Biomechanics Study

"VACOPED"

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August/September '94

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Content:

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Introduction

VACOPED serves as a replacement for a plaster cast, which is suitable for use in the initial post-operative treatment phase where the lower leg is to be fully immobilised, throughout the following stages of recovery and even as an ankle joint orthosis.
Due to the modular construction and its ability to be adapted to each individual patient, VACOPED can be used in the treatment of various injuries or illnesses in the lower part of the lower leg, the ankle joint and the foot. During the immobilisation period at the start of treatment, VACOPED serves as a lying cast (half mould) as well as a walking cast replacement. In the further course of healing, a guided plantar/dorsal flexion can be permitted to a limited extent. In the final phase of treatment or in the case of other indications, VACOPED can be used as an orthosis for ankle joints. VACOPED is therefore adapted to the relevant stage of treatment and does not need to be replaced by another aid when transitioning to another phase of treatment.

The primary requirements of the cast replacement are the rigid fixation of the lower leg, as complete a suppression of supination/pronation movements in the ankle joint as possible, and the complete suppression of dorsal/plantar flexion movements of the ankle joint in the immobilisation phase as well.
The natural rolling movement when walking should also be impeded as little as possible. Traditional lower leg plaster casts frequently lead to a highly unnatural gait, with the patient no longer trying to roll over the sole, but rather rotating the entire leg in the hip joint with every step.

The study investigates to which extent VACOPED allows movement of the ankle joint when used as an alternative to a cast. The supination/pronation and extension/flexion angle of the ankle joint was measured. The measurement sensors were applied directly to the skin of the test subjects, with the ankle being measured within the cast.

The measurements were carried out on ten healthy test subjects.

In one investigation, these parameters were also measured using a traditional cast for the purpose of comparison.

Definitions:

The definitions of ankle joint axes and the designations of the different rotations the study is based on are in accordance with the conventions of B. M. Nigg (cf. Fig. 1). Other authors oft choose their own deviating or contrary definitions (e.g. H. U. Debrunner).

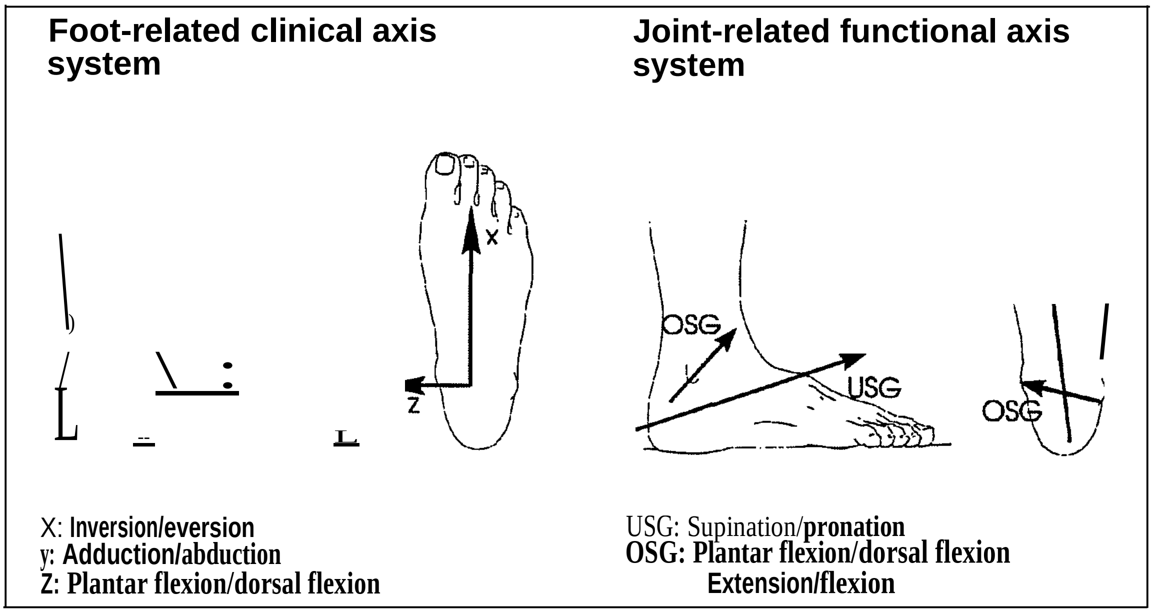

Fig. 1, definition of the axis systems and rotations in the ankle joint

Upper ankle joint (UAJ) = talocrural joint,

Lower ankle joint (LAJ) = talocalcaneal joint

Pronation/supination = An outwards rotation of the foot around the axis of the LAJ

Eversion/inversion = An outwards rotation of the foot around its longitudinal axis

Extension/flexion = Up and down movement of the foot around the LAJ axis

The terms plantar flexion/dorsal flexion are not differentiated between for each axis system to the same extent as movements that concern the lower ankle joint (LAJ). The study primarily simply talks about extension/flexion movements, which means the up/down movement of the foot around the axis of rotation of the upper ankle joint (OSG).

Test Structure

1. The structure of the VACOPED - Cast Replacement

VACOPED is made of a modular, plastic hard frame, which has a lattice-like construction to reduce weight, and an interior section adapted to the foot of the patient. The hard frame primarily consists of a basic element, which comprises the lower leg and the heel/foot area from behind or below. A cover element is pressed onto this base element by four belt straps, and thereby completes the shell as a stable tube. The inside is an air-extractable plastic cushion with a hard foam ball filling. When putting on the VACOPED, this cushion must first be aerated and therefore flexible. The plastic ball filling of the cushion can be distributed evenly within the subchambers. When sealing the hard frame, the vacuum cushions adapt to the shape of the individual leg. Particularly exposed areas, such as the ankle, can be impressed into the cushions by moving and redistributing the padding material accordingly. This prevents local pressure points from developing. The user can also pay attention to particularly pressure-sensitive areas of the foot, such as surgical wounds, by redistributing the cushion's filling prior to application accordingly. After shaping the vacuum cushion to the leg and closing the hard frame, the air is pumped out of the vacuum cushion. The cushion is therefore durably stabilised and hardened in this adjusted form.

The cast replacement is normally adjusted by the clinical staff or orthopaedists, or later by the patient him/herself.

When using the VACOPED as an ankle joint orthosis, a dorsal/plantar flexion between 80° flexion and 100° extension of the ankle joint can be permitted. The axis of rotation is horizontal, roughly at the axis of the upper ankle joint. A further increase in mobility in plantar/dorsal flexion to between 80° and 120° is possible if VACOPED is used without heel adapters. In this position, the VACOPED serves as protection against inadvertent lateral folding and further damage to ligaments that have not yet been restored to full functionality in the final phase of reconvalescence following ankle joint or tendon injuries. The cushion is not removed when using the VACOPED as an orthosis.

Due to their adaptability, the VACOPED is only delivered in two sizes by the manufacturer - one smaller one for shoe sizes up to around 42 and the larger size from shoe size 39 (also depending on foot shape and length, calf size etc.). No differentiation is made between the left and right cast. An copy of the larger edition of the study is available. In general, all measurements will be carried out on the right leg, including measurements in the cast and barefoot.

2. Parameters to be analysed, measurement devices

In this study, the sufficient stabilisation of the lower leg in the ankle joint area should be demonstrated, in order to be able to verify the suitability of the VACOPED as a cast replacement.

The supination/pronation and extension/flexion angle of the ankle joint was measured in various test situations, primarily during normal walking.

The standard method to measure movement of the foot is film or video analysis. Markers are stuck to points of the body and their coordinates are measured from the film or video images in order to be able to track them in the room. Three-dimensional coordinates are taken from synchronised recordings from different directions.
Direct measurements of the movement of the foot using electrogoniometers are used rarely, as it is difficult to attach the goniometer and may impede the process of movement. In this study to analyse foot movement in VACOPED, optical systems were not able to be used continuously. For this reason, two goniometers were used to measure angle changes in the ankle joint based on the DMS measurement principle. For checking purposes, recordings are also made using a video movement analysis system in barefoot measurements of the extension/flexion angle. The goniometers and markings for video analysis were therefore attached direction to the skin of the test subject. Fig. 2 shows its position on the right leg of the test subject.

