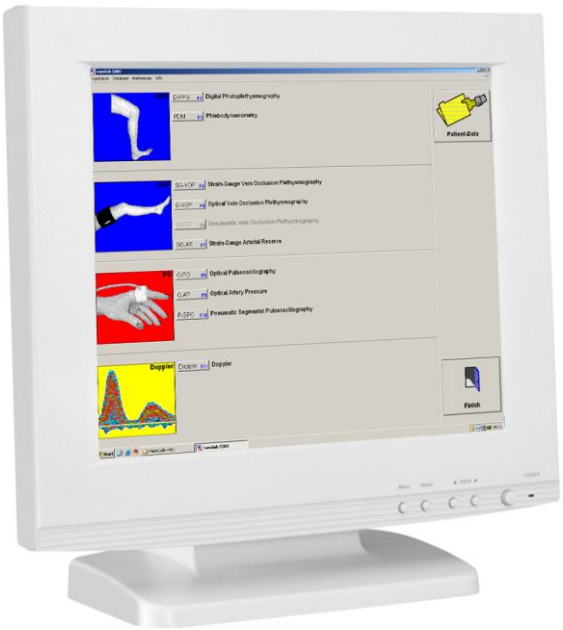
Plethysmographic Applications



ELCAT GmbH

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Plethysmographic Applications

Plethysmographic Applications **1.0**

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1 O-PO Optical Pulse Oscillography

1.1 Preparing Examination

Examination room

An O-PO examination should take place in a room having normal room temperature (approx. 20 °C / 68 °F).

Preparing patient

- Prior to examination, patient should stay in a room having normal room temperature for 15 minutes or longer.

  Cold extremities will distort measuring result

Note

- Warm up fingers or toes in warm water if necessary; skin temperature should be 37 °C / 99 °F.
- Introducing patient to measuring process

  Inform patient to keep on being relaxed during measurement and refrain from moving the fingers (toes) too.

Note

Positioning patient

- The patient is put in a flat position and the head should be supported by a headrest if necessary.
- The acra to be measured should be put very steady and positioned at heart level. Place feet or hands on soft pillow for steady and stable position.
- Ideally place O-PO sensors on finger tips or toe tips (outer acral member). Select skin area as healthy as can be.
- Fix O-PO sensors with rings gluing on both sides or with a sensor clamp but not “Hansaplast®” (band aid) or similar.

Note

Note sensor colours

- **Red** sensor = **right**
- **Blue** sensor = **left**

Positioning sensor and supporting extremity

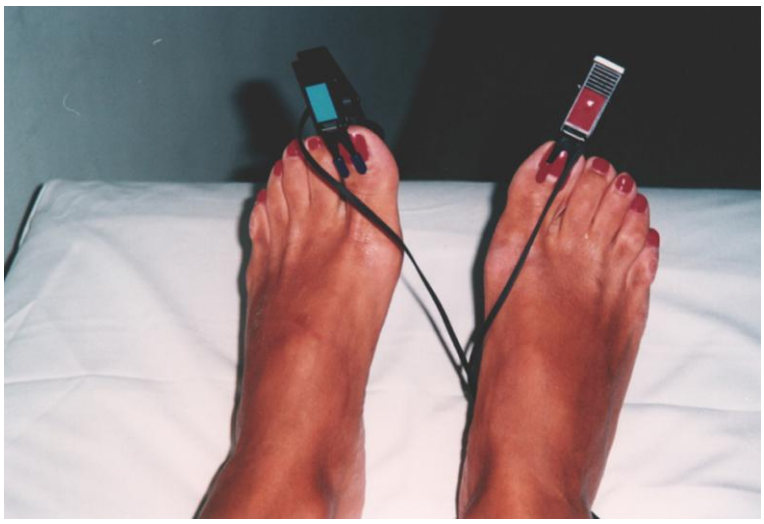

Fig. 1.1.1: Acral pulse measurement with optical sensors

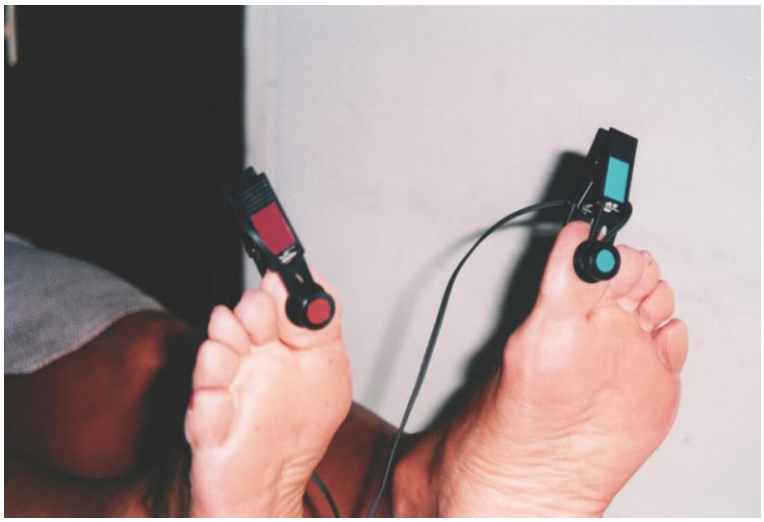

Fig. 1.1.2: Acral pulse measurement with optical sensors

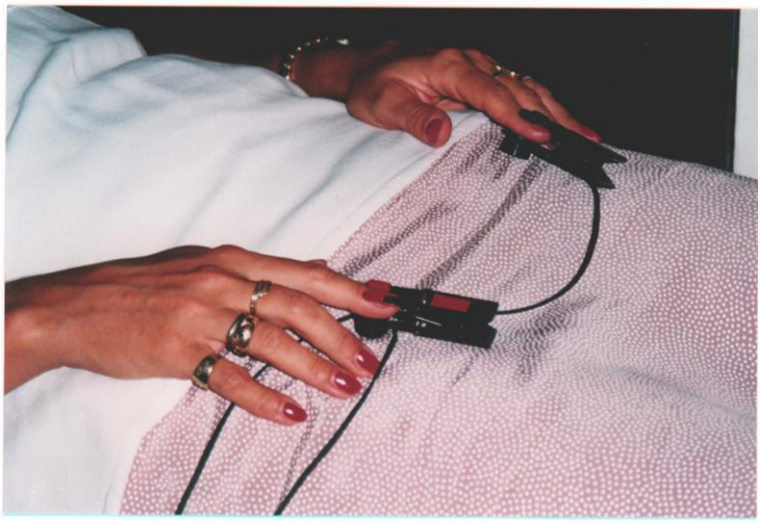

Fig. 1.1.3: Acral pulse measurement with optical sensors

1.2 General Medical Notes

General

Optical pulse oscillography O-PO (or electronically oscillography) is well suitable for acquisition of acral circular disorders. It also allows statements on patency of major arteries lending itself to screening method owing to simple and fast practicability.

Evaluating acral occlusions, you need to carry out O-PO under optimum rest conditions and room temperatures; else disturbing functional influences of circulation cannot be excluded.

Sensitivity of optical pulse oscillography O-PO is essentially higher than pneumatic segmental pulse oscillography P-SPO (pressure cuff is sensor in this case).

Also small acra blood volume deviations are well acquired.

You should principally examine each patient's acra by side-by-side comparison.

- The sensing points must be symmetric for that purpose.

Differentiating circulatory disorders

If there are unclear results, you should perform vasodilatory measures (e.g. application of heat or use of nitro spray) for better differentiation between function and organic acral circulatory disorders.

Pulse curve form analysis as well as calculation of its time values is possible.

Never submit an APO result without clinical results.

1.3 Notes on Measuring Results

General

A normal oscillogram would show an abruptly rising anacrotic and gradually falling off katacrotic leg with incisure and dicrotic wave.

- **Literature reference**

- **Rudofsky, G.**, *Kompaktwissen Angiologie,* perimed Fachbuch-Verlagsgesellschaft, Erlangen (1988)
- **Kappert, A.,** *Lehrbuch und Atlas der Angiologie,* Hans Huber, Bern Stuttgart Toronto (1989)
- **Gerok, W., Hartmann, F., Schuster, H.-P., Alexander, K.,** *Gefäßkrankheiten* (Ed. Alexander, K.) Urban & Schwarzenberg, München (1994)

Application fields

- Screening for acquisition of arterial occlusion processes
- Pulse wave analysis with information on differentiation
- Definition of functional against organic genesis
- Acquisition of haemodynamically effective stenoses (stress)

Results of pulse measurement

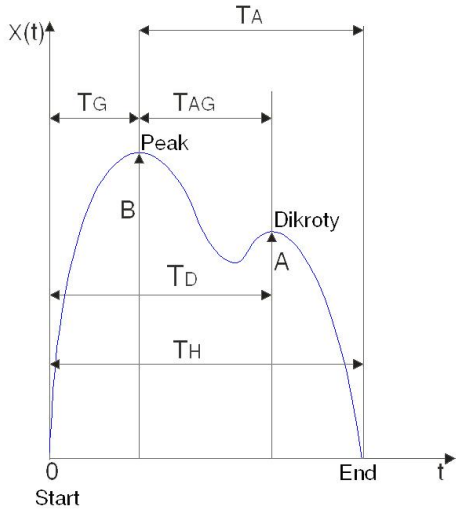

Fig. 1.3.1: Nomenclature and evaluation parameters

T_H	Duration of cardiac cycle
P	Pulse (beats/min)
T_G	Peak concentration time

T_D	Dicrotic time
T_A	Decay time
T_{AG}	Basic arterial speed
TG/TA	Standardized peak concentration time
TD/TA	Standardized dicrotic time
RI	Reflection index – RI = $\frac{A}{B}$ (in %)
SI	Arterial stiffness – SI = $\frac{Height}{T_{AG}}$ (in m/s)

Pulse amplitude

Pulse amplitude (PA) is not really convincing since depending on many, individually strongly fluctuating biological factors.

Side differences of 30 % up to 40 % must not necessarily be pathological.

Major criteria for artery patency are form of pulse curve, pulse wave travel time, and peak concentration time.

1.4 Medical Application Fields

Screening

Screening for acquisition of arterial occlusion processes

Analysis

- Pulse wave analysis with information on differentiation
- Definition of functional against organic genesis
- Acquisition of haemodynamically effective stenoses (stress)

2 O-AP Optical Arterial Pressure

2.1 Preparing Examination

Examination room

Optical measurement of arterial pressure should take place in a room having normal room temperature (approx. 20 °C / 68 °F).

Preparing patient

- Prior to examination, patient should stay in a room having normal room temperature for 15 minutes or longer.
  Cold extremities will distort measuring result

Note

- Warm up fingers or toes in warm water if necessary; skin temperature should be 37 °C / 99 °F.
- Introducing patient to measuring process
  Inform patient to keep on being relaxed during measurement and refrain from moving the fingers (toes) too.

Note

Positioning patient

- The patient is put in a flat position and the head should be supported by a headrest if necessary.
- The acra to be measured should be put very steady and positioned at heart level. Place feet or hands on soft pillow for steady and stable position.
- Ideally place O-PO sensors on finger tips or toe tips (outer acral member). Select skin area as healthy as can be.
- Fix O-PO sensors with rings gluing on both sides or with a sensor clamp but not “Hansaplast®” (band aid) or similar.

Note

Note sensor colours

- **Red** sensor = **right**
- **Blue** sensor = **left**

Placing the cuffs

Toe cuffs or finger cuffs are placed onto same acra, according to their colour marking, like the O-PO sensors.

Note

- Toe cuff = Toe 1 - 4, big toe (hallux) optionally, innermost member
- Finger cuff = All fingers, thumb optionally, innermost member

Placing sensors

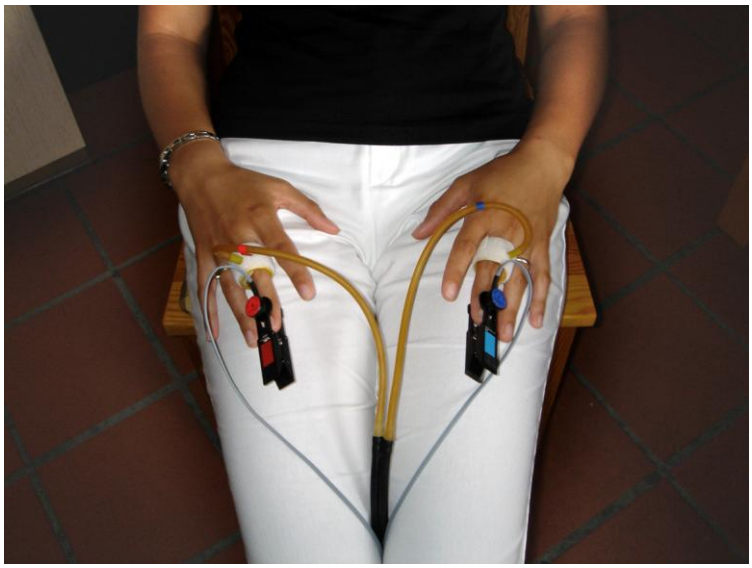

Fig. 2.1.1: Acral blood pressure measurement (O-AP) with optical sensors

2.2 General Medical Notes

General

Optical measurement of arterial pressure O-AP (also termed as electronic oscillographic pressure measurement in literature) is particularly suitable for acquisition of systolic pressure values on penis, fingers and toes. It also allows statements on patency of major arteries lending itself to screening method owing to simple and fast practicability.

You can perform measurement using optical acral measurement of arterial pressure much easier than sonographic Doppler pressure measurement.

Owing to oscillography, also small acra blood volume deviations are well acquired.

Using optical oscillography (i.e., electrically enhanced oscillography) you can evaluate pulse curves of fingers and toes.

Examination

Evaluating acral occlusions, you need to carry out O-AP under optimum rest conditions and room temperatures (approx. 27 °C / 81 °F), else disturbing functional influences of circulation cannot be excluded.

Every patient should principally have the acra checked by side-by-side comparison but the sensing point must be symmetrical for that purpose.

Pulse curve form analysis as well as calculation of its time values is possible.

Never submit an O-AP result without clinical results.

2.3 Notes on Measuring Results

General

A normal oscillogram would show an abruptly rising anacrotic and gradually falling off katacrotic leg with incisure and dicrotic wave.

Literature reference

- **Rudofsky, G.,** *Kompaktwissen Angiologie,* perimed Fachbuch-Verlagsgesellschaft, Erlangen (1988)
- **Kappert, A.,** *Lehrbuch und Atlas der Angiologie,* Hans Huber,

Bern Stuttgart Toronto (1989),

- **Gerok, W., Hartmann, F., Schuster, H.-P., Alexander, K.,** *Gefäßkrankheiten,* (Ed. Alexander, K.) Urban & Schwarzenberg, München (1994)

Results of pulse measurement

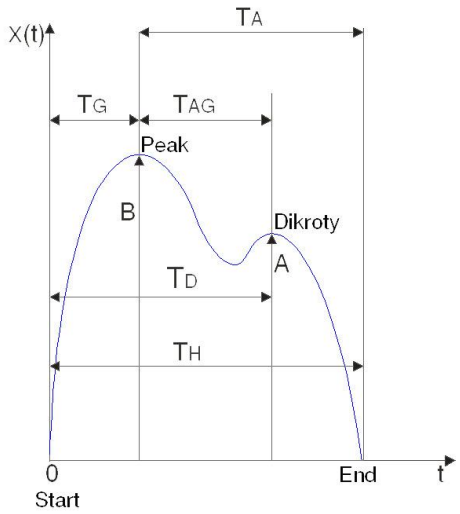

Fig. 2.3.1: Nomenclature and evaluation parameters

T_H	Duration of cardiac cycle
P	Pulse (beats/min)
T_G	Peak concentration time
T_D	Dicrotic time
T_A	Decay time
T_{AG}	Basic arterial speed
TG/TA	Standardized peak concentration time
TD/TA	Standardized dicrotic time
RI	Reflection index – RI = $\frac{A}{B}$ (in %)
SI	Arterial stiffness – SI = $\frac{Height}{T_{AG}}$ (in m/s)

Pulse amplitude

- Pulse amplitude (PA) is not really convincing since depending on many, individually strongly fluctuating biological factors.
- Side differences of 30 % up to 40 % must not necessarily be pathological.
- Acral pressure values are approx. 10 % above system pressure (max. brachial pressure) as a rule.

2.4 Medical Application Fields

General

- Arterial circular disorders (systolic blood pressure values)

Diabetic foot

- For diabetic foot clarification

Penis examination

- For clarification of physiological or psychological functional disorder (erectile dysfunction)

3 P-SPO Pneumatic Segmental Pulse Oscillography

3.1 Preparing Examination

Examination room

Pneumatic Segmental Pulse Oscillography P-SPO examination should take place in a room having normal room temperature (approx. 20 °C / 68 °F).

