_i - X_0)$$

was used to determine the stiffness of the orthosis C_{Orth} by means of regression calculation. (X_0: initial position in unloaded state, X_i: path covered in relation to the unloaded state, F_{Orth}: restoring force, C_{Orth}: stiffness of the orthosis, i = 1 ... (15 ... 18))

Based on the acquired knowledge of the orthosis characteristics, it was subsequently sufficient to measure the deformation of the orthosis while standing and walking. This was realised with three reflecting markers that were affixed to the orthotic joint as well as to the distal and proximal force application points (Fig. 4). The position of these markers can be measured three-dimensionally with high precision using the gait laboratory's optoelectronic camera system. Based on the three-dimensional coordinates of the markers, the actual deformation was then calculated with simple trigonometric relations in comparison to a measurement while standing without the orthosis being fixed. This value and the stiffness of the orthosis result in the restoring force and orthotic moment.

The deformation was measured during gait analysis. Due to the validity range of the trigonometric relations used, the orthotic moment was calculated within the first 50 per cent of the gait cycle. This means that the phases of gait that are important for the load on the knee joint are taken into account for the calculation.

***Fig. 2** Different basic settings of the orthosis. Left: little deformation in unfixed state = low orthotic moment after fixation on the thigh; right: strong deformation in unfixed state = high orthotic moment after fixation on the thigh.*

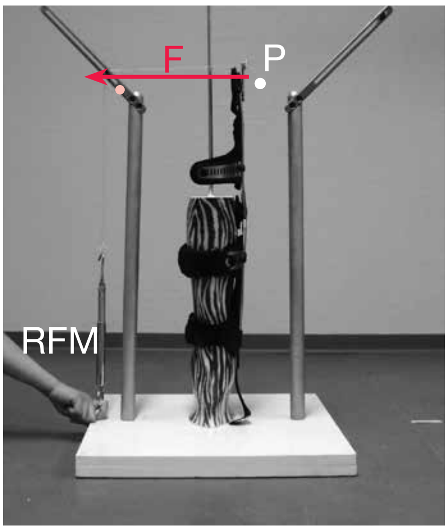

***Fig. 3** Force measuring device for determination of the stiffness of the orthosis (P: proximal force application point, RFM: resilience force meter, F: force required to deform the orthosis).*

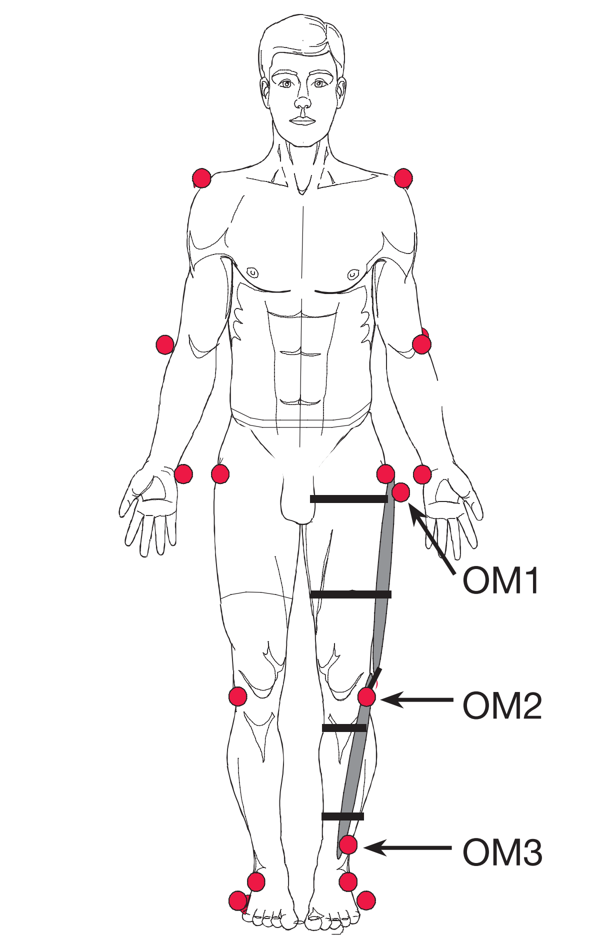

Fig. 4 Set of markers used (OM1, 2, 3: markers positioned on the orthosis).