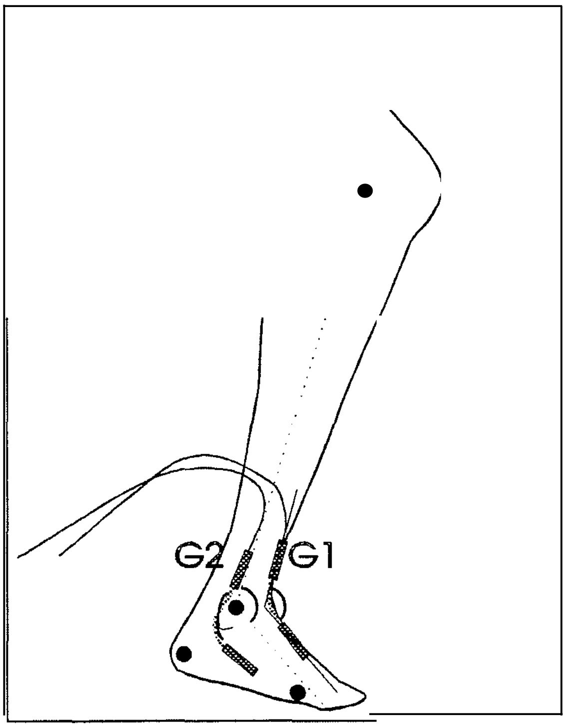

Fig. 2, Sensors or markings for angle measurement

Both goniometers are dual-axis goniometers, in which only the movement at one of the two levels is measured in the tests, however. Goniometer G1 measures the extension/flexion angle of the ankle joint between the front of the shin and the instep of the foot, with G2 measuring the supination/pronation angle on the outer side of the foot between the calf and the midfoot area. Markers made from retroreflecting material are attached to the knee, ankle and ball of the foot for the video movement analysis of the extension/flexion angle when walking barefoot.

Considerations when Measuring the Pronation/Supination Angle

The following images show the measurement values of the inversion/eversion or supination/pronation angle for various goniometer settings on the same test subject. In case (a), the goniometer is attached to the back of the foot along the Achilles tendon, in case (b) laterally along the Achilles tendon, in case (c) laterally on the foot with the goniometer case in a vertical position, with the strain gauge strips lying above the ankle. Figure (d) shows the only practical setting within the VACOPED.
In positions (a) and (b), the inversion/eversion movement of the foot is measured, i.e. the tilt of the foot around its longitudinal axis. This is the tilt movement exerted on the foot from outwards by the floor when walking. This position would be the usual one to adopt when investigating to which extent the VACOPED can resists external forces and movements that could lead to a lateral tilt. On the other hand, in position (c), and above all in position (d), the actual supination/pronation angle of the foot is measured, i.e. the tilt of the axis of the axis of the lower ankle joint according to the definition under Fig. 1. This axis moves from the front medial upwards through the instep, then backwards, obliquely laterally and downwards through the heel. Arbitrary tilting in the unburdened foot are made around this axis. According to Debrunner, it is tilted at around 42° upwards against the longitudinal axis and approx. 23° forwards and inwards, with in any case considerable, individual deviations from these average values. The movement of the ankle bone around the calcaneus is not a simply rotation. At the same time, the ankle bone moves in the direction of the axis of movement. Various further movements take place within the foot plate (the part of the foot skeleton lying below the ankle bone), i.e. in the crosswise tarsal joint: (Chopart’s joint).
It now depends on the position of the goniometers on the foot, which also include these many possible movements in the measurement result. In the attachment of the pronation/supination goniometer selected for this study, it is not only the rotation movement around the LAJ in a stricter sense that is measured, but other movements in the skeleton of the foot have a not inconsiderable influence on the measurement results.

As said earlier, the only practical attachment position within the VACOPED is position (d) in Fig. 3. This was also chosen for all measurements.

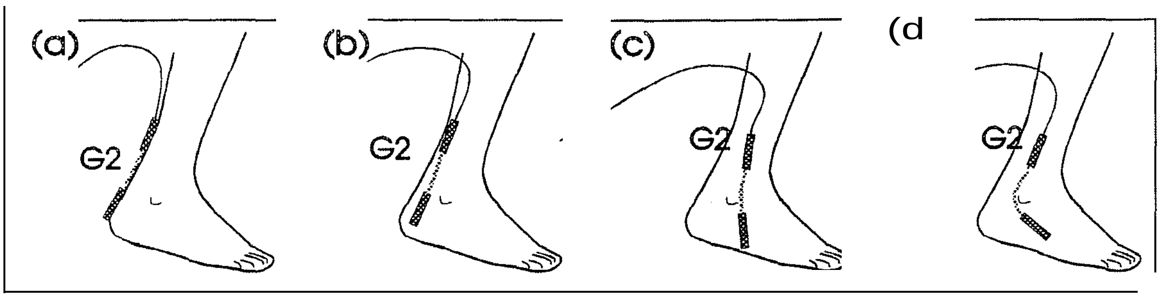

Fig. 3, Investigated goniometer position to measure the supination/pronation angle

In this selected position (d) of the pronation/supination goniometer, the largest measurement values for the angle were found (see Fig. 4: Each test subject walks for a minute, with each maximum in the curves representing one step). For the reliability of the measurement of the pronation/supination angle, see also the chapter “Sources of error in measuring angles” from page 10.

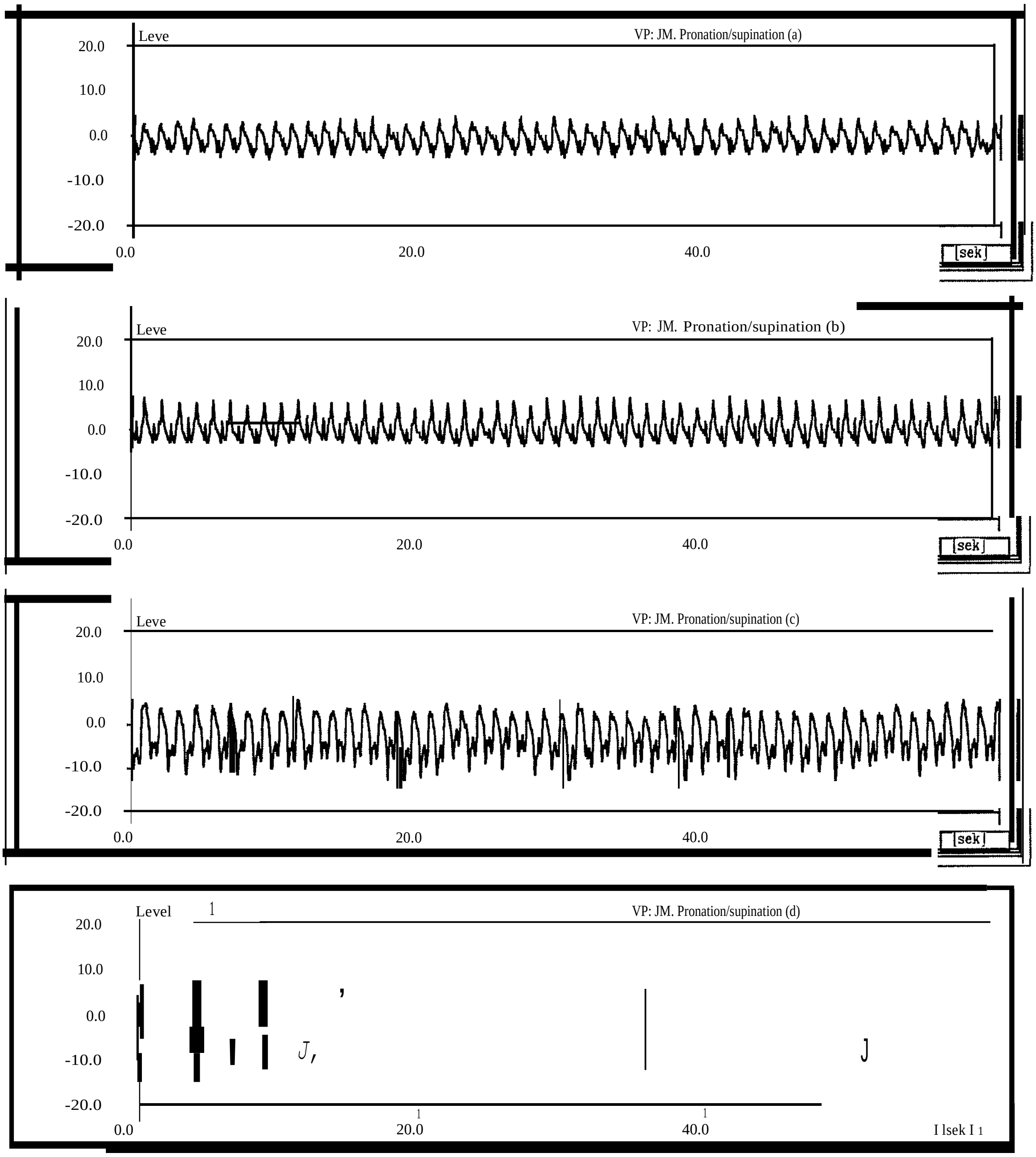

Fig. 4, Measuring the supination/pronation angle in various goniometer positions

The goniometer also displays a certain cross-talk of the angular movement from one level to another level, as well as in torsions. A comparison of measurement results between different test situations is also possible without huge limitations.