Preparing patient

- Prior to examination, patient should stay in a room having normal room temperature for 15 minutes or longer, under optimum rest conditions.

Note

Cold extremities will distort measuring result

- Introduce patient to measuring process

Note

Inform patient to keep on being relaxed during measurement and refrain from moving the fingers (toes) too.

Positioning patient

- The patient is put in a flat position and the head should be supported by a headrest if necessary.
- Place feet on soft pillow for steady and stable position.

Putting on cuffs

Cuffs

- Put on cuffs equally on both extremities. We recommend not putting on cuffs too loose.
  Important: If you put on the cuffs differently the result will be different amplitudes with the diagnostic arterial function investigation.
- Put on conical thigh cuff such that rubber ball of leg cuff is placed on inside of thigh with the hoses directing toward knee.
- You need to put on arm / leg cuff such that rubber ball is placed on inside of calf.
- Put on pull-on cuff such that rubber ball is placed on inside of foot or dorsum of foot.
- When using toe cuffs take care to put on cuffs carefully (best on toe) with the pressure hoses in direction toe tips.

Note

Note cuff colours

- **Red** cuff = **right**
- **Blue** cuff = **left**

Positioning cuffs and positioning legs

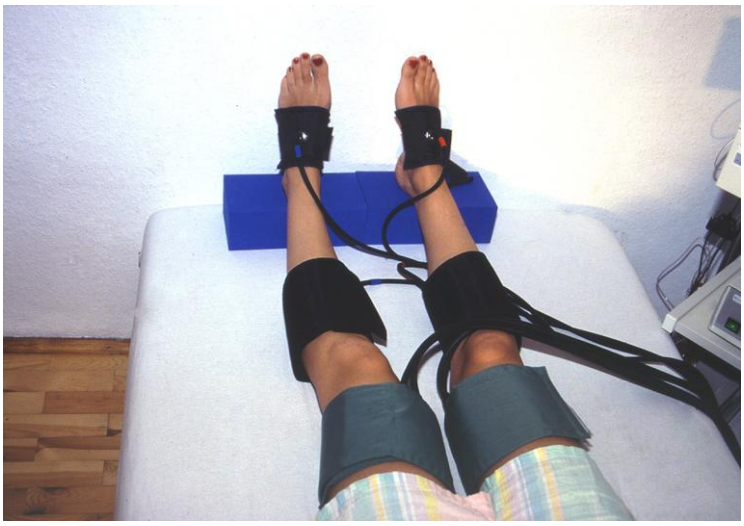

Fig. 3.1.1: Segmental pulse oscillography

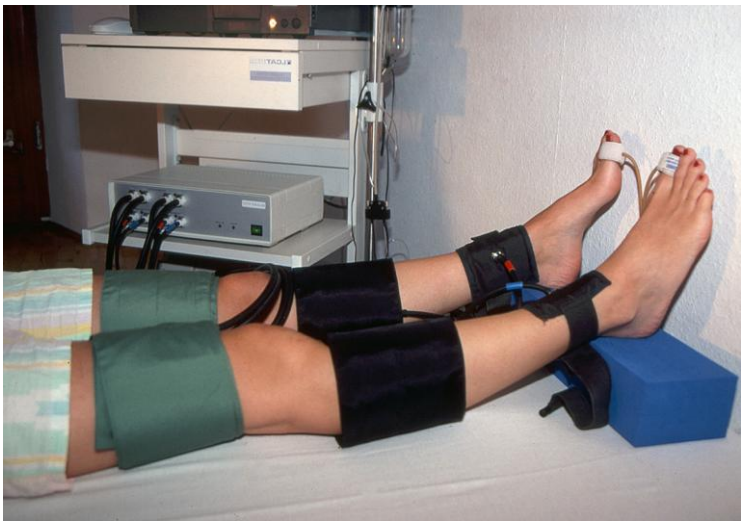

Fig. 3.1.2: Segmental pulse oscillography

3.2 General Medical Notes

General

When a patient is subjected to a first P-SPO examination, you should principally first exclude a suspected occlusive arterial vascular disease or possible arterial circular disorder e.g. by ultrasonic Doppler examination in the ankle area.

Every patient's legs should principally both be examined since only that would allow correct peak and side-by-side comparison.

P-SPO should be performed under predetermined rest conditions.

An exercise (stress) oscillogram should follow (in lying position again).

Examination

Pneumatic segmental pulse oscillography should be performed before and after stress.

Ask for strain test when suspecting:

- Femoral occlusions, e.g. 40 times on tiptoe
- Pelvic occlusion, e.g. 20 knee-bends

Never submit a P-SPO result without clinical results.

3.3 Notes on Measuring Results

General

There can be pathologically false measuring results on:

Venous outflow impediments (CVI, thromboses)

Right-sided heart failure

Raynaud's syndromes like Raynaud's attacks, etc.

In case of arterial stenoses inconspicuous resting pulse rate oscillograms can be feigned.

You would certainly find pathological oscillograms with present pelvic occlusions on lower leg, femoral occlusions on calf, and in case of peripheral occlusions over ankles and foot lead.

- **Literature reference**

- **Rudofsky, G.**, textbook: *Kompaktwissen Angiologie,* perimed Fachbuchverlagsgesellschaft, Erlangen, (1988)
- **Kappert, A.,** *Lehrbuch und Atlas der Angiologie*, Hans Huber, Bern Stuttgart Toronto (1989)
- **Gerok, W., Hartmann, F., Schuster, H.-P., Alexander, K.**, *Gefäßkrankheiten* (Ed. Alexander, K.) Urban & Schwarzenberg, München (1994)

Note

Exact evaluation is not always quite simple contingent on relatively low sensitivity of pneumatic segmental pulse oscillography.

Application fields

Localization of occlusion on members.

Segmental on side-by-side comparison (documentation of pulse palpation result).

Shape of pulse curve

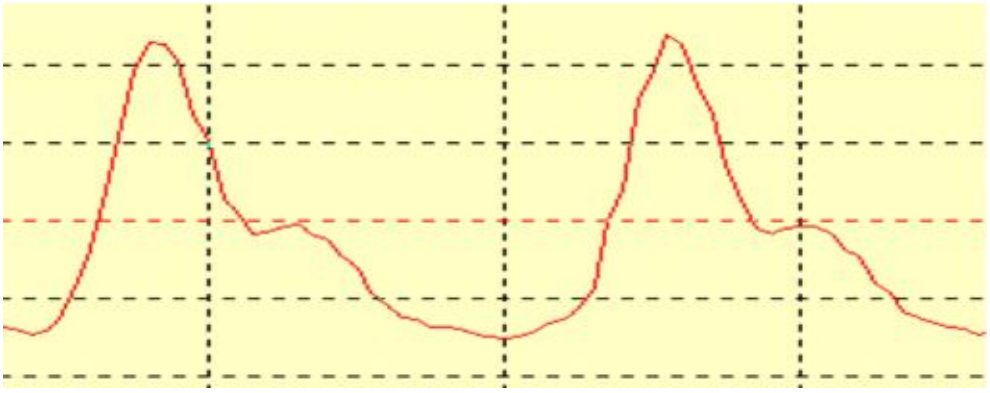

Fig. 3.3.1: Normal pulse curve

A normal pulse curve shows a steep rise with pointed maximum.

The dicrotic wave is localized on the decaying leg in the upper third; afterwards the pulse curve drops down to initial level.

The pulse curve of the normal acral oscillogram shows a steeply rising anacrotic leg and slower decaying katacrotic leg with incisure and dicrotic wave (due to autooscillation of artery = rebound wave).

Time from peak of pulse wave to peak of dicrotic wave is called basic artery period. In case of maximum vasodilatation incisure will intensify and

the dicrotic wave will approach baseline. Moving up dicrotism with incisure flattening suggests arterial constriction. In case of vasopastic condition, e.g. after stimulus of cold, dicrotism can disappear altogether and then reappear after heat application.

As opposed to normal curve shape the following pathological types can be distinguished:

Various pulse curves

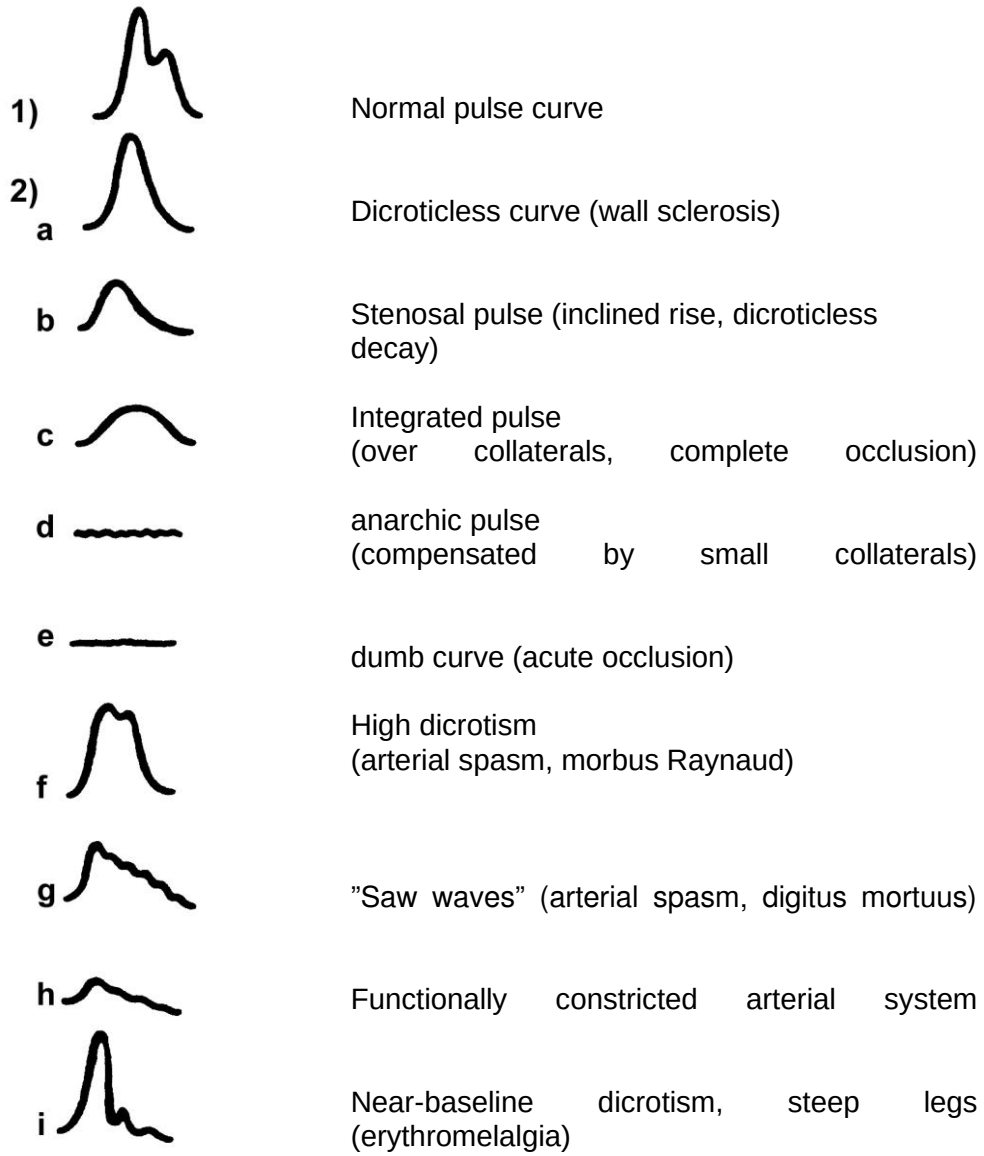

Fig. 3.3.2: Typical curve shape of electronic acral oscillogram.

1) Normal curve

2) Pathological curve shapes a - i (acc. Kappert 1981).

- **Pathological pulse curves**

a) Rigid form: Dicroticless curve at loss of artery elasticity due to wall sclerosis.

b) Stenosal pulse: Reduced amplitude, slowly rising leg but yet distinctly steeper than the dicroticless falling leg.

c) Integrated pulse form: Symmetrical, dicroticless pulse curve rounded

off on top with equal flattening of anacrotic and katacrotic leg. We are talking about a “compensatory pulse” of large-calibre collaterals compensating the main artery occlusions.

d) Anarchic curve shape: Small, arrhythmic response in case of occlusions compensated by small-calibre collateral system (“hypervascularity type”).

e) Dumb curve: Missing pulsations also at highest amplification, except for individual rises; particularly at acute arterial occlusions before development of a functional collateral circuit but also at very poorly compensated chronic occlusions.

f) High positioned dicrotism at functional angiopathies (morbus Raynaud, etc.).

g) “Saw waves” in decaying leg at altogether flattened curve in case of vasopastic diathesis.

h) Strongly flattened curve with steep anacrotic leg and flatly decaying portion in case of functionally constricted artery system (digitus mortuus, etc.).

i) Curves with steep anacrotic and katacrotic leg with near-baseline dicrotism in case of widened artery system (e.g. erythromelalgia).

Pulse amplitude

Quantitative evaluation of pulse amplitude is not possible at the moment as there are no standard values for the pulse amplitude.

Pulse amplitudes are approximately equal on thigh and calf.

Ankle distal, amplitudes are considerably lower.

Behaviour of pulse amplitude maximum

Mean arterial pressure (oscillographic index) is approximately within pressure value of pulse amplitude maximum.

Healthy patients show the maximum of pulse amplitude in the same or adjacent pressure values.

If the maximum of pulse amplitude is offset by more than 2 pressure increments (at 20 mmHg per pressure increment) when laterally compared then this would indicate vascular arterial obliteration proximal to direct leads.

When maximum of pulse amplitude over calf and distal leads becomes distinctly less and when maximum of pulse amplitude moves toward less pressure values then this is indication of occlusions, e.g. of arteria femoralis superficialis.

Following table shows the relation between the most widespread oscillographic results and the presumably occluded or stenosed artery segments where pulse palpation result and auscultation allow further diagnose specification. The oscillation results mentioned here merely describe the proximal furthermost localization of arterial flow impediments.

Oscillographic results	Diagnosis or arterial segments affected
Resting oscillogram normal	Probably no pAVK. Well compensated flow impediments do not show though ==> Exercise (stress) oscillogram
Resting- and exercise oscillogram normal	pAVK of major vessels can practically be ruled out (foot / hand or digital arteries not acquired though) ==> Acral oscillogram

Resting oscillogram normal but:	
Pathological reaction particularly after knee bends	Flow impediment above inguinal ligament (mostly stenosis)
Pathological reaction particularly after standing-on-tiptoe exercise	Flow impediment below inguinal ligament mostly stenosis)
Amplitude reduction proximal thigh cuff	Iiiaca segment or A. femoralis-communis segment or A. profunda femoris plus A. femoralis superfacialis
Amplitude reduction distal thigh cuff	A. femoralis superfacialis
Amplitude reduction calf cuff	Distal A. femoralis superfacialis and / or A. poplitea
Amplitude reduction distal low leg cuff	Crural (lower leg) arteries (at palpable artery pulse: Truncus tibiofibularis)
Amplitude loss on sole cuff only	A. tibialis posterior
Amplitude loss on dorsal cuff only	A. tibialis anterior
Amplitude superelevation distal thigh and / or calf (resonance overshoot or “ringing”)	Aneurysm or dilatating arteriopathy A. femoralis / A. poplitea, hypertension
Amplitude reduction below thigh cuff with amplitude regeneration at calf / lower leg area	Iliaca stenosis (well compensated) or femoral stenosis or condition after fem. / pop. Bypass or artifact

3.4 Medical Application Fields

General

Segmental mechanical pulse oscillography SPO as orienting preliminary examination is particularly legitimated for confirmation and documentation of clinical pulse state.

Resting oscillography

- Segmental at side-by-side comparison

- Documentation of pulse palpation result
- Localization of occlusion on extremities

Exercise tolerance test Acquisition of haemodynamically effective stenoses (stress).

3.5 Scientific Basics of Measuring Method

Pneumatic Segmental Pulse Oscillography P-SPO (incremental oscillography) has its origin in mechanical oscillography according to the Gesenius-Keller method. When using method after Gesenius-Keller, pulsation was registered directly over a mechanical graph recorder.