Gait Analysis

The gait of all patients was analysed. The ground reaction forces were measured using two force plates (measuring frequency 1080 Hz). An optoelectronic six-camera system recorded the kinematics of the movements by means of passive markers (measuring frequency 120 Hz). The set of measuring markers used has already been described in detail in an earlier paper [13]. The external torsional moments acting on the large joints of the lower extremity were calculated for the period of the stance phase on the basis of the ground reaction forces and kinematic data.

Execution of the Test and Data Preparation

The gait analysis was completed for all patients in random order, with and without the orthosis. During each measuring situation, eight to ten partial tests were analysed which were then used to form a gait cycle standardised mean value for the biomechanical parameters. This formed the basis for the calculation of group mean values, so that comparisons between the two measuring situations and between the arthrotic and contralateral knee joint were possible. Distinctive peaks of biomechanical parameters were examined for any significant differences using the WILCOXON test.

After the gait analyses, the stiffness of the orthosis was determined as described in the previous section, in order to be able to calculate the valgising orthotic moment. Finally, the patients answered questions regarding the anamnesis of their disease and the quality of the orthotic fitting. With respect to the characteristics of the orthosis, the patients were asked to assess on a scale between zero ("very poor") and six ("very good") the fit of the orthosis, wearing feeling of the individual components, design and handling.

Results

Subjective Judgement

15 of the 16 examined patients said that the pain situation had clearly improved due to the use of the orthosis. In this context, seven patients mentioned feeling a higher degree of stability in the knee joint when wearing the appliance. Regarding the characteristics of the orthosis assessed with the scale, all criteria achieved good results with average points between 4.3 and 4.9, except the category "Wearing feeling on the thigh". Here, a mean value of 3.4 was achieved, which can mainly be explained by the fact that six patients said they sometimes had a feeling of slipping between the orthosis and thigh.

Time-Distance Parameters

The mean walking speed was 1.27 m/s while measuring without the orthosis and rose significantly to 1.36 m/s when walking with the appliance ($p<=0.05$). For the affected extremity, the step length increased from 0.71 m without the orthosis to 0.73 m with the orthosis, while for the contralateral extremity there was a reduction in step length from 0.75 m to 0.73 m. The patients thus showed symmetrical step lengths when walking with the orthosis.

Ground Reaction Forces and Load on the Knee Joint

The analysis of the ground reaction force shows considerable differences in terms of the braking force acting during the first half of the stance phase in the comparison of the examined situations (horizontal component of the ground reaction force, Fig. 5). In the situation without the orthosis, a significantly reduced force is measured for the arthrotic extremity in comparison with the contralateral, sound extremity (14.3 versus 17.9 per cent BW). When using the orthosis, this force action is considerably increased for the arthrotic leg with 16.4 per cent; there is no longer a significant difference in comparison with the sound side.

During the analysis of the load on the knee joint in the sagittal plane, striking differences are measured for the torsional moment that has a flexion effect in the first half of the stance phase. In both examined situations, the mean maximal value of the contralateral knee joint is 0.45 Nm/kg. Without the orthosis, the arthrotic knee shows a significant reduction with 0.23 Nm/kg. When using the orthosis, this value increases without significant proof but clear tendency to 0.33 Nm/kg and thus approaches the normal situation (Fig. 6). The described load characteristics correlate with reduced movement amplitudes during the flexion/extension cycle which the arthrotic knee joint undergoes under load. Both stance phase flexion and stance phase extension are reduced by approximately three degrees in comparison with the contralateral side in both situations.

The torsional moment acting externally in the frontal plane on the knee joint – the most important standard gait parameter for knee load assessment in case of arthrotic changes – confirms the findings of earlier studies [5]. Independently of the measuring situation, a mean

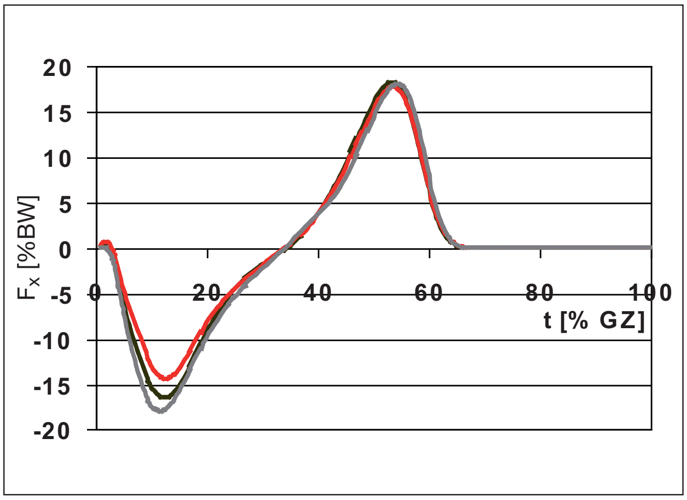

Fig. 5 Mean horizontal component of the ground reaction force (red: arthrotic extremity without orthosis; black: arthrotic extremity with orthosis; grey: contralateral extremity without orthosis; GZ: gait cycle).