Description of the Angle Curves Measured

In most tests, the test subject walked for two minutes at a very even speed on the treadmill. Approx. 100 steps are taken over this period. The measurement curves of the angles vary somewhat from step to step, but always have the same structure. The phases of a step are marked on the angle curves in Fig. 5.

The phase from putting down the heel to lifting the toes, i.e. the phase in which the foot has contact with the floor, is generally referred to as the stance phase, with the phase in which the foot does not have contact with the floor being known as the swing phase. In a normal walking cycle, the stance phase takes up approx. 60% to 64% of the total step duration. In the example presented, the standing phase took up 62%.

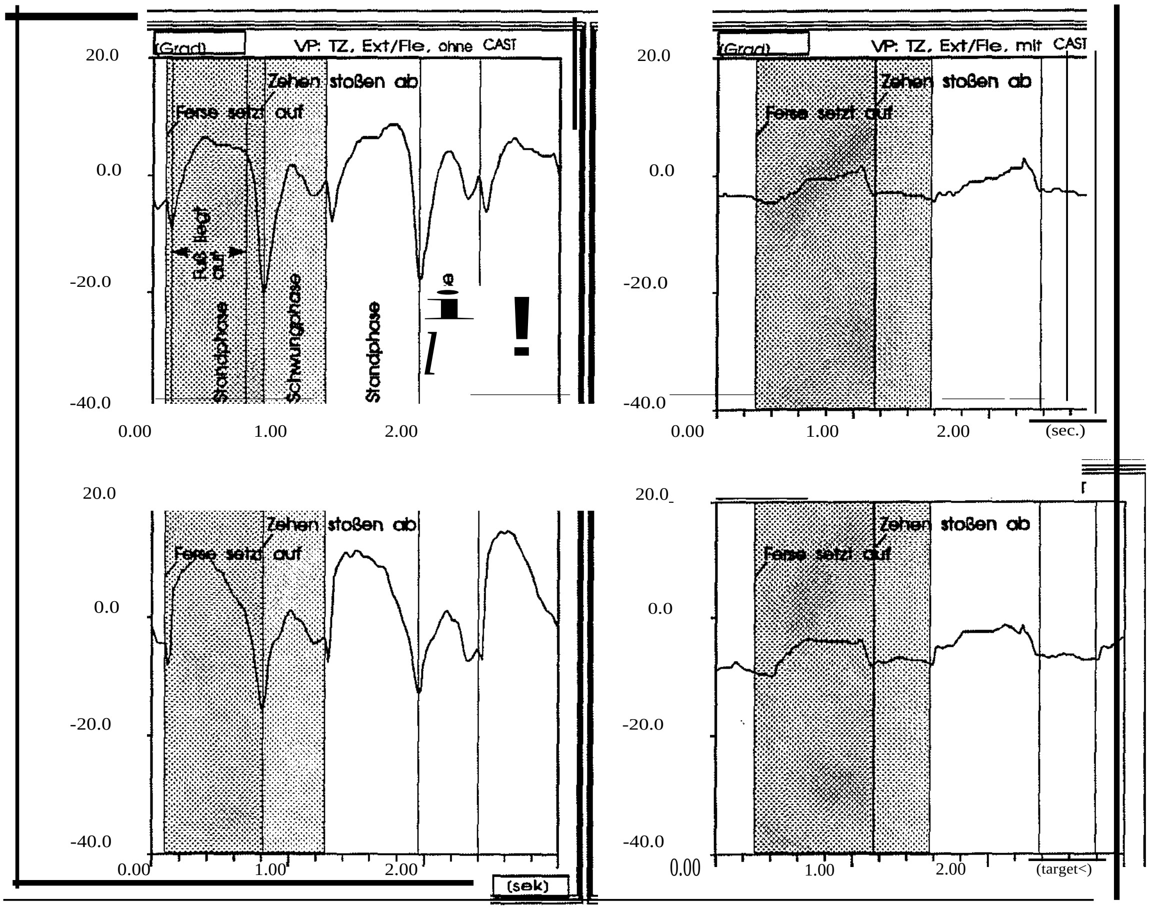

Fig. 5, Extension/flexion angle during a step (above), pronation/supination angle (below). On the right, the angle when wearing the VACOPED

In this study, individual step analyses were not made, but the frequency distribution and range of angle distribution is determined over many steps (approx. 100) and compared. Fig. 6 depicts an example of such an angle frequency distribution. The maximum spread is regarded as the spread of this distribution (excluding individual outliers), as even the most extreme angle values are particularly undesirable and must be prevent by the splint.

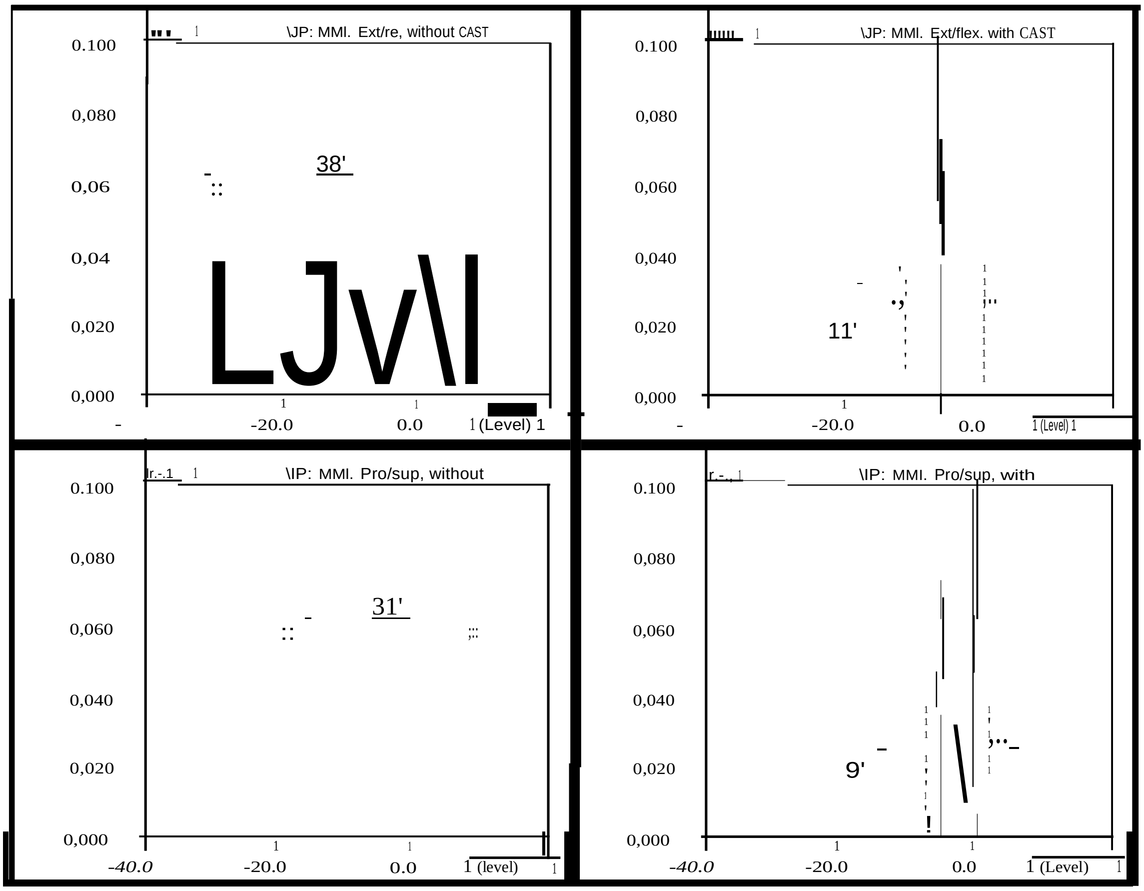

Fig. 6, frequency distribution of the extension/flexion angle (above) and pronation
Supination angle (below) summed up over approx. 100 steps and then standardised. On the right, the distributions when wearing the VACOPED

The angle is measured approx. 250 times per second. This amounts to 30,000 times over a measurement period of two minutes. The measurement range of the angle (-50° to +50°, and -60° to +90°) is divided into 256 sections. Each individual measurement value increases the counter in the assigned angle range. At the end, the frequency distribution achieved is standardised to 1. A joint that does not move at all would only increase the counter in one section; this would have a frequency of p = 1, with all others having a frequency of 0. The broader and flatter the distribution, the more and more sweeping movements the joint has made.