When performing pneumatic segmental pulse oscillography P-SPO, cuffs are put on and cuff pressure is changed for registering vascular wall oscillations and reducing damping influences (larger blood volume of capacitive vessels, fluid accumulation in tissue). Pulsation causes pressure fluctuations in limbs and these are transferred to the cuffs for acquisition. Measurement is made over pressure sensors that record pressure in the cuffs.

Until now, it was only possible to measure with one cuff. This required new placement of sensor after each segment measured and one extremity after the other had to be measured. The new method of pneumatic segmental pulse oscillography using vasolab 5000 allows you now to measure pulsation on both extremities simultaneously. Up to three cuff positions are measured in sequence permitting automatic sequence of measuring now.

Now you can record pulse amplitude maximum at cuff pressure values that approximately correspond with mean arterial pressure. You should consider, however, that tissue pressure can distort measurement slightly since the cuff bearing pressure needs to be overcome at first.

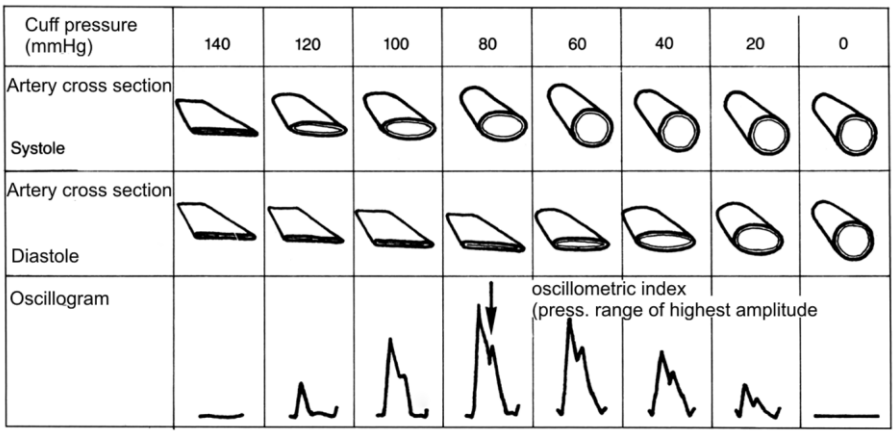

Fig. 3.5.1: Arterial cross section (from: **Rudofsky, G.,** *Kompaktwissen Angiologie,* perimed Fachbuch-Verlagsgesellschaft, Erlangen (1988))

3.6 Technical Information on Measuring Method

The P-SPO measurement procedure is made up of several sections that are all monitored and controlled by vasolab 5000.

The P-SPO examination program can control and document up to five pairs

of cuffs in one measurement run.

vasolab 5000 controls the compressor required for pressure generation. You may connect three different pairs of cuffs to the compressor at the same time. Snap locks provide for quick change of cuffs. The compressor is connected to vasolab 5000 via serial interface and can be operated at maximum pressure of 250 mmHg.

4 D-PPG Digital Photoplethysmography (LRR)

4.1 Preparing Examination

Examination room

D-PPG examination should take place in a room having normal room temperature (approx. 20 °C / 68 °F).

Preparing patient

Prior to examination, patient should stay in a room having normal room temperature for 15 minutes or longer.

Skin temperature should be 20 °C to 25 °C (68 °F to 77 °F).

Note

Cold extremities will distort measuring result.

Patient should take off shoes, stockings, and tight clothing.

Positioning patient

Patient takes examination position. There are two exercise programs for routine examination (see below Exercise Program). “Dorsal extensions from a sitting position” or “Half knee bends”.

Placing of the sensor

Take the D-PPG sensors from their holder and place one of the double-side gluing rings onto face of D-PPG sensor. Ensure that both lenses are free.

Fix D-PPG sensor approx. 10 cm proximal to inside ankle by pressing double-side gluing ring firmly against it.

- If there is however a trophic disorder (hypodermitis, eczema, atrophia blanche) on the “ideal measuring point” the D-PPG sensor should be glued onto the next proximal skin area but not onto a varix or insufficient perforating vein.
- If there is no sufficient adhesion you should degrease the measuring area or remove hairs.
- Align D-PPG sensor cable toward foot.
- Note colour coding:

  D-PPG sensor **red** = **right**

  D-PPG sensor **blue** = **left**

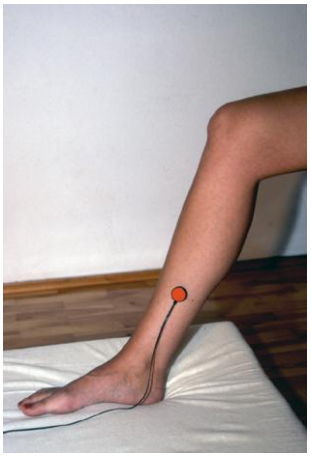

Fig. 4.1.1: D-PPG measurement w / out Tourniquet cuff

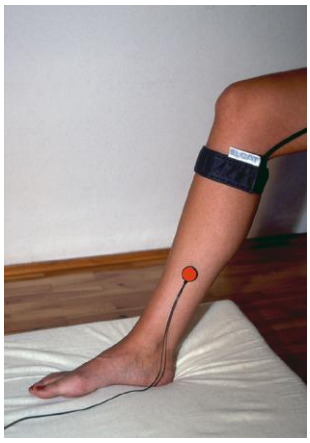

Fig. 4.1.2: D-PPG measurement with Tourniquet cuff

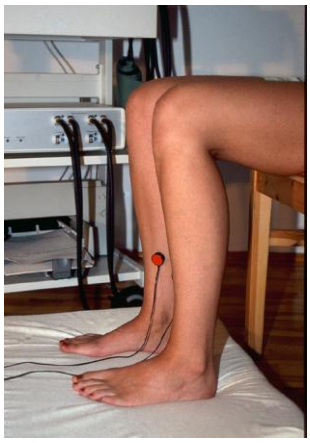

Fig. 4.1.3: D-PPG measurement with wrong leg position

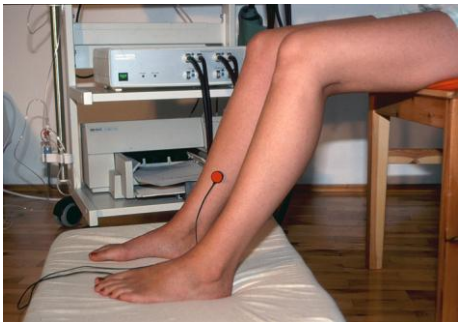

Fig. 4.1.4: D-PPG measurement with correct leg position

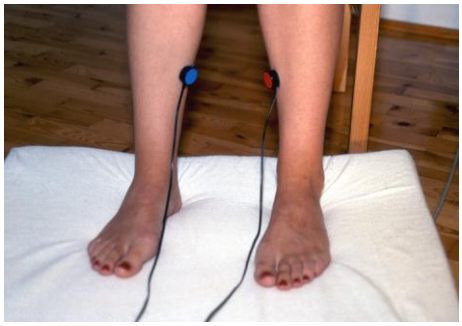

Fig. 4.1.5: D-PPG measurement with correct sensor position

Note Never use tape (e.g. “Hansaplast®” = band aid) for fixing D-PPG sensor. Depressing D-PPG sensor would change haemodynamic conditions on measurement area.

Performing Examination

Examination is subdivided in:

- exercise program and
- refilling phase

- **Kinetic program**

With the D-PPG sensor safely fixed, we recommend to have patient exercise the exercise program prior to D-PPG examination under instructions or have it demonstrated.

There are two exercise programs recommending themselves to routine examination:

- Patient sits relaxed on and leaning against a chair with legs relaxed and knees bent by approx. 110 degrees. Pelvis plane angle about 110 degrees.

- Patient performs maximum dorsal extensions (maximum lifting of toe) in synchronism with metronome rhythm and with heel fixed

onto floor.

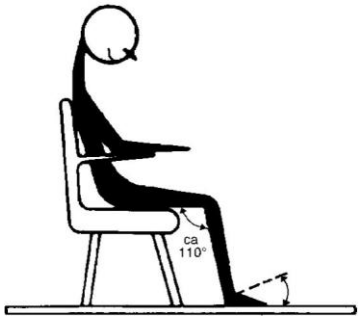

Fig. 4.1.6: D-PPG exercise program “Sitting dorsal extensions”

- Patient stands relaxed perhaps holding to a holding device. Legs are slightly straddled, toes slightly directed inward with a clearance of about a foot wide between toes; knees should be pressed against each other.
  Patient performs half knee bends keeping time with metronome rhythm.

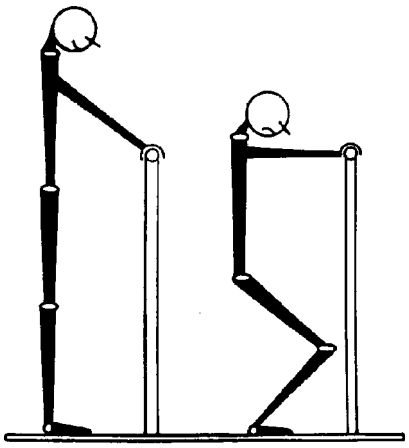

Fig. 4.1.7: D-PPG exercise program “Half knee bends”

Note Significant measurements, with stiff joints or hypokinetic restrictions in ankle joint present, will be possible to a limited extent only. Use exercise program “Half knee bends” for such cases please.

- **Refilling phase** It is important that patient sits or stands relaxed after the exercise program i.e., during refilling phase and does not move or talk breathing calmly and steadily.

Finishing examination Carefully remove D-PPG sensor from leg after finishing measurement please.

Caution Never remove D-PPG sensor by pulling cable but by holding it on the D-PPG sensor shell.

4.2 General Medical Notes

General

When a patient is subjected to a first D-PPG examination, you should principally first exclude a suspected occlusive arterial vascular disease or possible arterial circular disorder e.g. by ultrasonic Doppler examination in the ankle area.

You should principally examine both legs of any patient.

D-PPG examination is to be understood as screening test at unclear results, grave flow malfunction or great discrepancy between D-PPG measurement and clinical results. Consider other examination methods (e.g. phlebography, phlebodynamometry) in this case.

Measuring with Tourniquet cuff?

A second measurement using a Tourniquet cuff below knee on a patient having D-PPG rating I to III is recommended. If haemodynamic action of venous refilling time T_0 or venous pumping capacity V_0 improve using this cuff then surface vein reflux is evident.

Note

Use our special Tourniquet cuffs (width 2.5 cm). We recommend working with pressure of approx. 120 mmHg.

Caution

Never use wide Tourniquet cuffs (width greater than 3 cm). You would influence the deep venous system even at low pressures.

4.3 Notes on Measuring Results

Definition of evaluation parameters

You can take definition of individual evaluation parameters from below figure.

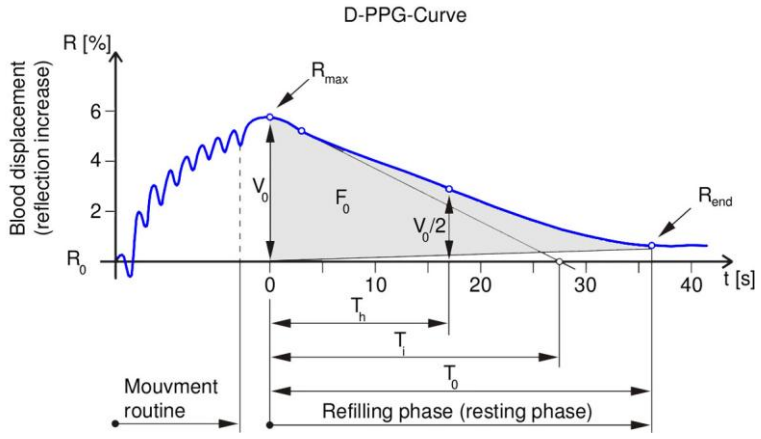

Fig. 4.3.1: D-PPG curve nomenclature and evaluation parameters

T_0 "Venous refilling time T_0" is the 1st main parameter of the D-PPG curve. T_0 is the time between R_{max} and R_{end}. R_{max} is the maximum of the D-PPG curve after termination of the exercise program. Final value R_{end} is reached when the recorded D-PGG measuring signal is not significantly changing for approx. 5 seconds (plateau formation).

Note

Generally the D-PPG curve would reach a final value that may insignificantly deviate from start value R_0 (baseline), and in some cases final value R_{end} is below baseline. R_{end} is not the crossing of measuring signal with time axis!

T_h "Venous half-life T_h" is the time at which half of the pumping capacity during refilling phase (resting phase) – i.e., half of amplitude – has been reached again. So value T_h does not indicate half of T_0.

T_i T_i evaluates initial blood inflow into the measurement area (i.e., for a person with health veins the initial arterial inflow) and represents the crossing of a straight line determined by curve peak with decay after 3 seconds and zero line.

V_0 "Venous pumping capacity V_0" is the 2nd main parameter of the D-PPG curve. V_0 is a measure of maximum venous pump power achieved by muscular pumping actions of the lower extremity. The value is stated in percent. Scaling is done automatically depending on maxima.

$V_0[\%] = (R_{max}-R_0)/R_0 \times 100$ **QUANTITATIVE PLETHYSMOGRAPHY**

F_0 "Venous pumping work F_0" represents, as integral of D-PPG curve refilling phase, the total of input pumping capacity. The unit is percent times second.

Categorizing the evaluation parameters

By international definition, there are three insufficiency degrees for evaluating muscular pump function on the basis of evaluating venous refilling time.

- Normal: T_0 greater 25 s (healthy veins)
- Insufficiency degree I: T_0 = 24 to 20 s (slight flow disorder)
- Insufficiency degree II: T_0 = 19 to 10 s (medium grave flow disorder)
- Insufficiency degree III: T_0 below 10 s (grave flow malfunction)

Using QUANTITATIVE PLETHYSMOGRAPHY, "venous pumping capacity V_0" as further reproducible parameter will be at your disposal. Although "venous refilling time T_0" has been internationally standardized so far, practice-based experience in evaluating "venous pumping capacity V_0" has resulted in following assessment:

- Normal: V_0 >= 3 %
- Pathological: V_0 < 3 %

Note

This graduation is only valid for exercise program "Dorsal extensions from a sitting position".

Caution

Verify the calculated parameters.

Medical notes on Measuring Results

Even if D-PGG diagnoses are easily established, never disregard clinical results.

If difference between R_0 and R_{end} is too high then you need to repeat measurement. Furthermore, adhesion of D-PPG sensor should be checked.

The smaller the parameters the more pronounced the haemodynamic disorder. Only the “venous refilling time” has been internationally standardized up to now but you will have determined your standard for the other parameters soon.

Repeat measurements where there is large discrepancy between your clinical results and the measuring results obtained.

We would recommend repeating measurement in case of difficultly interpretable curves or problematic measuring results in order to avoid possible erroneous interpretations.

Artifacts (e.g. movement of patient, coughing, etc.) may possibly distort measurement end so that venous refilling time T_0 may be wrongly determined causing incorrect determination of pumping work F_0 too. Parameters V_0, T_i, and T_h are correctly calculated though.

4.4 Medical Application Fields

General

Basically applies: D-PPG quantifies venous haemodynamic action of the lower extremities.

D-PPG cannot make a diagnosis but well exclude or confirm diagnosis. A selection of application fields will be presented in the following section (selection does not claim to be complete):

Quantification at a clinically diagnosed venopathy

Performing regular status control is important for this kind of patients in order to respond with a therapy on worsening of illness well in time.

Early diagnosis of venopathy

Not every venopathy would immediately show a visible change of the saphenous veins. As soon as there is evident clinical or anamnestic suspect you should perform D-PPG examination.

Indication and prognosis of a stripping operation or sclerotherapy

If major vessel or side branch varicosity of the saphenous vein has been verified by clinical results or ultrasonic Doppler examination you should perform a functional test using D-PPG. For that purpose, conduct normal measurement at first. Afterwards carry out a second measurement occluding vena saphena magna by finger pressure or by application of a tourniquet. If haemodynamic action improves after this maneuver then there is a functional indication for surgery or sclerotherapy.

Therapy control, relapse control

Whether varicose vein exeresis or sclerotherapy, every therapy requires efficiency control using D-PPG. Required are three examinations minimum: Before and after therapy as well as one at the end of one year.

Pregnancy monitoring

Risk of venopathy during pregnancy is high. This risk will increase by any further pregnancy. D-PPG offers you the possibility of monitoring patients at risk.

Preoperative employment

Venous haemodynamic action can be measured prior to any plan able operation, e.g. for making targeted prophylaxis of thrombosis.

Confinement in bed

Patients who are bedridden for a longer period of time can be monitored as required in order to initiate prophylaxis of thrombosis in good time.