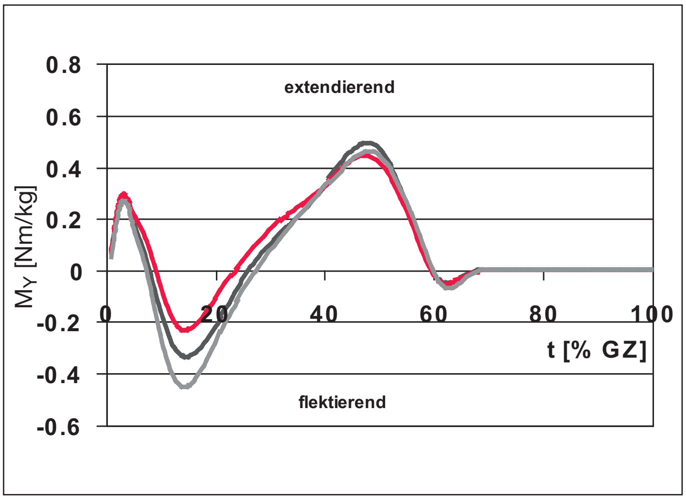

Fig. 6 Mean external torsional moment acting on the knee joint in the sagittal plane (red: arthrotic extremity without orthosis; black: arthrotic extremity with orthosis; grey: contralateral extremity without orthosis; GZ: gait cycle).

maximal value of 0.53 Nm/kg is measured here for the non-affected extremity. The arthrotic knee, in comparison, again shows an insignificant increase with clear tendency, however, of the value with 0.63 Nm/kg (Fig. 7). The gait analysis with the orthosis applied does not result in measurable differences for this parameter on average.

Determination of the Orthotic Moment

When calculating the orthotic moment in the range of the first 50 per cent of the gait cycle, it becomes obvious that the time structure of this value varies greatly. No uniform peak values can be identified at distinctive points in time of the stance phase. Figure 8 shows the structure of the mean group value. It shows the tendency of the valgising moment generated by the orthosis to slightly increase in the course of the stance phase. This increase is clearly visible between zero and ten per cent of the gait cycle and then noticeably slows down between ten and 30 per cent of the gait cycle, i.e. during stance phase flexion. In the range between 30 and 50 per cent of the gait cycle, i.e. during stance phase extension, the valgising effect of the orthosis once again increases slightly more.

The relation between the orthotic moment and external frontal moment also varies significantly. When comparing the respective maximum values, the mean value of the orthotic moment is 8.9 per cent of the external frontal moment, with individual fluctuations lying between two and 27 per cent. When taking a mean value between zero and 50 per cent of the gait cycle as an assessment parameter, the mean value of the orthotic moment is 9.1 per cent of the external frontal moment with similar fluctuation ranges (two … 28 per cent).

Discussion

Thanks to the method applied in the present study, the effect of the gonarthrosis orthosis that was used leads to known positive clinical results which are quantifiable based on objective biomechanical measuring data. It has becomes

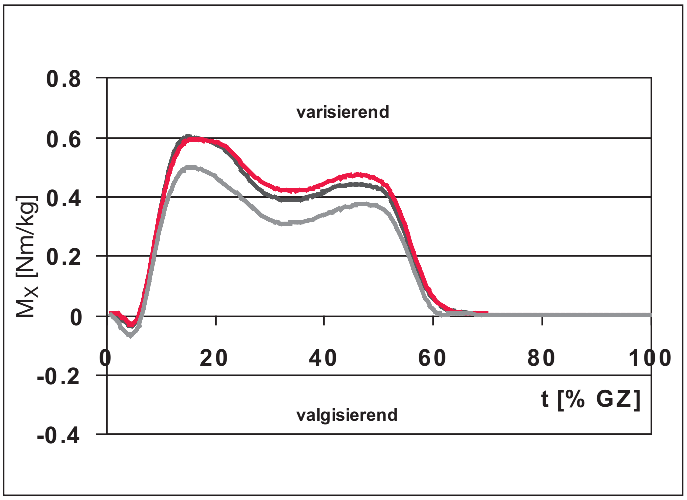

Fig. 7 Mean external torsional moment acting on the knee joint in the frontal plane (red: arthrotic extremity without orthosis; black: arthrotic extremity with orthosis; grey: contralateral extremity without orthosis; GZ: gait cycle).