Potential sources of error in measuring angles:

1. The extension/flexion angle is measured using a goniometer between the front of the lower leg and the midfoot (instep). The parts of the casing must be attached far forward enough on the instep before exercising the foot flexor tendon (tendo musculus tibialis anterior) and the ligament (retinaculum musculi extensorum inferius), so that the toe flexor tendons (tendines musculus extensori digitorum longi) bind to the instep area, and/or far enough above the edge of the shin so that no significant raising of the tendo musculus tibialis anterior is discernible. By tensing the foot flexor muscles and the tendons, the goniometer would usually move slightly and a false angular increase would be measured in the ankle joint.

For the test, some test subjects should tense the musculus tibialis anterior while standing without changing the position of the joint. Fig. 7 depicts such a measurement.

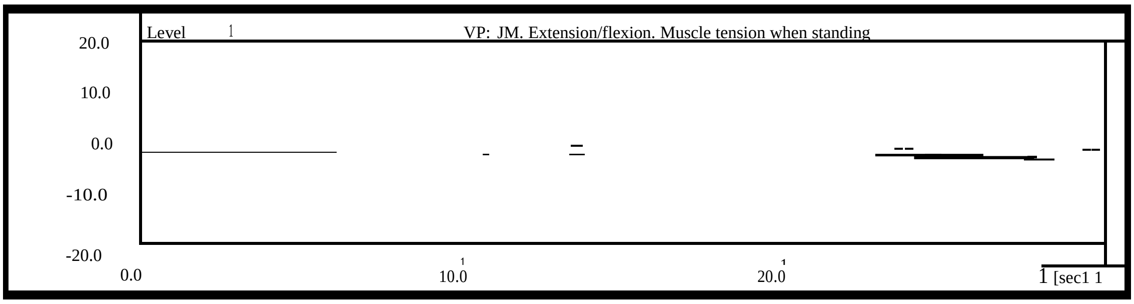

Fig. 7, influence of repeated muscle tension on the measurement of the extension angle

The test subject tensed and released the muscles in the leg repeatedly for 30 seconds while standing upright and barefoot. Except for the gradual reduction in the extension angle over the total duration by the test subject slightly leaning forwards slowly, almost no indication of muscle tension was recognised in the measurement data. The errors in measurement caused by the influence of the foot flexor tendons lie within ±0.5°.

2. The pronation/supination angle is measured between the lower leg and the outside of the foot. With the exception of the problems regarding attaching the goniometer to measure the angle that have already been mentioned, even more influences or sources of error are conceivable in measurements: When the foot treads on the floor, the tissue of the sole of the foot is vertically compressed and laterally pushed apart. As the angle is measured on the outer side on the foot, there may be a supposed pronation angle when the foot is put down. The lowering of the transversal arch of the foot when it is put on the floor creates the same effect. Fig. 8 displays the angle measurement of one test subject, who repeatedly places the foot on the ground and lifts it up again, where possible without allowing movement in the ankle joint.

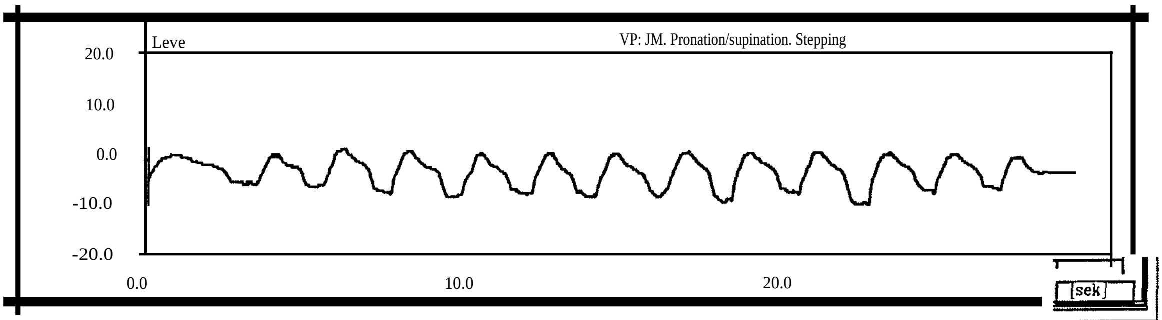

Fig. 8, Movements in the foot skeleton (pronation/supination) under multiple stepping with a rigid joint

The deflection of results on the goniometer and therefore the supposedly measured pronation angle is clearly not inconsiderable, in the example approx. ±4°. The same measurement was also carried out when wearing the VACOPED (see Fig. 9). The breadth of the angle curve is somewhat lower here, but still large, approx. ±3°. In all further measurements of the pronation/supination angle, it must always be noted that a certain amount of angle change is to be expected, without the actual lower ankle joint needing to have moved already. Each type of splinting to only immobilise the ankle joint will as a result not be able to reduce the measurement curves of the pronation/supination angle to 0°, but only to a minimum value - in this test subject, 6°.

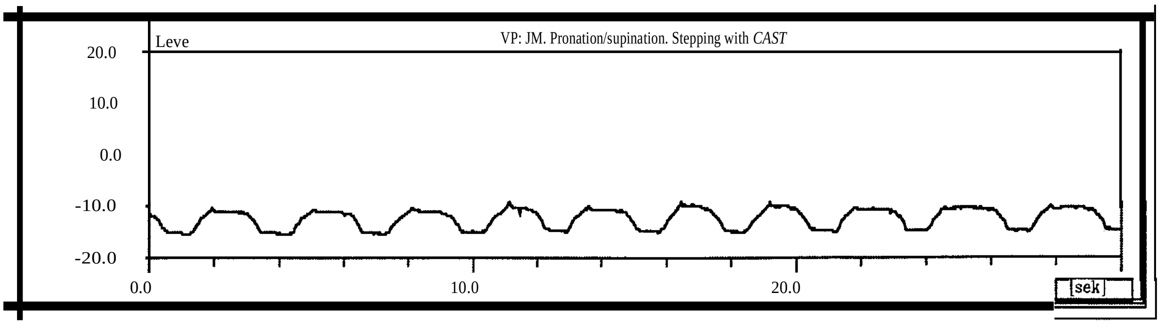

Fig. 9, Movements in the foot skeleton (pronation/supination) under multiple stepping with a rigid joint with VACOPED

For the treatment of injuries in the tarsal and in the forefoot area, it may be necessary, including in the case of mobilised ankle joint, to prevent any movements of the foot skeleton that could otherwise still occur. A step in this direction would be, for example, the use of an anatomically adapted foot pillow in the VACOPED.

The measurements of the pronation/supination angle specified in this study below are also to be differentiated in the analysis: non-critical when it comes to only fixing the ankle joint, but more critical when the entire skeleton of the foot has to be kept in place.

Comparison of the measurement results of both measurement systems

The extension/flexion angle was also recorded using the video movement analysis system for monitoring purposes. Figures 10 and 11 depict the goniometer and video analysis values measured at the same time. Markers were attached to the outside of the cast when measuring with VACOPED. Here, the video movement analysis did not measure the extension movement of the foot, but rather the casing of the VACOPED.

The extension/flexion angle values of both systems determined had highly similar structures (the other value range of the angle in video analysis data is system-based and of no further relevance. In the example depicted, all the measurement values deducted a constant offset of approx. 72°). The goniometer data was consistently approx. 20% larger than the video analysis data. This is presumably due to the amplification of the goniometer output being set too high. Repeated checks of the calibration did not display any errors, however. This is of no significance for the interpretation of measurement data, however, as all measurements were taken with the same amplification and calibration setting.