Suspected phlebothrombosis

D-PPG can support but not verify diagnostic suspicion; it is merely a routine examination prior to venous occlusion testing.

Diagnostic exclusion investigation at unclear leg troubles

Orthopedic or neurological diseases in many cases cause similar pain symptoms like venopathy. D-PPG examination can help in verifying the differential diagnosis in this case.

4.5 Scientific Basics on Measuring Method

General

Application of optical measuring methods on skin has been known to the medical world ever since 1930. CARTWRIGHT used infrared rays for measuring blood circulation fluctuations. In 1938, HERTZMAN found a connection between intensity of skin light reflection and its blood content: He called the apparatus “photoelectric plethysmograph”. Ever since photoplethysmographs have been employed for recording acral or dermal arterial pulsation i.e., for measuring skin perfusion.

In the 70ies, it was established that this method also allowed measuring venous pumping capacity of the lower extremity and that this measurement correlates well with phlebodynamometry. In 1981, BLAZEK and WIENERT introduced a more sophisticated method to diagnostic phlebological investigation, the light reflection rheography (LRR). Further consequent development of this measuring method (LRR) at the RWTH Aachen (institute of technology) lead to development of digital photoplethysmography (D-PPG). In fall 1988, within the framework of interdisciplinary cooperation, the BLAZEK and SCHULTZ-EHRENBURG (Aachen and Bochum) team introduced D-PPG equipment VQ1000 for the first time. The D-PPG equipment records and stores changes of reflection within the measuring area mainly developing from blood volume displacements in cutaneous and subcutaneous venous vascular plexus due to movement exercises or changes of position.

The D-PPG sensor features in-depth optimization using an appropriate wavelength of light and radiation geometry at simultaneous suppression of surface reflection and stray light thus enabling safe sensing of the entire venous cutis plexus.

As opposed to all systems used hitherto, the D-PPG system contains a self-calibrating amplification system by which the reflected input signal is calibrated. During this process, all essential components including the optical sensor are part of a microprocessor-controlled loop. This arrangement grants standardized and reproducible measurements independent from skin structure and skin pigmentation. This allows QUANTITATIVE PLETHYSMOGRAPHY for the first time.

Biophysical basics

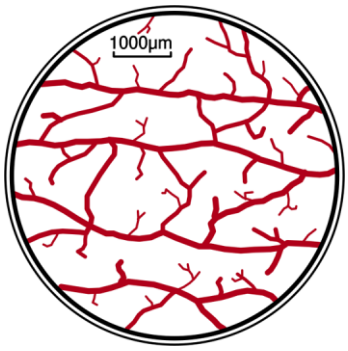

Fig. 4.5.1: Measuring window under the D-PPG sensor

Indicated here are the typical reflection and extinction properties of the human skin. It is known that a particularly favourable “measuring window” for optical sensing is in the 940 nm range of invisible rays. The radiated light is insignificantly absorbed by the epidermis (approx. 15 %). Furthermore, there is a big difference between reflection of bloodless skin and reflection of blood vessels.

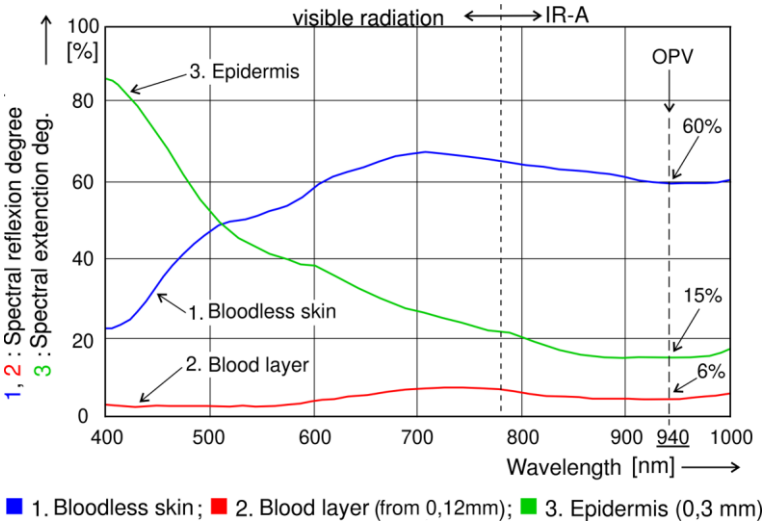

Fig. 4.5.2: Optical characteristics of biological samples in the visible and infrared range

This figure shows a schematic view of skin’s vascular system under the D-PPG sensor. Since the filled blood vessels reflect about 10 times less light than bloodless skin tissue would they appear as dark lines against a relatively light surround.

Blood stagnates by occlusion causing peripheral venous pressure to rise and surface of the elastic, capacitive vessels to enlarge. This reduces mean measuring window reflection recorded by rise of the D-PPG curve. So the D-PPG optoelectric measuring principle is based on acquisition of reflection fluctuations of subepidermal skin layers, before and after occlusion, where the changes are caused by filling fluctuations in the skin vessel plexus.

The Tourniquet cuff manages to tie the surface venous system haemodynamically stronger to the deep venous system.

Following biophysical laws are used

There is direct and immediate connection between the deep venous system filling states of the lower extremities and the degree of filling of the cutis vessels sensed by the D-PPG system.

Any change of pressure in the venous vessel system causes a change of vascular surface and thus change of D-PPG signal.

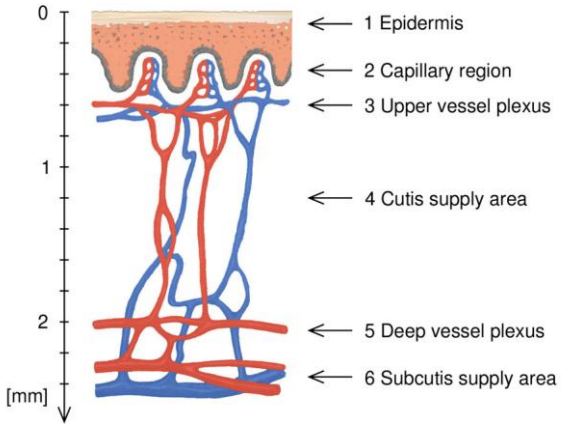

Fig. 4.5.3: Topography of the skin vessels in the lower leg (schematic)

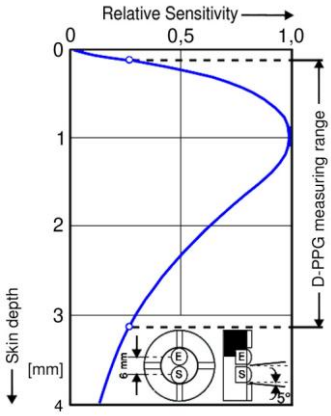

Fig. 4.5.4: Relative sensitivity of D-PPG sensor as a function of skin depth

Besides transmitting diode S and detector diode D, there is a micro signal amplifier incorporated in the D-PPG sensor. The D-PPG sensor measuring range is defined by 1/e decay of maximum sensitivity. It spans approx. 0.1 to 3.1 mm enabling safe reaching and evaluation of the cutis vessel plexus.

4.6 Scientific Basics on Measuring Method

D-PPG sensor

The D-PPG sensor is directly cable-connected to the equipment. It has two optoelectronic elements. The transmitter sends infrared waves into the skin and the receiver picks up the reflected light waves.

Steps

The D-PPG measuring procedure is made up of eight work steps all of them controlled through the microcomputer and running automatically. Figure 6.3.5.1 shows the automatic test sequence illustrating the single program steps.

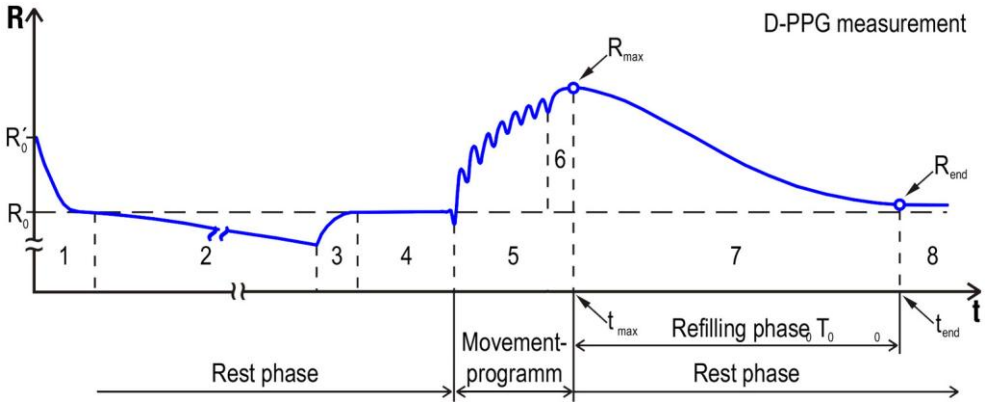

Fig. 4.6.1: Automatic measuring process

Progress of measuring procedure

1. Automatic calibration
   - The individual reflectance value R_0 is calibrated to the intended value of quiescent reflection R_0 (baseline of D-PPG curve).

Note The D-PPG display shows: "Please wait, measurement follows".

2. Determination of the stationary hemispheric blood flow
   - The quiescent value is reached when two successive average values do not show a great difference over 4 seconds. After 30 seconds latest, however, measurement will commence.
3. Further calibration
   - Transmission power is readjusted for compensating the drift that possibly may have happened.
4. Start phase
   - Exercise program starts in 5 seconds

Note The D-PPG display shows: "Start in 5 s".

5. Execution of exercise program in synchronism with metronome measure.
   - Muscular pumping activity “skims off” blood and in consequence peripheral venous pressure will decrease and skin reflection will increase.
6. Identification of reflection maximum value
7. Refilling phase
   - Reflection changes generated by onset of venous refilling are indicated to the examiner both acoustically and optically on the D-PPG display in form of a bar chart.
8. The haemodynamic parameters are automatically calculated by the P-PPG equipment after end of measurement and printed and stored together with the measurement report.

5 PDM Phlebodynamometry (CP Compartment Pressure)

5.1 Preparing Examination

Examination room

Prior to examination, patient should stay in a room having normal room temperature for 15 minutes or longer and PDM examination itself should be performed in a room having normal room temperature (approx. 20 °C / 68 °F).

Note

Cold extremities will distort measuring result.

Preparing patient

Patient should take off shoes, stockings, and tight clothing.

Preparing the measuring system

Take pressure transducer from holder and remove protecting cap.

Ensure to have a clean pressure transducer.

Note

The following description refers to pressure measurement using an electronic compressive stress converter (Statham element).

Hold pressure transducer upright and completely cover flat surface with water or physiological solution.

A uniform liquid meniscus without air bubbles should form.

Connect diaphragm dome to pressure transducer. Carefully tighten coupling ring of pressure transducer to diaphragm dome. This will displace excessive liquid. Take care that there are no air bubbles between diaphragm dome and pressure transducer.

Connect pressure line system (Heidelberg extension) to 3-way tap.

Connect pressure line system (Heidelberg extension) to butterfly cannula.

Connect infusion container (with physiological solution) to diaphragm dome.

Activate rinsing process by applying lever on diaphragm dome.

Ensure that diaphragm dome and entire measurement system fill bubble-free.

Note

Connect 3-way tap to direct (straight) port of diaphragm dome.

Caution

High pressure values damaging pressure transducer can sometimes build up because stopcocks to diaphragm dome are all closed during setting-up process. Open 3-way tap to atmosphere before attaching diaphragm dome.

- **Positioning sensor**

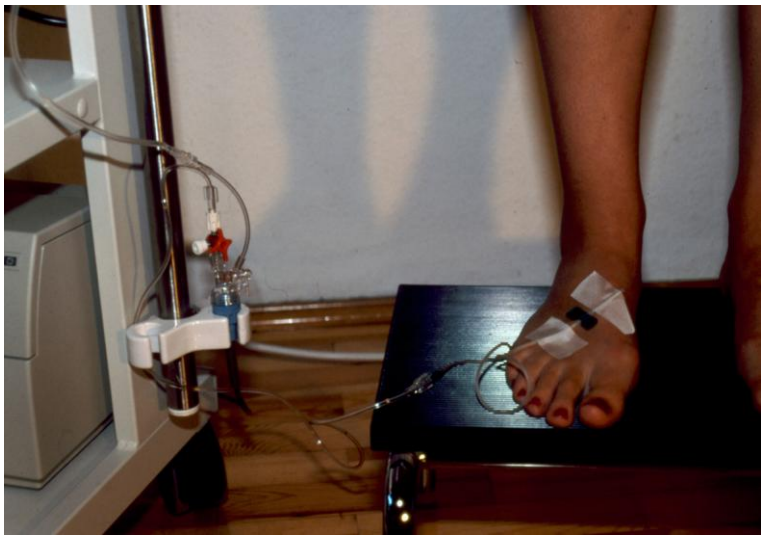

Fig. 5.1.1: PDM examination

Preparing PDM examination

Examination is subdivided in:

- Exercise program
- Refilling phase

- **Exercise program**

Patient assumes measurement position.

Rinse measuring system, repeating that during measurement breaks. This will prevent blood coagulation in the butterfly cannula.

Puncture venous system in the forefoot area using the butterfly cannula. Absolutely ensure that tip of butterfly cannula is free and is not clinging to venous wall.

Fix butterfly cannula.

Monitor value of static pressure; it should be constant over 3 to 5 seconds.

Patient performs exercise program under instruction. Several exercise programs suggest themselves:

- 10 times on tiptoe (standing) in approx. 15 seconds
- Half knee bends
- Dorsal extensions while sitting
- Running (walking) on the spot
  Exercise program “Running (walking) on the spot” is performed until minimum pressure is reached.

You can select between acoustic or optical metronome measure.

Note If there is no immediate pressure reduction, check position of butterfly cannula. It should not cling to the venous wall.

- **Refilling phase**

It is important that patient sits or stands relaxed after the exercise program i.e., during refilling phase and does not move or talk breathing calmly and steadily.

After having reached static pressure value, patient should stay steady for

further 10 seconds; this will help you detect excessive pressure values.

Note Accessing varicose veins, we recommend repetition with appropriate compression tests using pads.

Finishing examination

With measurement finished, carefully remove butterfly cannula and measuring set-up respectively please.

Caution Ensure that no sodium chloride solution can issue. Sodium chloride solution dripping from infusion holder and penetrating lab cart housing can cause short circuit and corrosion on lab cart in the long run.

5.2 Notes on Measuring Results

Standard and free examination program

General

You need to contemplate results, pressure drop, and venous refilling time separately.

Pressure drop

Standard values correspond to a pressure drop of min. 60 mmHg.

If pressure drop is less than 60 mmHg then this might indicate heart valve defect in the epifascial or deep venous system.

If no pressure reduction occurs during the exercise program (exercise-related response recognizable) and pressure rise occurs immediately thereafter, then this would indicate a postthrombotic syndrome (PTS).

Venous refilling time

Error source for apparently normal refilling time despite of heart valve defects can be an arterial circular disorder.
By international definition, there are three insufficiency degrees for evaluating muscular pump function on the basis of evaluating venous refilling time:

- Normal: T_0 greater 25 s (healthy veins)
- Grade I: T_0 = 24 to 20 s (slight flow disorder)
- Grade II: T_0 = 19 to 10 s (medium-grave flow disorder)
- Grade III: T_0 below 10 s (grave flow malfunction)

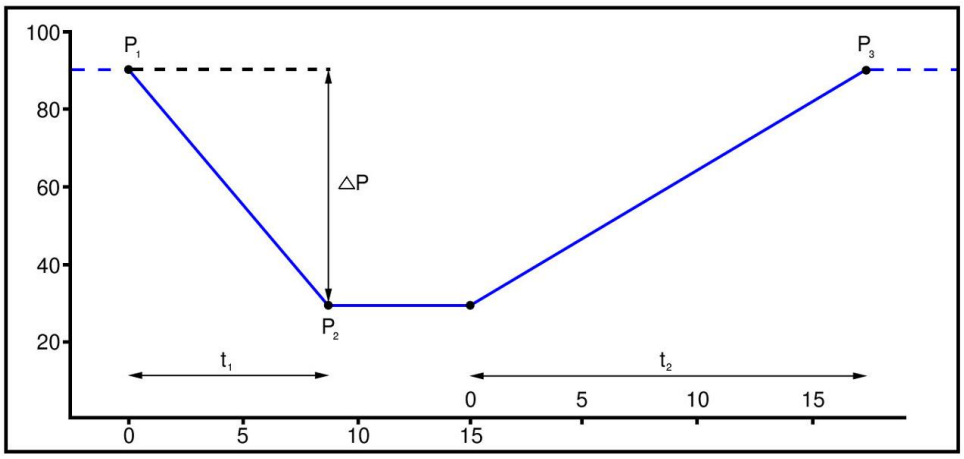

Fig. 5.2.1: nomenclature and evaluation parameters of the PDM-curve

CP Compartment Pressure

Evaluation parameters

Following values apply for subfascial pressure measurement (see below Further information on compartment pressure):

Normal values correspond to a pressure of less than 10 mmHg.