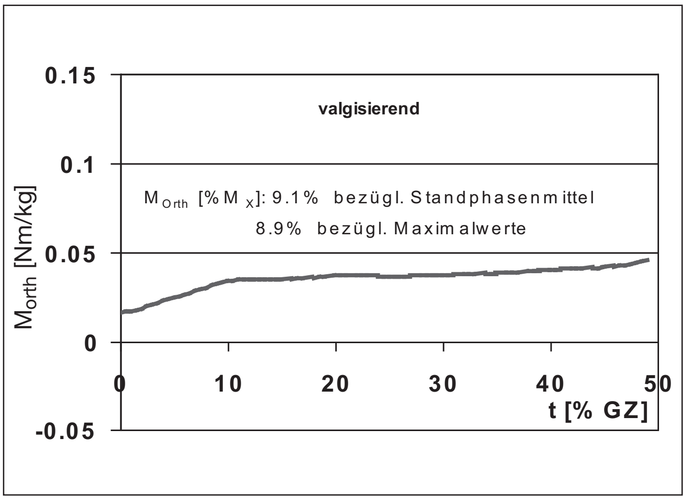

Fig. 8 Mean orthotic moment between 0 and 50 per cent of the gait cycle (GZ).

obvious that there are very different structures – both with regard to the scope of the effect and with regard to the variation in time during the stance phase of the gait cycle. Probably reasons include the problems of possible significant individual anatomical differences between patients known from fitting practice. They can lead to very different fit characteristics that can have an influence on the functional effect of the appliance. The maximum effect of the Genu Arthro orthosis tends to be recognized during stance phase extension. To a large extent, this is in compliance with the results of an earlier study made with another gonarthrosis orthosis [5].

The averaged portion of approximately nine per cent of the orthotic moment in relation to the external varising moment is of the same order as identified by Pollo et al. [12] with 10.7 per cent in a study with an instrumented orthosis with ten patients. Pollo et al. additionally used the data of the gait analysis to calculate the joint force acting in the medial compartment. The result was that the joint force is reduced by approximately 80 to 90 N due to the effect of the orthosis; the percentage of this reduction is similar to the portion of the orthotic moment on the external moment. Obviously, a compensatory orthotic effect of this order is sufficient to achieve the proved reduction in pain.

During measurement without the orthosis, the most important standard parameter of gait analysis for general assessment of the knee load, which is the torsional moment that acts externally in the frontal plane, confirms that one has to start with the assumption that gonarthrosis patients have an unphysiologically increased value even when no serious incorrect axial positions are present [3, 4, 5]. This parameter could therefore be very useful for diagnostic purposes to support the prediction of risks for the genesis of arthrosis. There are controversies about whether or not knee orthoses have an influence on this parameter. In the literature, comparable studies report about both, reduction [3, 11] as well as approximately unchanging peak values [5, 6, 12]. The present study thus joins the latter group. The very different study approaches (e.g. examination of healthy test subjects, use of instrumented orthoses, unrealistic orthosis settings) might be a reason for this discrepancy. The results of this paper suggest the conclusion that the effect of the orthosis is too unimportant in the patient's real everyday situation for significantly reducing the external varus moment. Reports stating that gonarthrosis orthoses are capable of accomplishing corrections of false axial positions [10] should be critically scrutinised in this context. The measured orthotic moments are too low for this; moreover, no relevant indications in this regard were found in an earlier study with comprehensive x-ray diagnostics [5].

In addition to the measured parameters that were important for the direct goal of the present study, the results of the gait analysis provided other information for the characterisation of the gait pattern of gonarthrosis patients. Without the orthosis, the reduction of the braking force of the arthrotic extremity directly after the beginning of the stance phase as well as reduced sagittal load on the knee joint during the flexion/extension cycle under load are clearly measurable. This can be interpreted as a protective mechanism due to pain. Regarding these effects, a positive influence as a result of the orthosis is measurable. While walking with the appliance, patients are less careful when putting load on the affected leg; the corresponding characteristics of the arthrotic extremity are noticeably closer to those of the contralateral side. In addition to the knee relieving effect, the orthosis thus also contributes to a more harmonious and dynamic gait pattern.

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