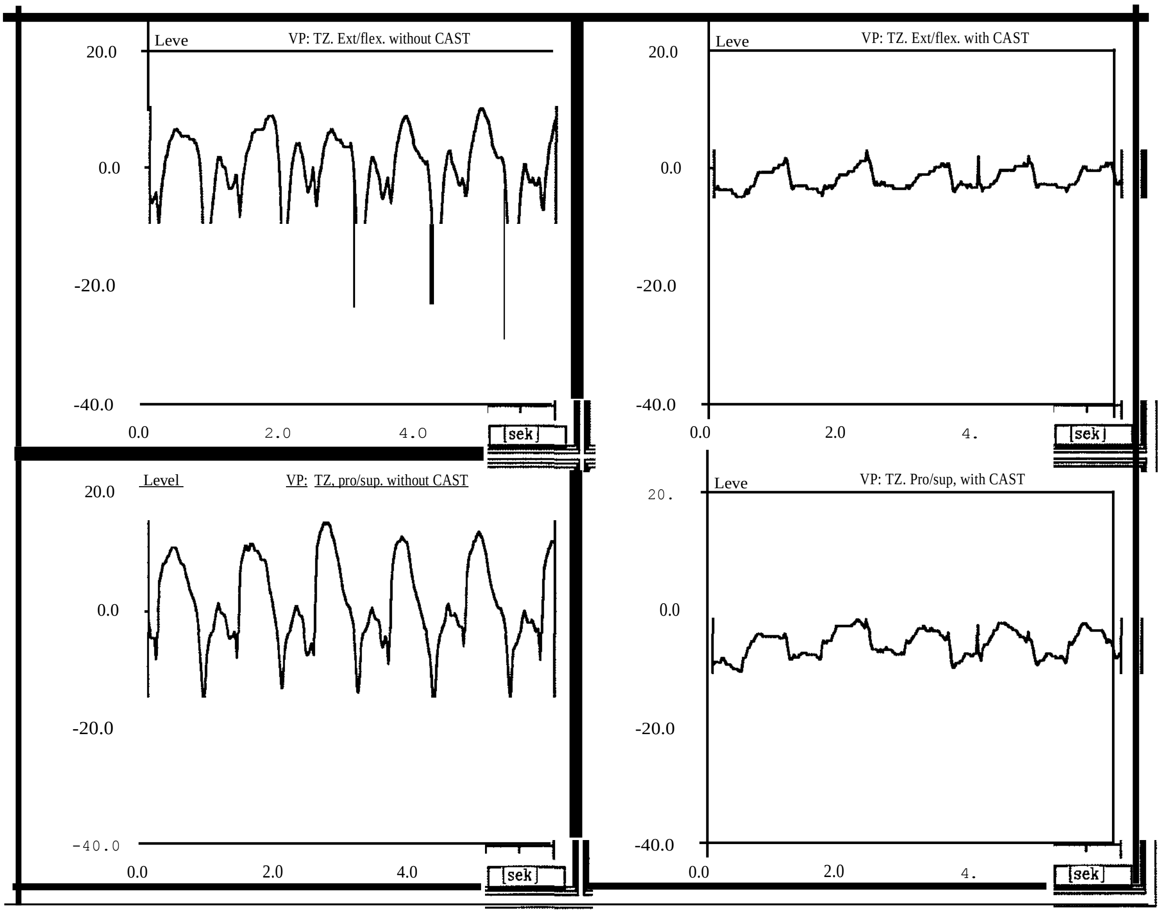

Fig. 10, ankle joint angle measured with goniometers

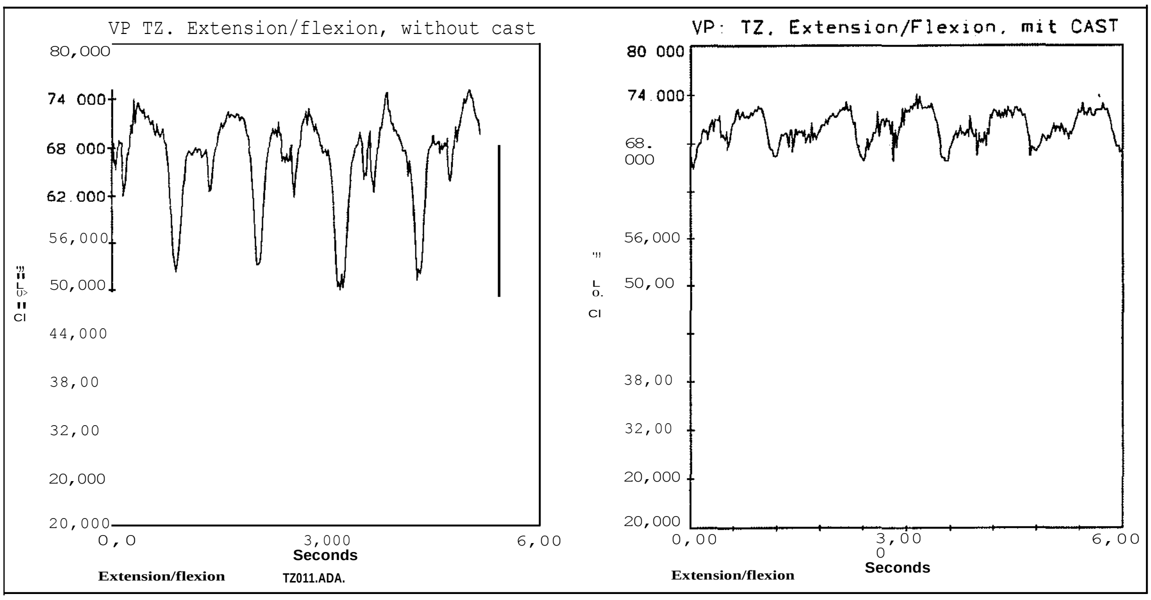

Fig. 11, ankle joint extension angle measured using video movement analysis system, recorded synchronously with the measurement in Fig. 10

Test Results

1. Tests of the reproducibility of the results under the repeated wearing of the VACOPED

On one test subject (MM), the measurements were carried out three times alternately. I.e. the pronation/supination angle and flexion/extension angle were first measured during barefoot walking. The VACOPED cast replacement was then adjusted and the corresponding measurement carried out. A further measurement was then carried out again on the bare foot. During this, the vacuum pads in the cast are aerated and shaken and then readjusted again for the next measurement. etc.

The three measurement curves of the barefoot measurements were highly consistent. The frequency distributions of the angle values measured were close to consistent in terms of the size of the maximum and minimum ankle joint angle, as well as in the structure of these distributions. There were some larger differences in the angular distributions measured in the VACOPED. It is also to be expected that, when putting on the splints, there were always certain differences in the padding and fixation of the leg. The width of the distribution of the angle does not change significantly - only by a small angle. The angle range covered was reduced to approx. 1/3 or even lower, from on average 37° extension/flexion to 10° or from 30° pronation/supination to approx. 10°. (The pronation/supination angle measured describes, as mentioned in the chapter “Considerations when Measuring the Pronation/Supination Angle”, not merely the movement of the foot around the lower ankle joint, but rather more generally as well the mobility in the foot skeleton)

Depictions of the measurement curves of these tests are attached to test subject MM.

2. Measurements on ten test subjects

First of all, the test subjects walked barefoot on the treadmill for two minutes. The speed of the spreadsheet was always the same for all test subjects and all tests, as well as being moderate, meaning that no problems arose during walking with VACOPED. During these two minutes, both ankle joint angles were continuously recorded via the goniometer. From this side, the extension/flexion angle is always filmed with a video camera for video movement analysis. The VACOPED was then adjusted to the test subject and the measurement was repeated. Depictions of all angle curves of the ten test subjects are attached. Table 1 below contains a summary of the spread of the angle distributions and their average values.

VP	Shoe size	Height	Weight	Age	*PIS* With	*PIS* with	%	E/F with	E/F wit	%
EB	43	185	80	30	22	12	55	39	8	21
FS	45	186	73	31	27	9	33	41	13	32
GS	42	181	70	30	25	12	48	43	7	16

VP	Shoe size	Height	Weight	Age	*PIS* With	*PIS* with	%	E/F with	E/F wit	%
JK	43	180	73	31	35	9	26	41	8	20
JM	42	178	77	36	34	13	38	34	10	29
MB	42	178	71	20	46	12	26	60	11	18
ML	44	191	84	24	29	11	38	44	8	18
MM	42	180	69	26	30	10	33	37	10	27
TZ	42	179	77	28	35	11	31	45	7	16
YJ	43	183	73	24	33	13	39	36	8	22
Av.					31.6	11.2	36.7	42.0	9.0	21.9
hrs					6.4	1.4	8.7	6.9	1.8	5.3

Table 1 *PIS* without: Pronation/supination barefoot
PIS with: Pronation/supination with VACOPED
E/F with: Extension/flexion barefoot
E/F with: Extension/flexion with VACOPED
%: reduced to xx%, from without to with

Although the body masses of the test persons only differed slightly, some of the differences in the parameters measured were not inconsiderable. The variability of the angle measured during barefoot walking differed greatly from person to person.

The most extreme deviations in results from the average values were found in some female test subjects (MB).

On average, the extension/flexion movement of the ankle joint in the VACOPED reduced to 10° (22%) of the average of the barefoot measurement. The reduction in the pronation/supination angle (and the movements in the skeleton of the foot) is less clearly marked, at 11° (37%) of the barefoot value. A certain balance display here is also to be expected without actual joint movement in the LAJ.