Pressure values between 20 - 40 mmHg are found at reduced perfusion.

Pressure values greater than 40 mmHg indicate existence of manifest compartment syndrome.

Studies of W. Hach and Ch. Schwahn-Schreiber published under “Chronic Venous Fascial Compression Syndrome” show following mean values (measured in deep dorsal compartment):

Normal

- lying: 13.6 mmHg
- standing: 29.9 mmHg

Abnormal

- lying: 21.1 mmHg
- standing: 62.5 mmHg (patients with chronic fascial compression syndrome)

Compartment syndrome

Etiology and pathogenesis

Synonym: Anterior tibial syndrome

A compartment syndrome is particularly found in spatium tibialis anterior. A compartment syndrome leads to reduced arterial and venous blood flow resulting in rising of capillary permeability with enhancement of edema formation (vicious circle). Consequence is neuromuscular malfunction and ischemic muscle necrosis and that would end with scarred muscular contracture. A compartment syndrome would often occur after fractures, muscle crushing, posttraumatic muscle edema as well as following too tight, non-split plaster bandage or circular dressing.

Functional compartment syndrome

Functionally conditioned muscle ischemia after stress has specially been described for spatium tibialis anterior. We distinguish between acute and chronic form. The acute functional compartment syndrome would occur during or immediately after larger stresses – particularly after longer marches – and can acutely lead to extensive muscle necroses. The chronic functional compartment syndrome develops from muscular swelling due to sports activity. This form would appear much more frequently than the acute form and often appears bilaterally. We can observe that in serious sports mainly and in particular on contest walkers and middle-distance runners.

Classification

We distinguish between threatening compartment syndrome with decent neurological symptoms, intact peripheral perfusion, and profound, dull tension aches as well as manifest compact syndrome with pains, swellings, neurological deficits and reduced peripheral perfusion.

Symptoms

As a rule, patients would complain about pretibial pains and tensional sensation and there is frequent observation of soft tissue swelling. Sensory disturbances often start in the space between first and second toe and in such cases weakness will be in lifting toes and feet. The symptoms of n. peroneus / n. tibialis lesion are dangle foot or steppage gait.

Diagnostic investigation

Anamnesis

Asking for a possible injury pattern and previous therapy is of particular importance.

Clinical examination

Testing of sensibility, motoricity as well as perfusion of extremity affected is important. Subfascial pressure measurement is of decisive importance. Values < 10 mmHg are considered to be normal and values between 20 - 40 mmHg are found under reduced perfusion. Values > 40 mmHg would indicate a manifest compartment syndrome. Generally, the difference between diastolic blood pressure and compartment pressure should not be less than 30 mmHg else it might come to micro circulation disturbances.

Imaging examination

Phlebography is often carried out in order to exclude phlebothrombosis by differential diagnose. Typically you would find a narrowed, deep venous system on a compartment syndrome. Sonography is also suitable for representation in principle.

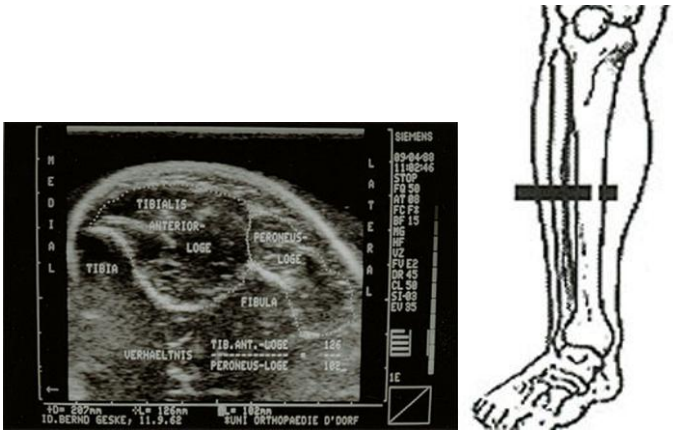

Fig. 5.2.2: Sonogram of compartment syndrome

Experimental studies on ultrasonic compartment syndrome examination did not show certain connection between sonographic changes of soft tissues and actual compartment pressure. Distinct increases of pressure, however, would accompany widening of spatium anterior tibialis that may become evident using side-by-side comparison. The figure in hand shows cross-sectional sonographic anatomy of the lower leg on the anterior transverse plane. The individual muscle compartments can be well demarcated over the echo-rich structures of tibia and filbula as well as the strong echo band of the interosseous membrane.

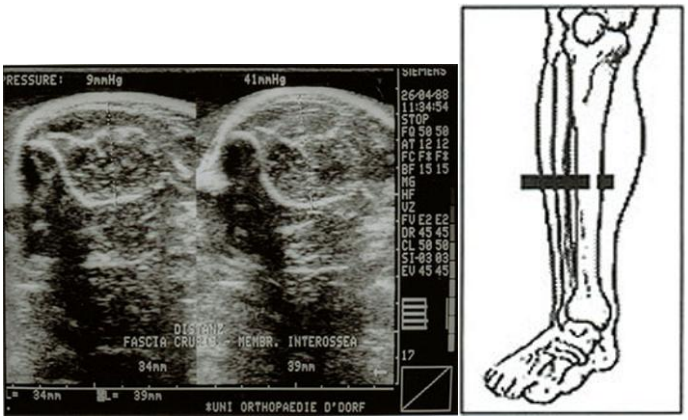

Fig. 5.2.3: Sonogram of compartment syndrome

Rise in pressure present at compartment syndrome – spatium tibialis anterior in this case – can be detected indirectly by increase of muscle diameter (right side 39 mm) in comparison with the healthy side (left side 34 mm). Distance between crural fascia and interosseous membrane is determined on the sonic image (arrows). The pressure values actually present measured for comparison amounted to 9 mmHg left and 42 mmHg right. Changes in muscular echogenicity cannot be used for certain evaluation.

Differential diagnoses

Disease/ stage	Symptoms	Remarks/ peculiarities
Phlebo-thrombosis	Circumferential difference, pressure pain, Lowenberg test, Meyer pressure points (exit of perforating veins), Homans test (pain at dorsal reflection of foot), Payr's sign (pressure pain of plantar muscles)	Phlebography, Doppler sonography, X-ray, scintigraphy
Phlegmasia coerulea dolens	Edema, cyanosis, pain, swelling, cool skin, necroses, gangrene, possibly hypovolemic shock	Doppler sonography, phlebography, pulse state
Thrombo-phlebitis	reddened palpable cord, minor swelling	clinical examination

Therapy and rehabilitation

Conservative

The affected extremity should be cooled and rested at heart level on impending compartment syndrome. Antiphlogistic medication is also indicated.

Surgical

Early intervention is of vital importance. Within the first 6 hours – preferably within 4 hours –, the affected muscle compartment must be relieved by fascial splitting and subsequent open wound treatment. You should principally open all four compartments of the lower leg. If fasciotomy is performed too late irreversible nerve damages will remain already after one day. Infection rate, too, will strongly increase with growing time – up to 50 % after the first day.

Muscle compartments

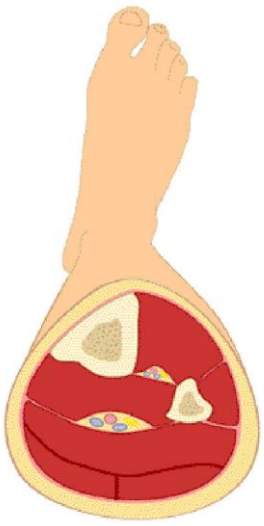

Fig. 5.2.4: Representation of muscle compartments in cross-section of lower leg

Further information on compartment pressure

Publications
www.jerosch.de/publikationen/zeitschriften/

Institute of Sports Medicine
Prof. Dr. J. Jerosch
www.gvle.de/kompendium/unterschenkel/0025/0015.html

Sports medicine (compendium) Compartment syndrome Diagnostic investigation
www.gvle.de/kompendium/unterschenkel/0025/0020.html

5.3 Medical Application Fields

PDM Phlebodynamometry

General

Phlebodynamometry (bloody peripheral measurement of vein pressure) is rating highly as little invasive and well reproducible method in specialized venous function diagnosis. The measurement acquires objective data on venous system functionality both in regard to pump-down capacity and valves of vein function (refilling time). External edemas or trophic changes of skin do not impede the measuring result.

As opposed to other examination methods, phlebodynamometry delivers quantitative values under stress required for the therapeutic measures intended.

Phlebodynamometry can also be applied during pregnancy.

Venous pressure in the foot is approx. 6 to 10 mmHg lying and 70 to 90 mmHg standing. The exercise program will cause a pressure drop of approx. 40 to 60 mmHg. This pressure drop will be less at haemodynamically significant varicosis and at postthrombotic syndrome (PTS) in particular. PDM can be an important examination prior to invasive therapeutic measures (stripping operation, sclerosis). Functional importance of insufficient saphenous veins and / or perforating veins or their elimination can be clarified in combination with compression test using pressure pads.

Following an exercise program and venous refilling time, pressure drop is determined or response with or without compression of the saphenous vein mouth (v. saphena et parva) or exit of insufficient perforated veins (specially Dodd, Boyd, and Cockett group). As a whole, PDM delivers well reproducible information on lower extremities venous function. Venous pressure conditions can be evaluated by puncture of v. femoralis in the pelvis area thus allowing evaluation of indication for by-pass operation according to Palma.

Employment of phlebodynamometry

- Alternative and complementary method of phlebography prior to operation of the superficial venous system.
- At given clinically suspected changes in deep venous system or its phlebographic proof before operation. This would require a complementary compression test.
- Differential diagnostic significance at unclear phlebological results
- Prognosis on success of treatment
- Verification of therapeutical success
- Expert expertise

Diagnostic venous investigation

- Measurement of venous pressure
- Proof of existing PTS

CP Compartment Pressure

Compartment syndrome

A compartment syndrome would often occur after fractures, muscle crushing, posttraumatic muscle edema as well as following too tight, non-split plaster bandage or circular dressing.

This syndrome occurs particularly often on spatium tibialis anterior of the lower leg.

Functional compartment syndrome

In case of functionally conditioned muscle ischemia after stress exposure we distinguish an acute and chronic form.

The **acute functional compartment syndrome** would occur during or immediately after larger stresses – particularly after longer marches – and can acutely lead to extensive muscle necroses.

The **chronic functional compartment syndrome** develops from muscular swelling due to sports activity. This form is found more frequently than the acute form. It can be mainly observed on serious athletes and on soldiers after forced marches.

The **chronic venous compartment syndrome** develops in the course of venous diseases showing a grave chronic-venous congestive syndrome. This disease basically differs from the function syndrome hitherto known. W. Hach and Ch. Schwahn-Schreiber describe its gravest form as chronic fascial compression syndrome. This prevailing syndrome is a crural (“cuff”) ulcer, hitherto incurable.

Classification

We distinguish between **threatening compartment syndrome** (with decent neurological symptoms, intact peripheral perfusion and profound, dull tension aches) as well as **manifest compact syndrome** with aches, swellings, neurological deficits and reduced peripheral perfusion.

Symptoms

Patients would normally complain of pretibial pains and tensional sensations. Swellings on soft tissues are frequently occurring too. Sensory disturbances often start in the space between first and second toe and in such cases weakness will be in lifting toes and feet.

Diagnostic investigation

Diagnostic compartment investigation

- Inquiry about a possible injury pattern
- Testing of sensibility
- Testing of motoricity
- Testing of perfusion
- Measurement of compartment pressure

Measuring arrangement

The following diagram describes the measurement arrangement in the KP.

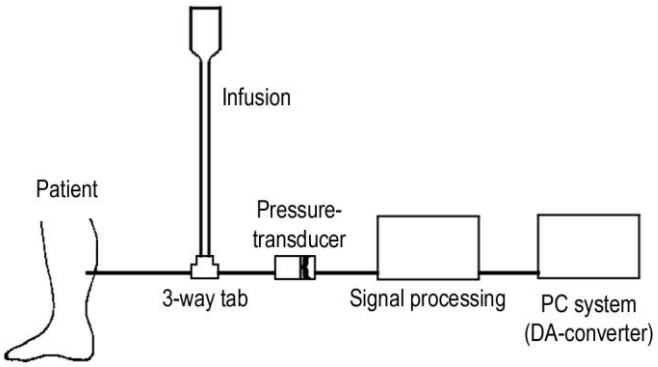

Fig. 5.3.1: Measurement arrangement in the KP

5.4 Scientific Basics of Measuring Method

General

Phlebodynamometry (PDM) determines venous pressure invasively. PDM is a technically simple method of determining function of the superficial and deep venous system of the legs. It allows predictions on elimination success of individual insufficiency points within the superficial venous system.

Principle

According to Bernoulli's law, pressure in a tube depends on flow rate. Therefore, venous pressure is high while patient is standing, strongly decreasing on calf pump muscle work. Static pressure (approx. 95 mmHg) of healthy persons, after puncture of vein on back of foot, corresponds to the differential level between sole and right atrium, decreasing to values below 50 % of initial value (40 mmHg) when under maximum stress by knee bends or tiptoe standings. This pressure drop under maximum muscle work will become significantly less at chronic venous insufficiency.

Where chronic insufficiency is mainly caused by superficial veins the raised venous pressure under stress ($\Delta P > 15 - 20$ mmHg) can be significantly reduced by eliminating the insufficiency points (by constriction of vena saphena or digital compression lock-up of perforating veins).

Where chronic venous insufficiency is mainly caused by insufficiency of the deep system there will be no pressure drop after translocating superficially widened veins, raise of pressure might possibly occur.

The following diagram describes the measurement arrangement in the PDM.

Measuring arrangement

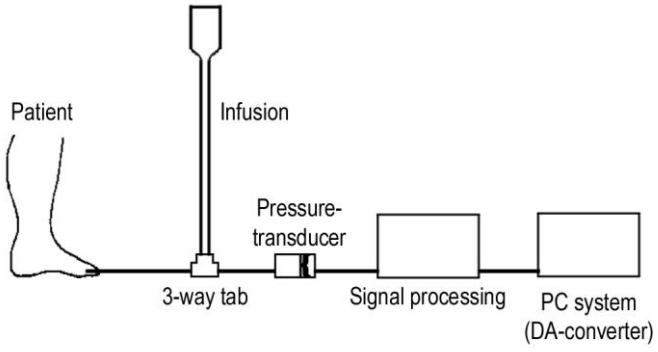

Fig. 5.4.1: Measurement arrangement in the PDM

Parameters of venous pressure curve

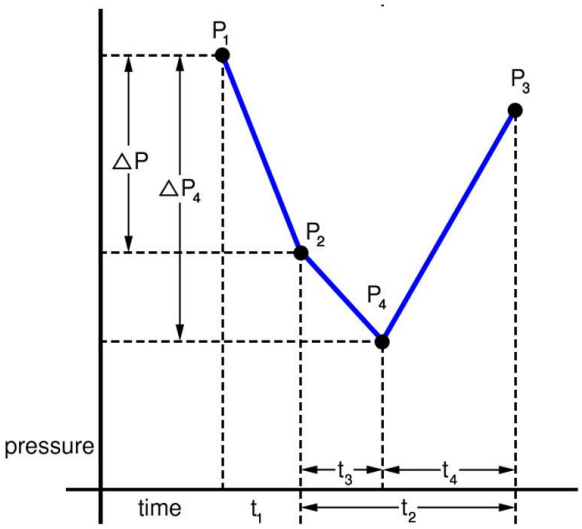

Fig. 5.4..2: Venous pressure curve

P_1 hydrostatic static pressure of standing patient

P_2 lowest mean pressure reached during stress

ΔP absolute pressure drop (P1 - P2 or P1 - P4)

t_1 regained static pressure after stress (normally P1 = P1, frequently below P1)

t_2 pressure compensation time

Examination process

The measuring system needs to be filled with sterile, bubble-free sodium chloride solution before starting examination. The pressure transducer has two terminals on its pressure dome. You need to connect a so-called “3-way tap” to one of the ports and a “2-way tap” to the second one. Filling of the pressure dome is made by sodium chloride infusion connected to the 3-way tap. The pressure dome is held upright with the 2-way tap opened and rinsed with the infusion until it is free from air bubbles. Close 2-way and 3-way tap thereafter. Then attach extension hose (so-called Heidelberg extension) to free port of 3-way tap. Attach flat-ground butterfly cannula of strength G 21 to its front end to be used for puncture of vein on back of foot.

Sensor

Pressure measurement is made by an electronic pressure-voltage converter.

Heidelberg extension

The Heidelberg extension is necessary:

- Improves patient’s free mobility.
- Prevents blood reflux to membrane dome.

- **Literature reference**

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- **Varady, Z.,** 10. Internationaler Frankfurter Workshop für Phlebologie 1996 und 11. Internationaler Frankfurter Workshop für Phlebologie 1997, Phlebo
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6 SG-VOP Strain-Gauge Venous Occlusion Plethysmography

6.1 Preparing Examination

Examination room

An SG-VOP examination should take place in a room having normal room temperature (approx. 20 °C / 68 °F), since cold extremities would distort measuring result.

Preparing patient

Prior to examination, patient should stay in a room having normal room temperature for 15 minutes or longer.

Patient should take off shoes, stockings, and tight clothing.

Introduce patient to measuring process.

Positioning patient

Patient takes examination position. Position lying patient's leg such that knee joint is slightly bent and lower leg is placed approx. 20 cm above heart level. Fix heel by support and ease thigh by wedge. Turn knee outward thus avoiding flow impediment. When putting on the leg cuff please take care to place rubber ball on thigh inside since only this will ensure that occlusion pressure will act on the deep venous system.

Place upper part of the body flat and lift head by headrest if necessary.

Put on conical leg cuff such that rubber ball of leg cuff is placed onto inside of thigh with the hoses directing toward knee.

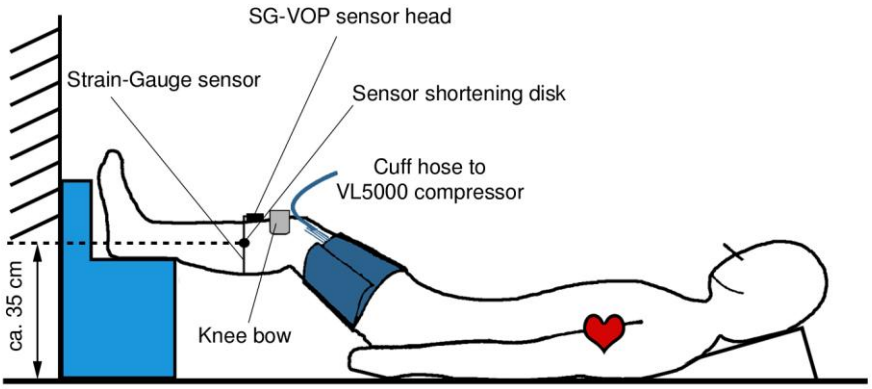

Fig. 6.1.1: Examination arrangement at SG-VOP examination

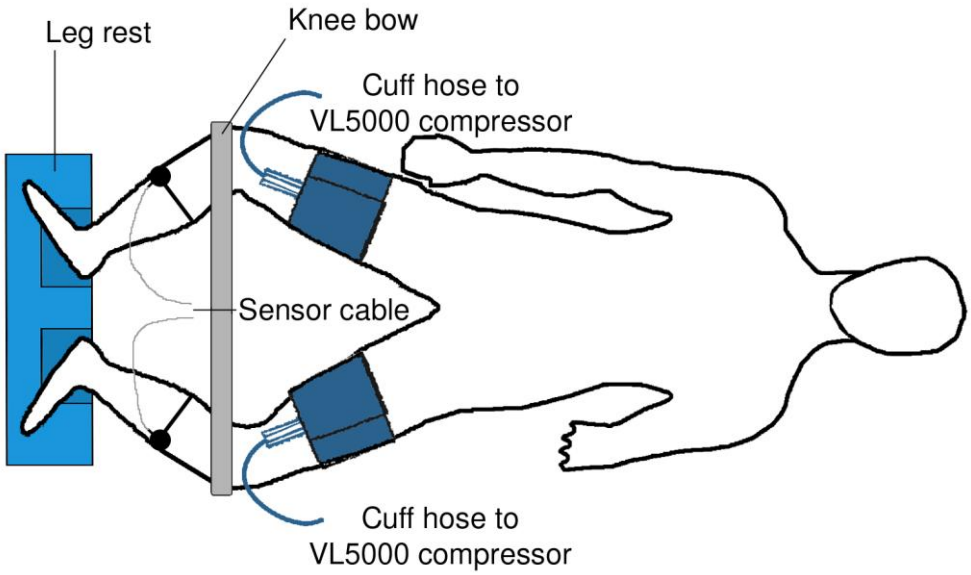

Fig. 6.1.2: Examination arrangement at SG-VOP examination

Note You should use a special angiology couch for better standardization of patient positioning.

Positioning sensor and legs

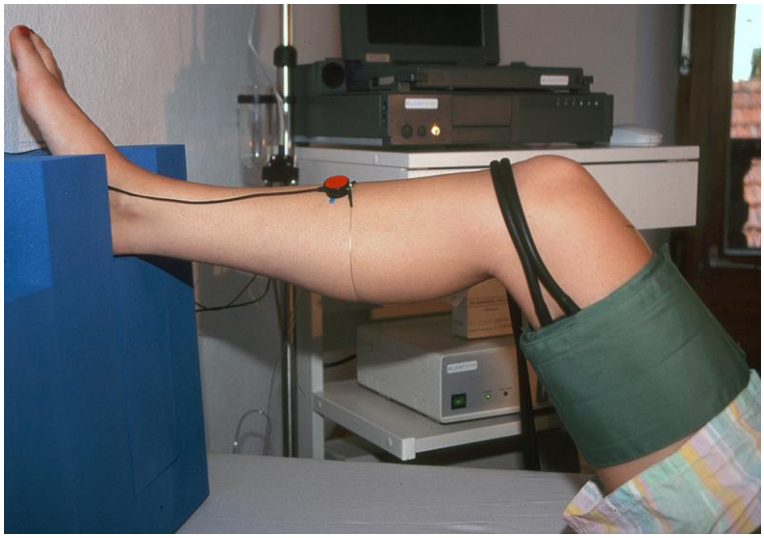

Fig. 6.1.3: Vein occlusion test (SG-VOP) with correct sensor position

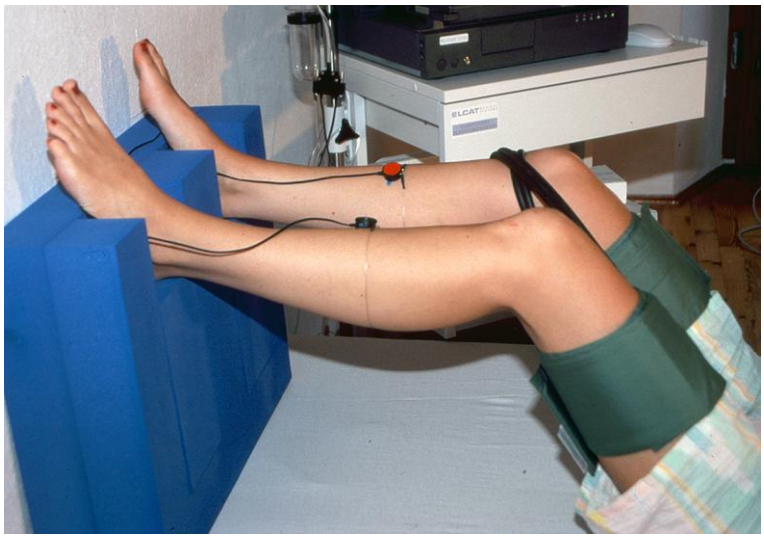

Fig. 6.1.4: Vein occlusion test (SG-VOP) with correct leg position

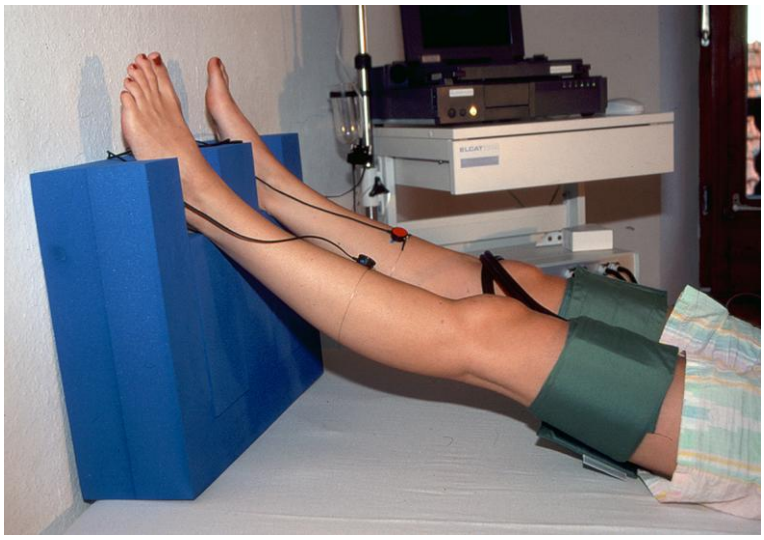

Fig. 6.1.5: Vein occlusion test (SG-VOP) with wrong leg position

SG-VOP examination of the arms

Examination position

Patient assumes measurement position. Arms of lying patient are positioned such that elbow joint is slightly bent and arms are above heart level. For this purpose, arms are laid e.g. on a rest or similar device that is appropriately arranged above patient's stomach / chest area. Angle of arm rest should be around 45 degrees.

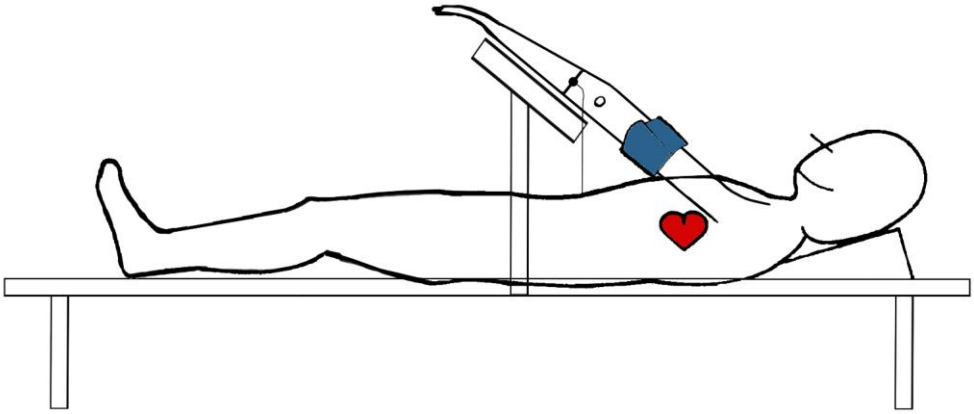

Fig. 6.1.6: Examination arrangement of arm SG-VOP examination.

Putting on cuffs

Cuffs are put on to the upper arms and the sensors to the forearms.

When putting on the arm cuffs please take care of placing cuff rubber balls on arm inside as only this will ensure that occlusion pressure will act on the deep venous system.

Examination Process

Measuring process the same as leg VVP examination.

Putting on strain gauge sensor

Fixing strain gauge sensor junction head

Remove strain gauge sensor junction head from holder placing one of the double-side gluing rings onto face of the strain gauge sensor junction head.

The strain gauge sensor junction head is attached to the circumferentially largest point of calf above the shinbone by the pressing double-side gluing ring firmly against the bone.

Note

Please take care to adjust cable either toward knee or toes.

Determining strain gauge sensor length

Select suitable length of strain gauge sensor. The strain gauge sensor must correspond to girth of calf; stretch of 1 cm minimum required.

Never stretch strain gauge sensor by more than one third of its rated length.

You can carry out possibly required shortening by means of the strain gauge sensor shortening disk. Attach it with a double-side gluing ring whenever required. Put strain gauge sensor not tightly but slackly and max. twice round the strain gauge sensor shortening disk.

Strain gauge sensors are available in different lengths to cope for strongly different girths of calf.

For special applications, the strain gauge sensor can be wrapped around the extremity several times; the measuring results will nevertheless be determined correctly.

Note

Never put strain gauge sensor to another position by rolling it; there is danger of damaging the strain gauge sensor. Put of strain gauge sensor and put it on again if need be.

Applying strain gauge sensor

Plug one end of the strain gauge sensor into a port of the strain gauge sensor junction head.

Carefully lay the strain gauge sensor circularly round the calf position having largest girth and connect strain gauge sensor to the other end of the strain gauge sensor junction head.

- The strain gauge sensor must lie on top of the skin (slight prestress necessary).

Vein occlusion test

Starting measurement

The thigh cuff should be pumped up to very low pressure (admission pressure had been enabled).

Start measurement through

Mouse [Measure start / stop F9]
Keyboard F9

Afterwards system carries out initialization, adjustment, and calibration. Sensors and cuffs are checked for correct function and status information informs you about the measuring process.

- **Occlusion phase**

Thereafter, occlusion phase will automatically start.

The thigh cuffs are pumped up to preset occlusion pressure (standard 80 mmHg). You can change occlusion pressure during measurement.

The occlusion period would normally last 180 seconds. The occlusion time (remaining time till end of occlusion phase) shows on the display and can be changed during measurement (in increments of 60 seconds).

- **Determining venous flow**

With occlusion time finished, the thigh cuffs are automatically deflated and venous flow is determined. Parameters AF, VC, and VO will display.

Changing to working area RESULT

All haemodynamic parameters are calculated and graphically represented here. Furthermore, optical evaluation of each trace is carried out (VC above VO).

Change to working area RESULT through

Mouse [RESULTS F6]
Keyboard F6

Checking the tangents

You may change the automatically calculated tangents for arterial inflow and venous flow at any time.

- **Changing to curve of arterial resting flow**

When you performed examination with arterial resting flow you may select over menu option **Traces** whether you want to have the curve of examination or the curve of arterial resting flow displayed. The actually shown curve is marked with a check on the menu (ŏ).

Changing to working area ANALYSIS

Change to working area ANALYSIS by clicking mouse onto trace representation (mouse cursor assumes shape of hand). Select trace desired.

Select desired trace by clicking onto trace number (e.g. #1).

Check the automatically calculated tangents.

6.2 General Medical Notes

Venous thrombosis is a grave health hazard. There are various plethysmographic measuring methods for phlebothrombosis. The vein occlusion test senses venous flow of the extremity. Pressure of the venous stagnation cuff should be greater than the existing venous pressure but less than the arterial pressure.

When a patient is subjected to a first SG-VOP examination, you should first quantify – particularly when suspecting occlusive arterial vascular disease – a possible arterial circular disorder by ultrasonic Doppler examination in the ankle area .

You should principally examine both legs of any patient. Never submit an SG-VOP result without clinical results.

A pathologic or unclear result must be followed by phlebography if there is no contraindication. A normal result does not exclude femoral vein thrombosis or even intracranial calf muscle sinus thrombosis.

6.3 Notes on Measuring Results

Definition of evaluation parameters

You can take definition of individual evaluation parameters from below figure.

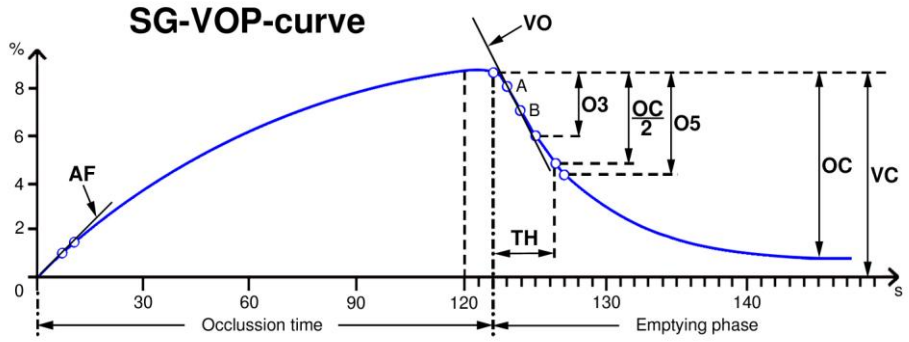

Fig. 6.3.1: SG-VOP curve nomenclature and evaluation parameters

VO The most important D-SGP parameter is “venous flow VO”. Venous flow is a straight line determined by points A and B. Point A is the final value of maximum slope and point B the measured value determined 1 second later. VO is the tangent to the (out)flow curve acquiring outflow dynamic.