<u>3. Comparison measurements in plaster</u>

In on test person (JM), the angle measurements described were also carried out with a plaster cast in order to compare with the VACOPED. The conventional lower leg plaster was applied by a doctor from the Staatliche Orthopädische Klinik (state orthopaedic clinic) Munich. The design of the plaster cast corresponded to a conventional lower leg cast with traditional padding etc., as most commonly used in this clinic. The goniometer was taped to the skin with the greatest of care, as following plastering, it was of course no longer possible to make any corrections or repositioning.

The angle measurements of certain movement patterns is displayed below, which was carried out in the same way in the cast as in the VACOPED. Some subjective comments regarding the individual measurements should explain or complement the curves measured, but can of course also be based on misrepresentations in some cases.

1. Extension/flexion movements of the foot with an unburdened leg.
The intention was to determine the possible extension/flexion range of the foot in the plaster cast/VACOPED. Here, particular attention was paid to applying the same force for these movements in both cases. Thus, this resulted in a specific subjective moment in this test (and more or less in the following tests as well), which is very hard to avoid, unfortunately. The estimation of the force exerted by the test subject is naturally not entirely without its errors, as the feeling of skin contact in the plaster cast and in the VACOPED, as well as their resistance, differs somewhat.

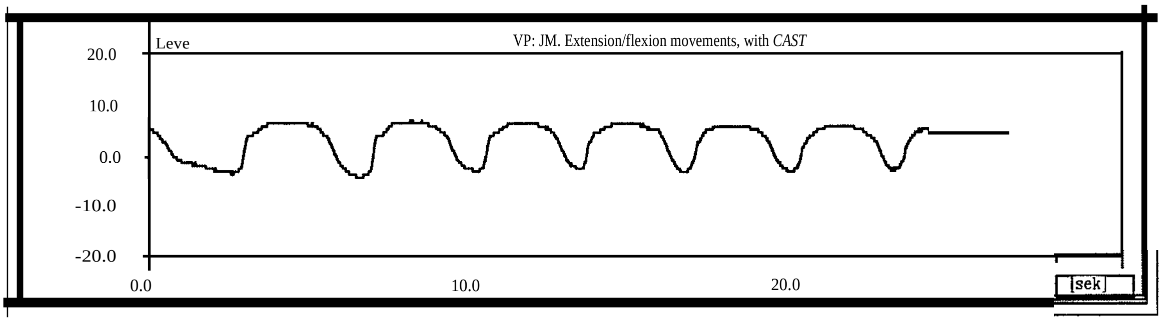

Fig. 12, extension movements with the unloaded foot in the VACOPED

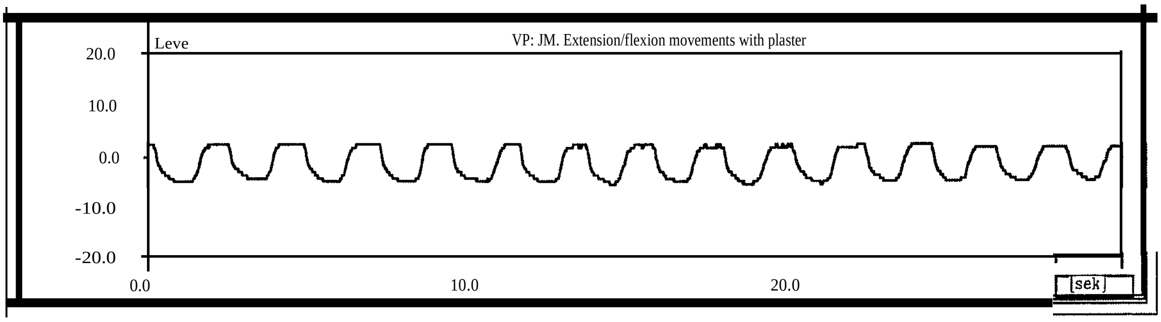

Fig. 13, extension movements with the unloaded foot in the plaster cast

The plaster cast allows a movement of a breadth of approx. 7°, and the VACOPED approx. 10°.
The padding in the plaster cast allows small movements of the foot relatively easily, but then the foot hits the hard plaster. With VACOPED, this feeling of impact is less pronounced.

2. Pronation/supination movements of the foot with an unburdened leg.
The determination of the possible pronation/supination range in the plaster cast/VACOPED was carried out in the same way as the previous test accordingly. In both cases, the test subject attempted to tilt the foot over the axis of the USG with the same force in both cases.

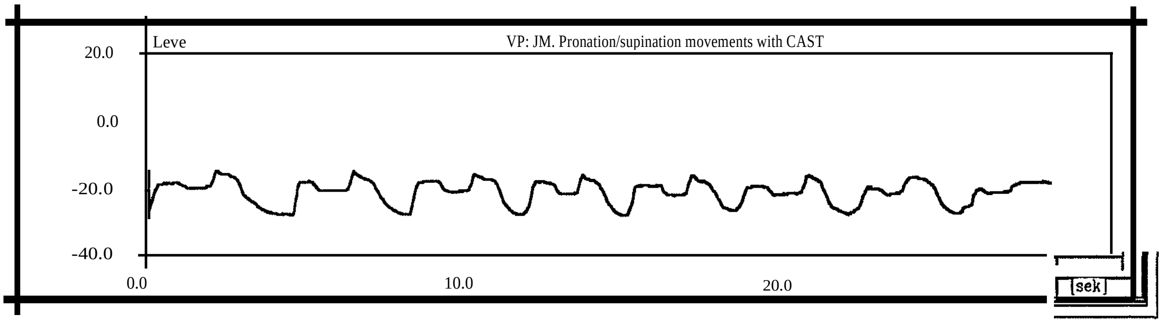

Fig. 14, pronation/supination movements with the unloaded foot in the VACOPED

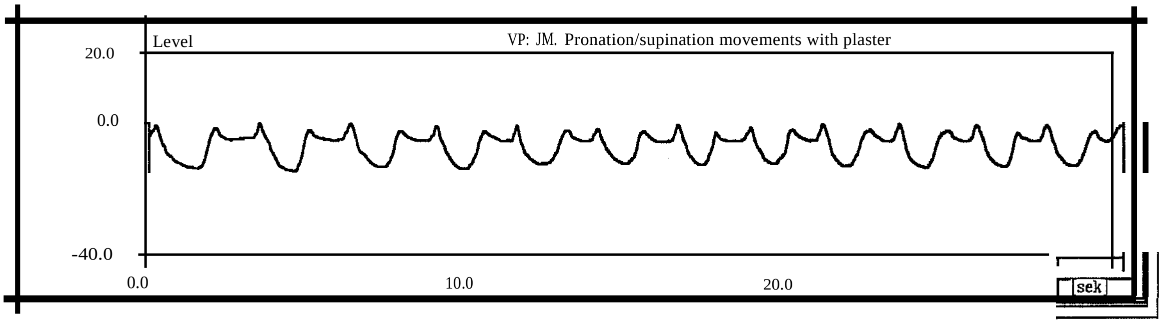

Fig. 15, pronation/supination movements with the unloaded foot in the plaster cast

The range of angles in movements is around 13° in both cases (with the limitations for the validity of this angle measurement as already mentioned). The structure of the curves measured repeated somewhat in both tests, with certain differences. In addition, many interesting deliberations would of course be possible, which should not be made here, however.

3. Use of plaster cast and VACOPED for normal activities: Climbing stairs. In comparison, both ankle joint angles were measured when walking over a specific course. The measurement curves are depicted in the following illustration. The upper curve was recorded in plaster cast, the middle one in VACOPED and the lower in a normal shoe without a supporting effect on the ankle joint. The effects of the various sections of the course on movement were more distinctly visible on the lower measurement curve: First was approx. 10m of walking on an even surface (t = 13 seconds to t = 24 seconds). The disturbances in the periodic sequence arose in two curves in this section and when opening a door. There is one step down between t=25 seconds and t=37 seconds. In this phase, the extension angle unsurprisingly displayed the largest range. After turning around between t = 37 seconds and t = 42 seconds, the stairs are then ascended again until t = 56 seconds. This is followed by a phase of horizontal walking. The same course was taken in the VACOPED and in the plaster cast. The ‘walking forwards’, ‘downstairs’, ‘upstairs’ etc. were less discernible from each other, however.
They did not take place at precisely the same times as when walking in normal shoes, however, as the speed could of course not be replicated precisely.
In comparison to this range of angle movements in the ankle joint when walking in shoes, movement in the plaster cast and in the VACOPED is reduced drastically. In this trial, the VACOPED performed considerably better than the cast in terms of stability. A reason for this is of course the assistive sole of the VACOPED, which enables comparatively natural rolling.