AF AF evaluates arterial blood inflow to extremity and is the tangent at the beginning of stagnation. The first 30 seconds after initiation of measurement were used for calculation. Rise gradation for a period of 3 seconds is determined for artifact suppression.

VC “Venous capacity VC” is proportional increase of measuring signal. The average of measured values for determining venous capacity is made

over 5 seconds before end of congestion.

TH "Venous half-value period TH" is duration between end of congestion and reaching half venous capacity.

OC "Outflow capacity OC" is the difference between measured value at the end of occlusion and constant measured value during outflow phase.

O3 "Outflow capacity O3" is drop 3 seconds after the end of occlusion.

O5 "Outflow capacity O5" is drop 5 seconds after the end of occlusion.

Classification of evaluation parameters

We categorize venous flow VO into three groups based on clinic examinations:

- Normal: VO > 30 %/min (normal outflow)
- Limits: VO 30 up to 15 %/min (limiting outflow value)
- Pathological: VO < 15 %/min (outflow impediment)

Following values result for venous capacity VC:

- Normal: VC > 3 %
- Pathological: VC < 3 %
- VC > 5 % Varicosis (primary / secondary)

Note 

This graduation applies only for evaluating SG-VOP parameters.

Medical notes on measuring results

Even if SG-VOP diagnoses are easily established, never disregard clinical results.

The smaller the parameters the more pronounced haemodynamic disorder. Only the "venous (out)flow" has been internationally standardized up to now but you will have determined your standard for the other parameters soon.

Repeat measurements where there is a large discrepancy between your clinical results and the measuring results obtained.

6.4 Medical Application Fields

Application fields for venous occlusion testing

General

Diagnostic investigation of haemodynamically effective outflow impediments

- Acute thrombosis
- Postthrombotic occlusions
- Venous stagnation by space requirement
- Haemodynamic follow-ups
- Thrombolysis
- Thrombectomy
- Rethrombosis

Pelvic plane

SG-VOP is dependably suitable for diagnosis of pronounced pelvic vein thrombosis.

Femoral plane

SG-VOP is dependably suitable for diagnosis of pronounced femoral vein thrombosis.

Crural plane

There are characteristic curves for haemodynamically relevant crural thrombosis i.e., occlusion of several crural veins up to v. poplitea. However, if only one crural vein or calf muscle sinus is occluded then there won't be a definite curve shape and therefore no definite diagnosis can be made.

Determining haemodynamic parameters

- Venous capacity
- Venous (out)flow
- Arterial inflow

Application fields for filtration test

In addition to venous occlusion testing, following parameters are determined through filtration test (filtration = venous tightness):

- Differential capacity from 4th minute to 3rd minute
- Differential capacity from 5th minute to 3rd minute
- Differential capacity from 6th minute to 3rd minute

These parameters inform whether and how filtration through venous wall takes place. This would allow, e.g. within the scope of follow-ups, how effective a medicament is that should seal the venous wall.

6.5 Measuring method and scientific basics on measuring method

Application of strain gauge sensors for medical volume measurement goes back to GLASER. He described a device for measuring breath-related, circumferential change of thorax by means of a mercury-filled rubber hose in 1939. In 1949, WHITNEY introduced the mercury hose in measuring technology for diagnostic vessel investigation.

Following biophysical laws are used:

Occlusion congests blood thus enlarging the area of leg plane. Increase of circumference resulting from that is acquired by the strain gauge sensor and this increase is recorded by a rising D-SGP curve.

If an extremity has cross-sectional area ***A*** and circumference ***U*** at measuring point, we can describe this connection with $U = g * \sqrt{A} \quad \Rightarrow \quad A = \frac{U^2}{g^2}$.

In this formula, ***g*** is a "geometrical factor" only depending on form of cross-sectional area that however is independent from the size of area (e.g. circle: $g = 2 * \sqrt{\pi}$, Square: g = 4). With length ***L*** of extremity segment, we have:

$$V = A * L = \frac{L}{g^2} * U^2 \Rightarrow \quad U^2 = \frac{g^2}{L} * V$$

If filling of strain gauge sensor has conductivity σ and length l,

cross-sectional area a and thus volume $v = a * l$, resistance between the electrodes is calculated at

$$R = \frac{l}{a * \sigma} = \frac{l^2}{\sigma * v}$$

If expansible length l of strain gauge sensor corresponds to circumference ***U***, we have:

$$l^2 = U^2 = \frac{g^2}{L} * V$$

and

$$R = \frac{g^2}{L} * V * \frac{1}{\sigma * v}$$

If volume of extremity segment changes by change of blood filling we can assume that length ***L*** of extremity will remain constant. In this case, change of volume will only show by change of cross-sectional area and circumference. If form of cross-sectional area is maintained, then:

$$\frac{L}{g^2} = const$$

If filling temperature remains constant during measuring time, we have additionally:

$$\sigma * v = const$$

Thus resistance ***R*** is proportional to volume. Relative resistance changes would then directly correspond to the relative volume changes of the extremity segment enclosed.

$$\delta R = \frac{R - Ro}{R} \qquad \Rightarrow \qquad \delta V = \frac{V - Vo}{V}$$

If you wrap the strain gauge sensor twice around the extremity segment and hose of the strain gauge sensor has identical cross-section ***a*** , the connection is:

$$I^2 = 4 * U^2 = 4 * \frac{g^2}{L} * V$$

$$v = I * a = 2 * U * a$$

$$R = 4 * \frac{g^2}{L} * V * \frac{1}{\sigma * v}$$

Like under single wrapping, also in this case relative resistance changes δR of the strain gauge sensor correspond to relative volume changes δV, same preconditions concerning ***L***, ***g***, σ , and ***v*** provided.

6.6 Technical Information on Measuring Method

Technological basics

Today's common strain gauge sensors consist of very thin silicone hoses filled with mercury or another fluid (gallium / indium alloy for instance). Both hose ends have electric terminals.

All venous occlusion plethysmographs known so far had the disadvantage of not sufficiently measuring reproducible, artifact-free attachment quality at the extremity. Movements of connecting cables between strain gauge sensor and measuring system often caused considerable signal disturbances. In addition, mechanical characteristics of the previous strain gauge sensor configurations did not always exclude possible application faults, among which mainly faulty acquisition of girth.

Theoretical deduction requires girth of extremity ***U*** to correspond with simple or multiple length ***l*** of the strain gauge sensor. This however was rarely the case in practice. Normally the expansible part of the strain gauge sensor would encompass only part of leg girth. If for instance girth is 30 cm at the beginning of measurement and the non-wrapped part of the leg 2.5 cm long then you would measure a resistance change of 5.46 % at a volume change of 5 %. This corresponds to a relative error of 9.2 %!

A further, widely spread error source is to be seen in the existence of length-depending resistance portions of the strain gauge sensor. Total sensor resistance would then consist of a length-depending and a constant portion (e.g. resistance of lines between strain gauge sensor and measuring instrument). A constant resistance component entices underestimation of true volume change of extremity. Lead resistances should therefore not be introduced in SG-VOP measurement. You can achieve that by employing usual four-wire resistance measurement method common in technical measurement practice.

Precise, relevant SG-VOP examination therefore demands following conditions:

Reproducible attachment of strain gauge sensor junction head to extremity to be examined for minimizing motion artifacts.

The strain gauge sensor needs to be designed such that practically total leg wrapping is ensured.

The strain gauge sensor must be connected to control and evaluation unit via 4 leads.

Measuring process

The SG-VOP measuring process consists of five execution phases which are microcomputer-controlled and run fully automatic. Below figure shows the automatic measuring process and illustrates the individual program steps.

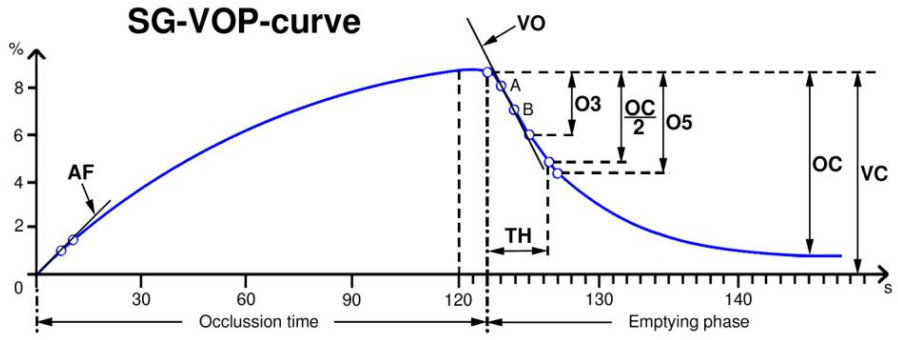

Fig. 6.6.1: Automatic measuring process of SG-VOP measurement procedure

1. **Automatic calibration**

   Individual measuring value R'_0 is calibrated against specified initial value R_0 (baseline of SG-VOP curve).

2. **Determining steady state circulation**

   The value indicating the steady state is reached when two consecutive average values do not differ greatly during a period of 4 seconds. The measurement however will start in 30 seconds at the latest.

3. **Further calibration**

   A further calibration corrects possibly occurred drift.

4. **Stagnation phase**

   Execution of venous occlusion for selected stagnation time.

5. **Outflow phase**

   The examiner can view resistance changes generated by venous outflow on the display.

6. **Evaluation**

   The haemodynamic parameters are automatically calculated after end of measurement.

7 SG-AR Strain Gauge Arterial Reserve (RH)

7.1 Preparing Examination

Examination room

SG-AR examination should take place in a room having normal room temperature (approx. 20 °C / 68 °F).

Preparing patient

Prior to examination, patient should stay in a room having normal room temperature for 15 minutes or longer.

Patient should take off shoes, stockings, and tight clothing.

Preparing examination

Patient assumes measurement position. Position stationary patient's leg such that knee joint is not overstretched and lower leg is positioned at heart level. You can fix the heel by a rest and support thigh with soft pillow for instance. When putting on the leg cuff please take care to place rubber ball on thigh inside since only this will ensure that occlusion pressure will act on the deep venous system. The upper part of the body is put to a flat position and the head should be lifted by a headrest if necessary.

Put on conical leg cuff such that rubber ball of leg cuff is placed onto inside of thigh with the hoses directing toward knee.

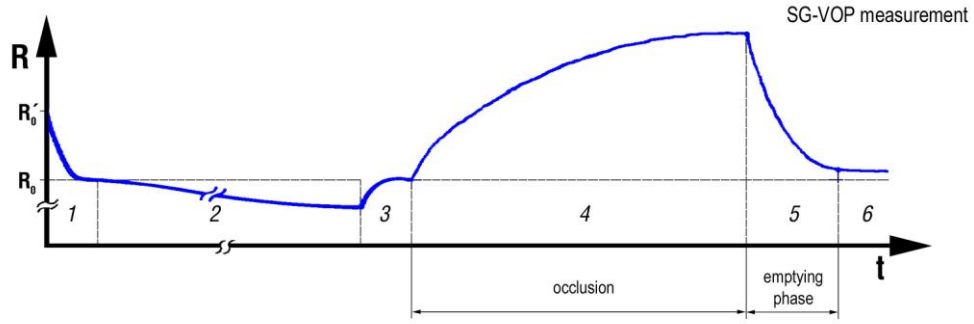

Fig. 7.1.1: Examination arrangement at SG-AR examination

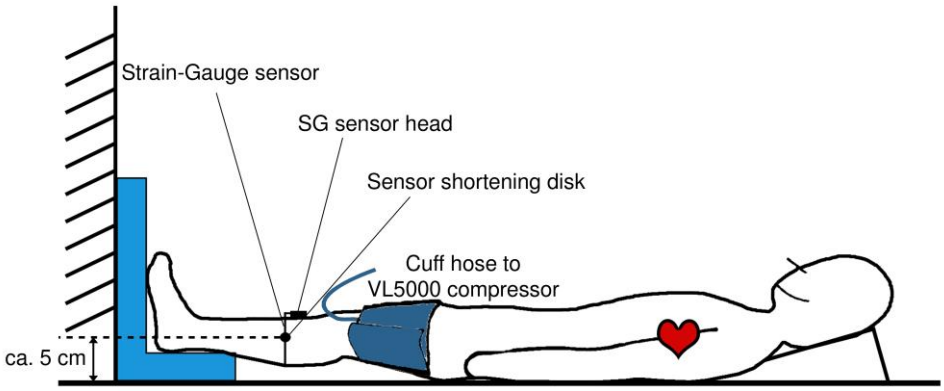

Fig. 7.1.2: Examination arrangement at SG-AR examination

Note You should use a special angiology couch for better standardization of patient positioning.

Positioning sensor and legs

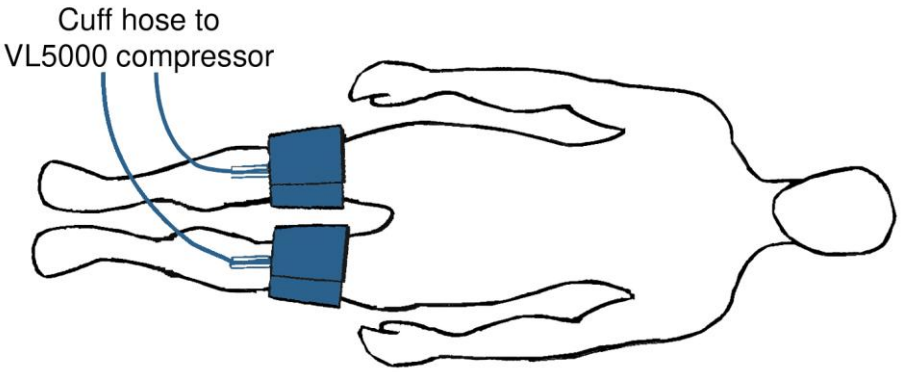

Fig. 7.1.3: SG-AR (RH) examination with correct positioning of leg and sensor

Putting on strain gauge sensor

Remove strain gauge sensor junction head from holder placing one of the double-side gluing rings onto face of the strain gauge sensor junction head.

The strain gauge sensor junction head is attached to the circumferentially largest point of the calf above shinbone by the pressing double-side gluing ring firmly against the bone. Please take care that the cable will show either toward knee or toes.

Plug one end of the strain gauge sensor into a port of the strain gauge sensor junction head. Carefully lay strain gauge sensor circularly round the calf position having the largest circumference and connect strain gauge sensor to the other end of the strain gauge sensor junction head. The strain gauge sensor must lie on top of the skin (slight prestress necessary).

Never put strain gauge sensor to another position by rolling it; there is danger of damaging the strain gauge sensor. Put off strain gauge sensor and put it on again if need be.

Note

Select suitable length of strain gauge sensor. The strain gauge sensor must correspond with girth of calf; stretch of 1 cm minimum required. Never stretch the strain gauge sensor by more than one third of its rated length. You can carry out possibly necessary shortening by means of the strain gauge sensor shortening disk. Attach it with a double-side gluing ring whenever required. Put strain gauge sensor not tightly but slackly and max. twice round the strain gauge sensor shortening disk.

Strain gauge sensors are available in different lengths to cope for strongly different girths of calf.

For special applications, the strain gauge sensor can be wrapped around the extremity several times and the measuring results will nevertheless be determined correctly.

With examination finished, carefully clean strain gauge sensor and strain gauge sensor junction head please. Store it carefully.

Caution

Never remove the strain gauge sensor junction head by pulling cable but by holding it on the strain gauge sensor junction head shell.

7.2 General Medical Notes

General SG-AR

Perfusion reserve in form of reactive hyperaemia (RH) after three minutes ischemia is measured with strain gauge Arterial Reserve SG-AR. This examination states severity of arterial circular disorder and compensation degree in case of occlusion (AVK). This examination evaluates the peak value (Peak flow), time of peak value (time to peak flow) as well as course of reactive hyperaemia.

General AVK

Arterial occlusive disease is a severe health hazard. There are some more or less large-scale occlusion-plethysmographic measuring methods that can acquire arterial inflow into extremity within the scope of arterial diagnostic occlusion investigation. Pressure of the inflatable venous stagnation cuff should be somewhat greater than the existing systolic pressure which must be higher by approx.50 mmHg to 70 mmHg.

If patient is suspected of having occlusive arterial vascular disease or possibly an arterial circular disorder, you should principally first quantify these by e.g. ultrasonic Doppler examination in the ankle area.

You should principally examine both legs of each patient. Never submit an SG-AVP result without clinical results.

A pathologic or unclear result must be followed by phlebography if there is no contraindication. Normal results do not exclude AVK (arterial circular disorder).

7.3 Notes on Measuring Results

Categorizing evaluation parameters

Peak flow

First criterion is the Peak Flow. This value is compared with the standardized table.