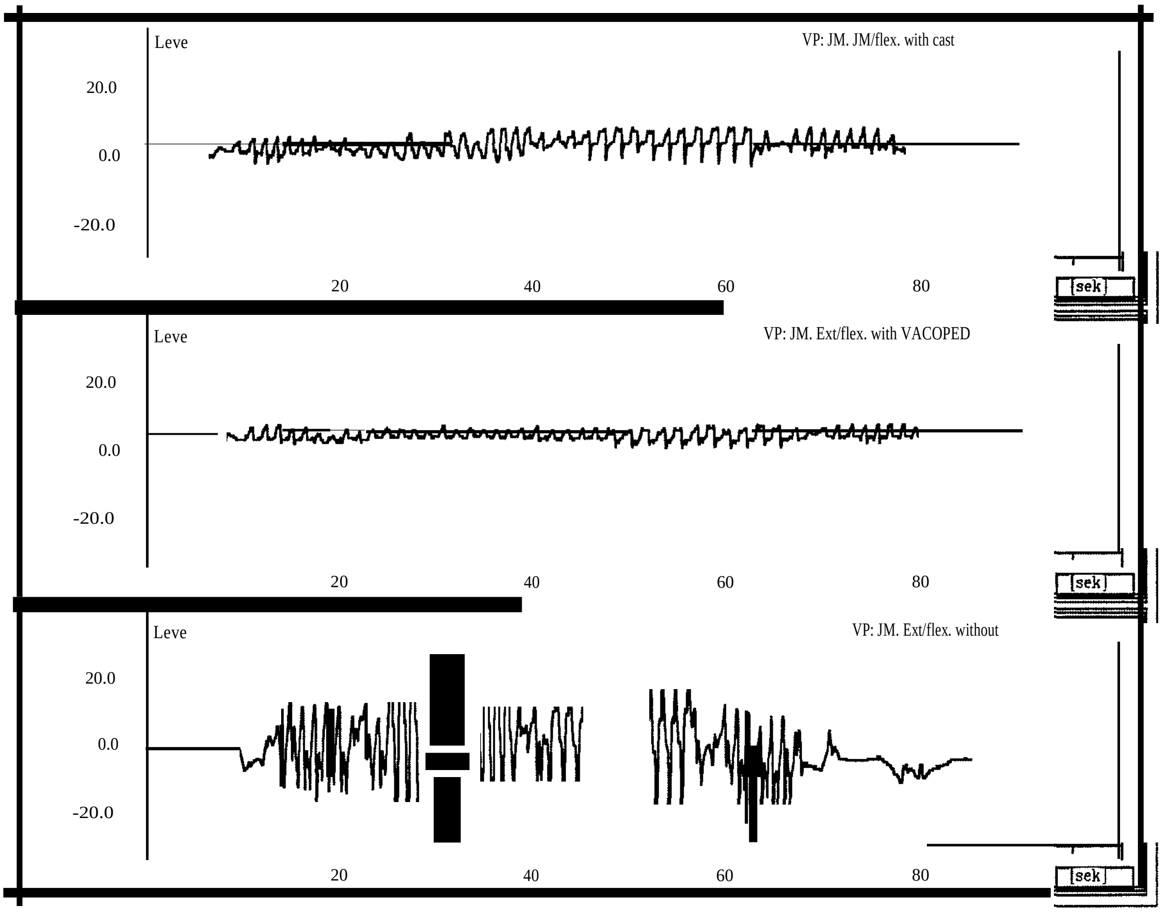

Fig. 16, Extension/flexion angles when climbing stairs, with plaster cast, with VACOPED, in shoe. In the final measurement in particular, a clear differentiation must be made within four phases: 1. Walking on a flat surface,
2. Descending stairs, 3. Ascending stairs, 4. Walking on a flat surface as in 1.

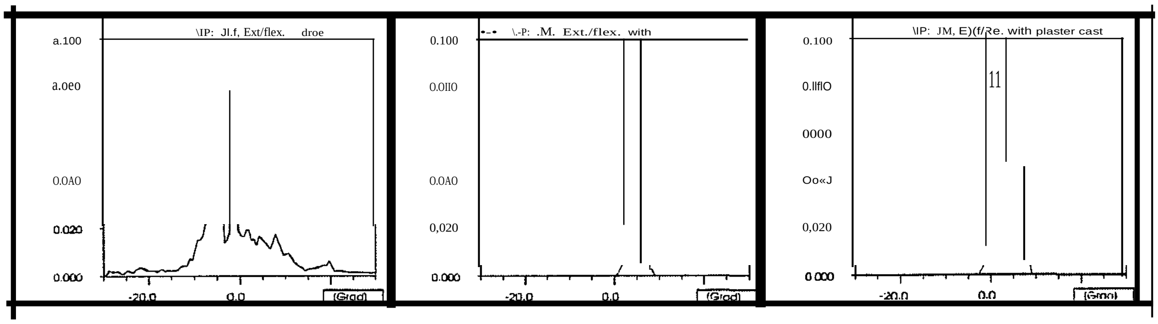

Fig. 17, The frequency distribution of extension/flexion angles when climbing stairs, with plaster cast, with VACOPED, in shoe from the previous image.

The breadth of the angle distribution reduces from approx. 60° in the shoe to approx. 10° in the plaster cast and to even 7° to 8° in the VACOPED.

The curves of the measured pronation/supination angle in Figure 18 below are to be interpreted with the necessary level of care. The spread of the angle distribution is lower with the VACOPED than with the plaster cast. The angle values measured are clearly primarily flattening effects of the foot when stepping and only to a lower extent actual pronation/supination movements in the ankle joint.

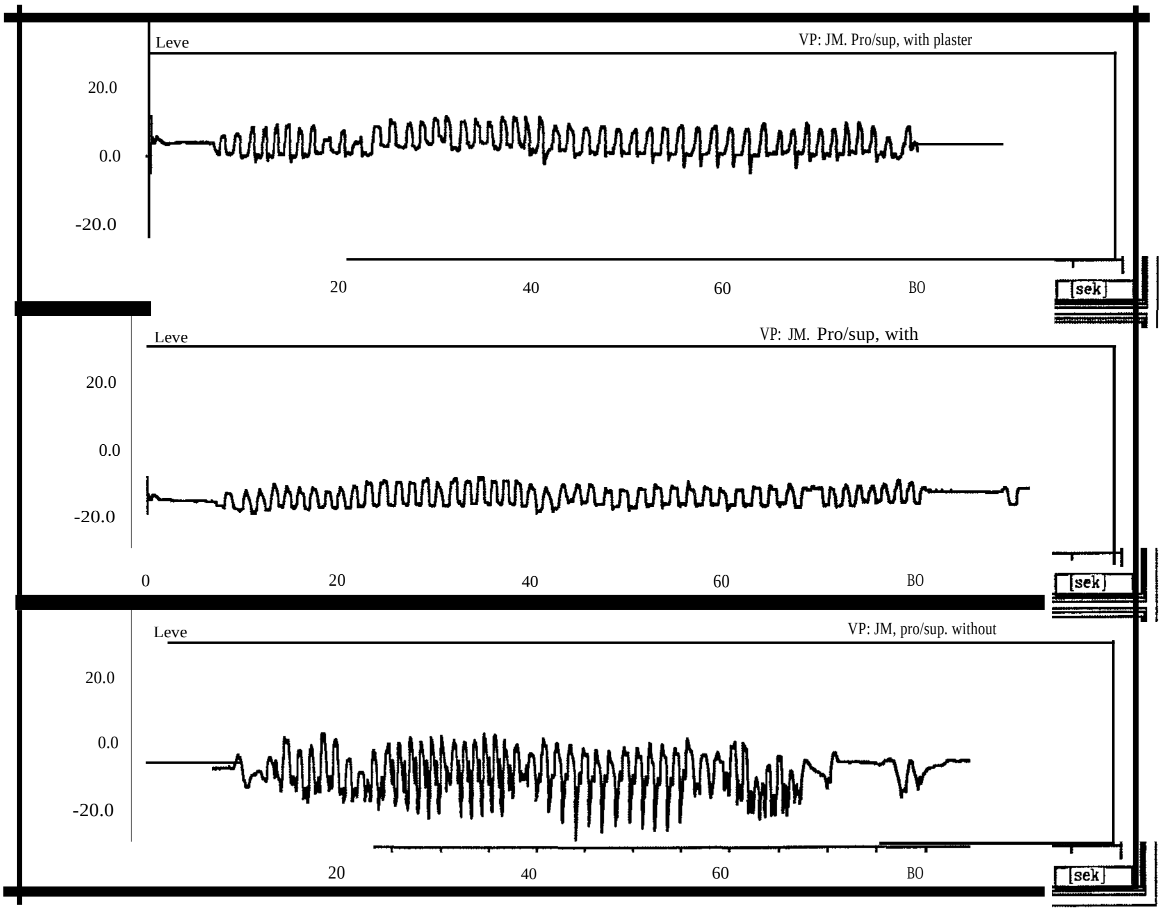

Fig. 18, pronation/supination angle (movements in the bones of the foot) when climbing stairs, with plaster cast, with VACOPED, in shoe, at the same time as measurements displayed in the previous image.

3. Walking on the treadmill

For a direct comparison between movement with plaster cast and with VACOPED, the treadmill test was also carried out with the plaster cast. In Fig. 19, the measurement results in the plaster cast are compared with those in VACOPED. This also shows the slightly better stabilising effect of the VACOPED. A reason for this is surely the walking aid sole of the VACOPED, as already mentioned, with enables significantly more normal walking than the plaster cast.

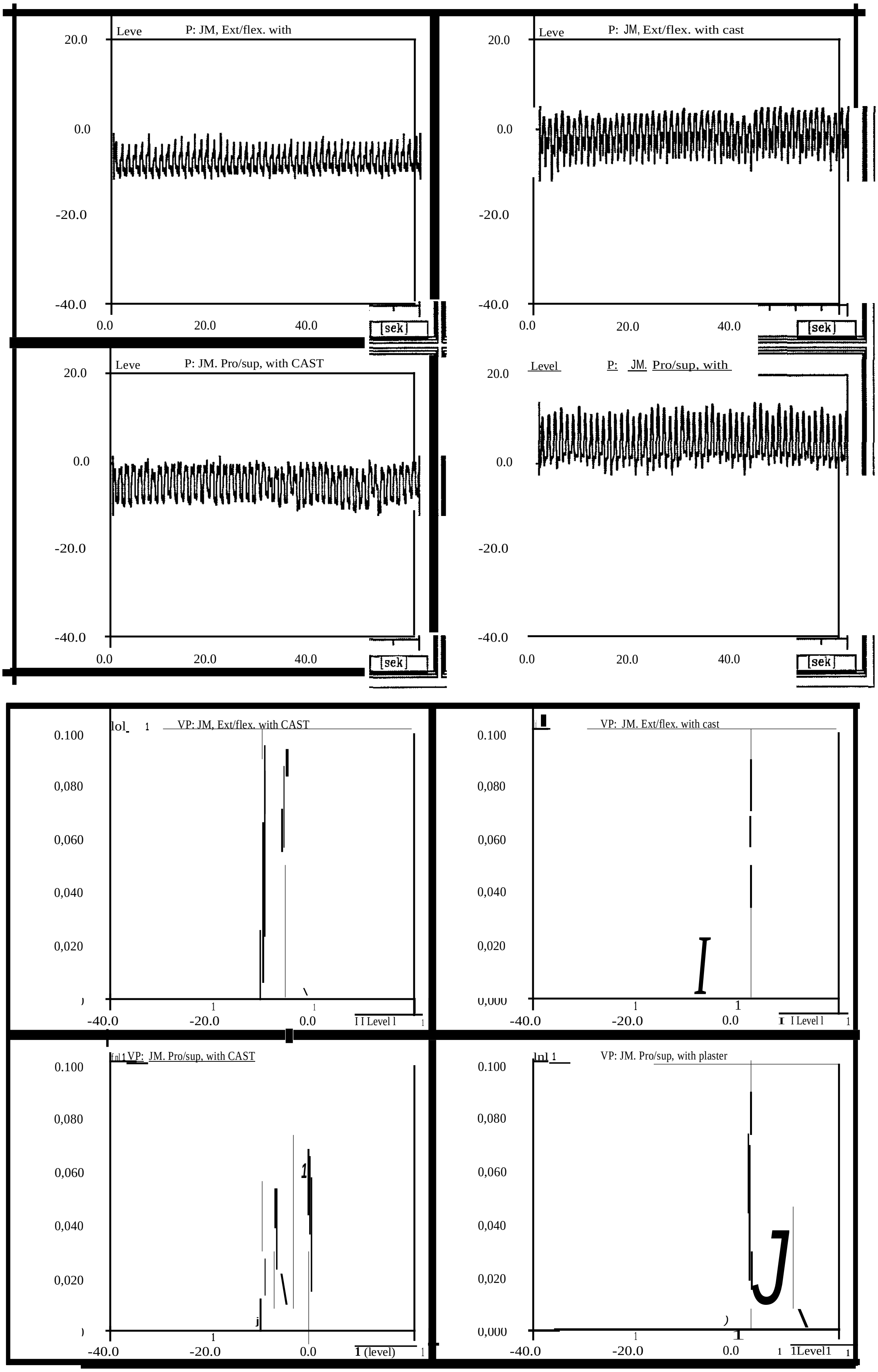

Fig. 19, Comparative measurement in VACOPED, plaster case while walking on the treadmill

Summary

Vacoped is: designed for quite distinct applications. The modular construction should enable the thorough treatment of a patient from the postoperative phase with complete immobilisation of the lower leg until the rehabilitation phase, in which the cast serves as an ankle joint orthosis.

In the study, the restriction in movement of the ankle joint was measured when using the VACOPED as a cast replacement.

When waking on the treadmill, the flexion/extension movement of the ankle joint was limited to 9° ±2° by the cast in ten test subjects. On average, there was a reduction to approx. 22% of movement amplitude compared to barefoot walking.
The pronation angle was reduced on average to 11° ±1°. In this case, it must also be considered, however, that for measurement reasons, an angle of at least 6° must also be assumed without any actual movement of the lower ankle joint. Based on the methods of angle recording, other movements in the foot skeleton must also be included in the measurements. Certain false measurements are also possible due to the movement of the foot sole tissue.

The majority of test subjects expressed the subjective finding that the VACOPED allowed greater freedom of movement in comparison to the plaster cast. This impression may simply be caused due to the fact that the cast fits well. A lower sensation of pressure or pain allows for greater freedom of movement.

In general, the wearing comfort was assessed as very good by the test subjects.

In one test on only one test subject, a direct comparison was drawn between the VACOPED and a conventional cast. In random movements of the foot without external pressure, the plaster cast displayed a stronger mobilisation of the ankle joint. VACOPED performed somewhat better in all walking attempts in comparison.

Outlook

The majority of investigations carried out were pure laboratory tests on a treadmill. The idea behind this was for the investigations to have clear and reproducible conditions, in order for the results to be able to be compared and easily summarised in the form of statistics. To conclude, an attempt to make a direct comparison with a conventional cast was carried out. Somewhat unexpectedly, it transpired that the differences were easy to present in measurements. In making a direct comparison between casts and VACOPED, it is advisable to carry out some equivalent comparative measurements in the plaster cast.

Other comments

The manufacturer tried to construct VACOPED for as large a scope of application, while at the same time also designing the adjustment to be as simple as possible. VACOPED is therefore only produced in two sizes, with no difference made between the left and right casts. It can also be used as post-operative patient treatment. In this phase of treatment, the ankle area is often swollen and sensitive to pressure. The measurements here were designed generously, accordingly. In persons without swelling in the ankle joint area, this space is sometimes too big. Almost all (healthy) test subjects felt that VACOPED allowed too much freedom of movement in the ankle joint and heel area.

One of the two joint rivets dislocated in the majority of tests. The construction needs to be reconsidered, here.

When extracting air from the vacuum cushions, it was apparent that the cushions appeared to harden again after some time (two hours). The explanation for this was the gradual absorption of air or the swelling of the padding material. In the case of padding made of plastic foam balls, this would be entirely possible if the foam bubbles stick to each other and to the outside through microholes. Conversely, this would also mean that the padding material would gradually expel air when air is extracted from the cushions, and the cushions would soften again somewhat. After a determined period of time following the adjustment of the VACOPED, it should then be drained again.

. The broad sole creates a lateral movement on the knee.

When using the VACOPED as an ankle joint orthosis, a dorsal/plantar flexion between 85° flexion and 105° extension of the ankle joint can be permitted: The axis of rotation is horizontal here, whereas the axis of the upper ankle joint ascends medially.

· The pronation/supination angles measured are, as mentioned earlier, not always angular movements of the ankle joint, but rather may also be caused by the flattening of the foot arch when walking. Depending on the type of foot or lower leg injury or illness to be treated, this flexibility can be permitted without reservations or reduced using suitable foot padding.