- **Normal**
  Arterial inflow is greatest on first stagnation maneuver and will steadily decay afterward.
- **Pathologic**
  Arterial inflow is not greatest on first stagnation maneuver.

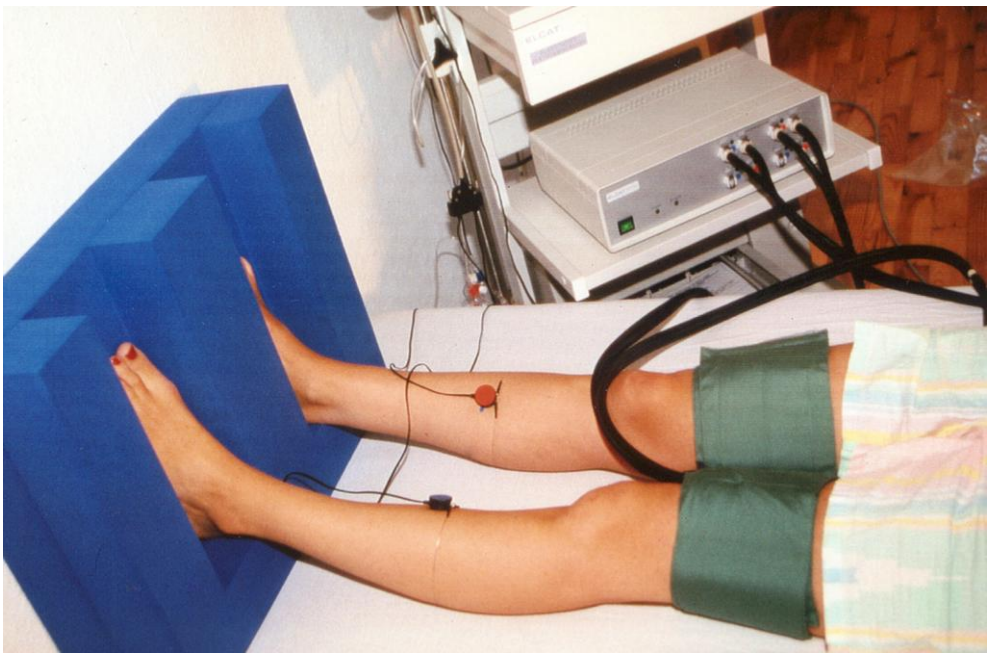

Fig. 7.3.1: Evaluation of Peak Flow

time to peak flow

Second criterion is time to peak flow.

- **Normal**
  Arterial inflow is maximum on first stagnation maneuver and will steadily decay afterwards.
  A healthy patient has this inflow within the first 15 seconds.
- **Pathologic**
  Peak flow happens with delay or not at all in severe cases.

Typical measuring results

Good arterial reserve

- peak flow greater than 12 %/min
- time to peak flow within 15 seconds

  Behaviour shows fast decay and hence good arterial reserve.

Older patients without circulatory disorder

- peak flow rising (peak flow less than 12 %/min)

- slowly decaying peak flow (time to peak flow comes late)

Indications of AVK (arterial circular disorder) at an advanced stage

- Peak flow slowly rising (peak flow less or much less than 12 %/min)

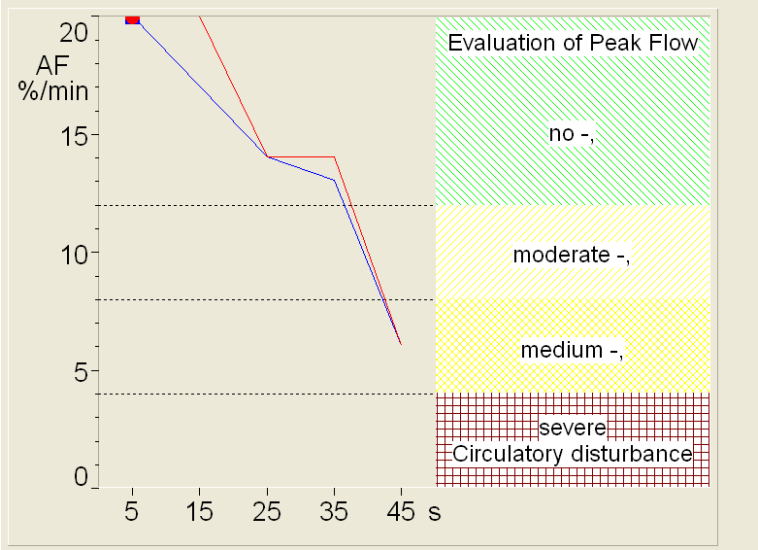

Fig. 7.3.2: Schematic evaluation course of reactive hyperaemia

Medical notes on measuring results

Arterial reserve by side-to-side comparison is performed during routine examination (i.e., at orienting examinations). The measuring results in this case are somewhat lower than at individual measurement. Hence no circulatory disorders can be overlooked.

Arterial reserve should not be performed at borderline cases because the blood volume then to be supplied from the heart can distort the measured values by cardiac factors.

When measurement is repeated on an extremity and significantly higher values are resulting now then this would indicate heart insufficiency.

7.4 Medical Application Fields

General

- Determination of circular arterial disorder severity
- Determination of compensation degree at manifest occlusion
- Exclusion of pAVK

8 O-VOP Optical Venous Occlusion Plethysmography

8.1 Preparing Examination

Examination room

O-VOP examination should take place in a room having normal room temperature (approx. 20 °C / 68 °F), since cold extremities would distort measuring result.

Preparing patient

Prior to examination, patient should stay in a room having normal room temperature for 15 minutes or longer.

Patient should take off shoes, stockings, and tight clothing.

Introduce patient to measuring process.

Positioning patient

Patient takes examination position. Position lying patient's leg such that knee joint is slightly bent and lower leg is placed approx. 20 cm above heart level. Fix heel by support and ease thigh by wedge. Turn knee outward thus avoiding flow impediment. When putting on the leg cuff please take care to place rubber ball on thigh inside since only this will ensure that occlusion pressure will act on the deep venous system.

Place upper part of the body flat and lift head by headrest if necessary.

Put on conical leg cuff such that rubber ball of leg cuff is placed onto inside of thigh with the hoses directing toward knee.

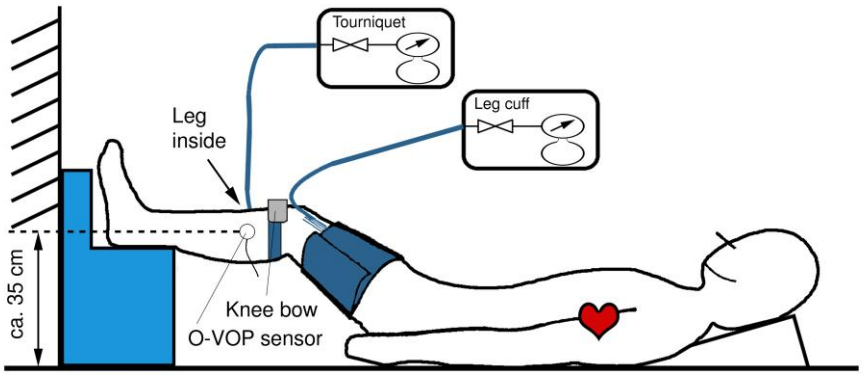

Fig. 8.1.1: Examination arrangement at O-VOP examination

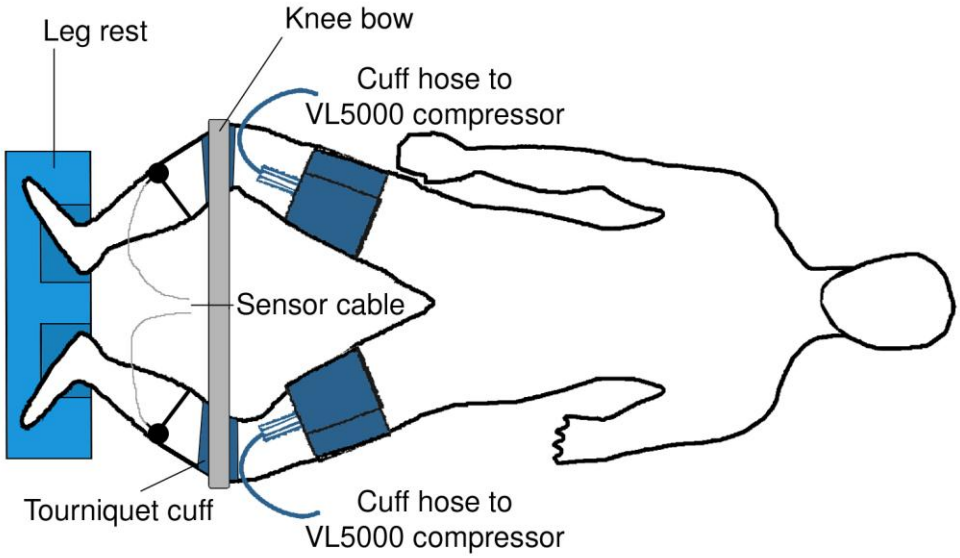

Fig. 8.1.2: Examination arrangement at O-VOP examination

Note You should use a special angiology couch for better standardization of patient positioning.

Positioning sensor and legs

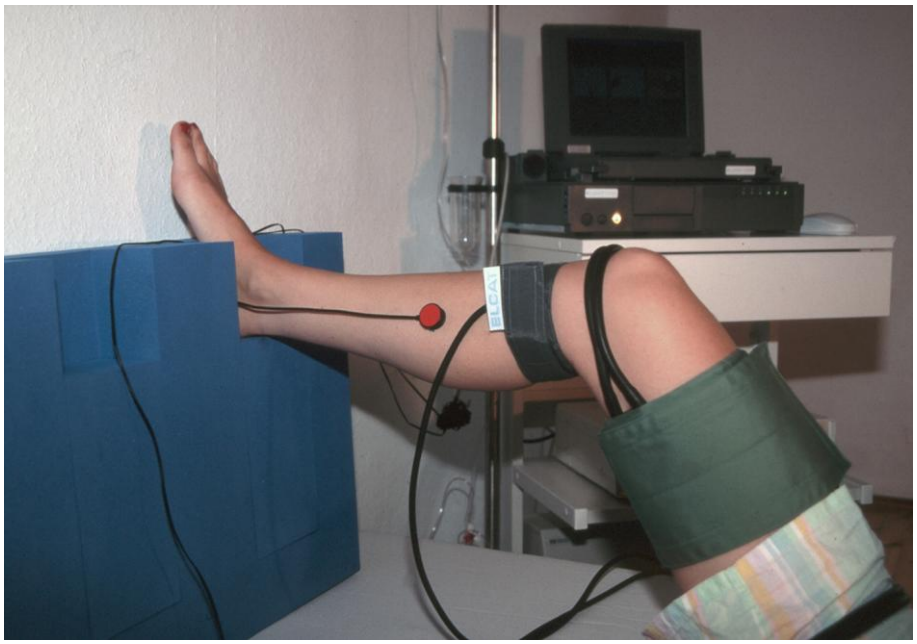

Fig. 8.1.3: Vein occlusion test (O-VOP) with correct sensor position

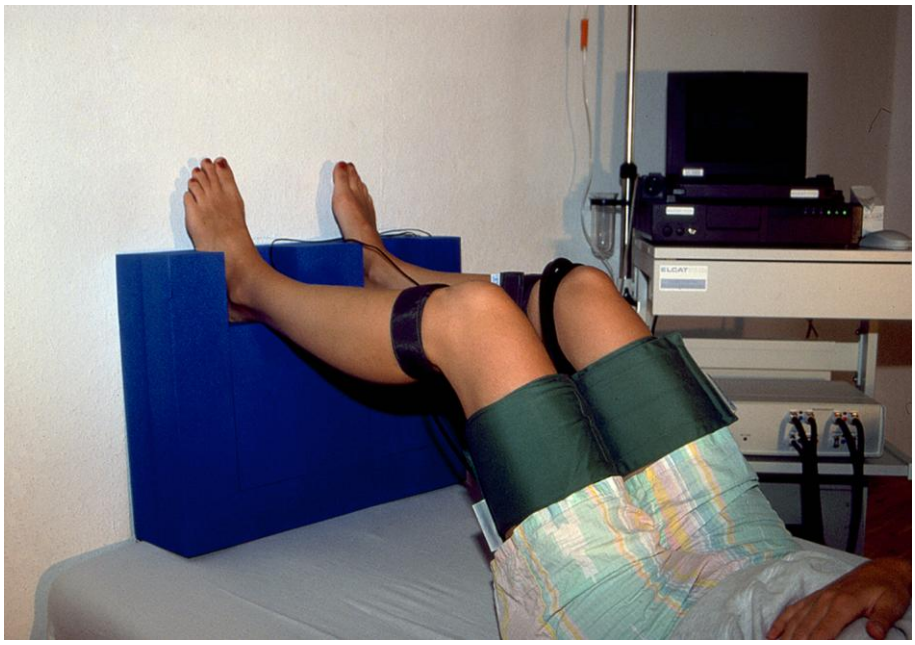

Fig. 8.1.4: Vein occlusion test (O-VOP) with correct sensor position

Putting on optical sensor

Remove sensor junction head from holder placing one of the double-side gluing rings onto face of the sensor junction head.

The sensor junction head is attached to the circumferentially largest point of calf (not above the shinbone) by the pressing double-side gluing ring firmly against the bone. Adjust cable in downward direction.

Carefully remove sensor junction head after end of measurement please.

Caution ⚠ Never remove sensor junction head by pulling cable but by holding it on the sensor junction head shell.

8.2 General Medical Notes

Venous thrombosis is a grave health hazard. There are various plethysmographic measuring methods for phlebothrombosis. The vein occlusion test senses the venous flow of the extremity. Pressure of the venous occlusion cuff should be larger than the existing venous pressure but less than the arterial pressure.

When a patient is subjected to a first O-VOP examination, you should first quantify – particularly when suspecting occlusive arterial vascular disease – a possible arterial circular disorder by e.g. ultrasonic Doppler examination in the ankle area .

You should principally examine both legs of each patient. Never submit an O-VOP result without clinical results.

A pathologic or unclear result must be followed by phlebography if there is no contraindication. A normal result does not exclude femoral vein thrombosis or even intracranial calf muscle sinus thrombosis.

8.3 Notes on Measuring Results

Definition of evaluation parameters

You can take definition of individual evaluation parameters from below figure:

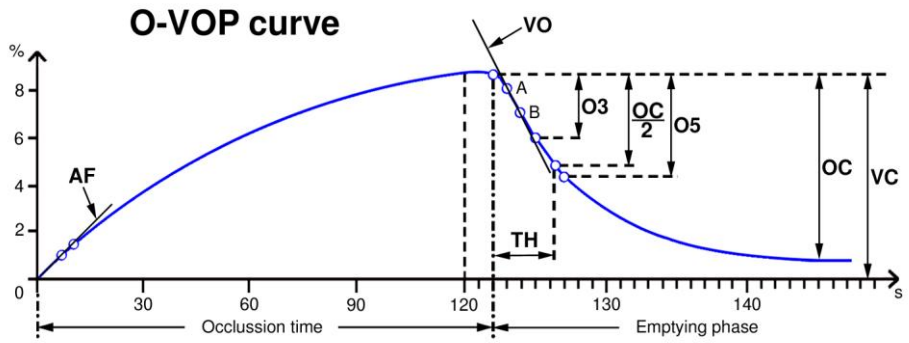

Fig. 8.3.1: O-VOP curve nomenclature and evaluation parameters

VO The most important O-VOP parameter is “venous flow VO”. Venous flow is a straight line determined by points A and B. Point A is the final value of maximum slope and point B the measured value determined 1 second later. VO is the tangent to the (out)flow curve acquiring outflow dynamic.

AF AF evaluates arterial blood inflow into extremity and is the tangent at the beginning of stagnation. The first 30 seconds after initiation of measurement were used for calculation. Rise gradation for a period of 3 seconds is determined for artifact suppression.

VC “Venous capacity VC” is proportional increase of measuring signal. The average of measured values for determining venous capacity is made across 5 seconds before end of congestion.

TH “Venous half-value period TH” is duration between end of congestion and reaching half venous capacity.

OC Outflow capacity OC is the difference between measured value at the end of occlusion and constant measured value during outflow phase.

O3 “Outflow capacity O3” is drop 3 seconds after the end of occlusion.

O5 “Outflow capacity O5” is drop 5 seconds after the end of occlusion.

Categorizing evaluation parameters

We categorize venous flow VO into three groups based on clinic examinations:

- Normal: VO > 30 %/min normal outflow
- Limits: VO 30 up to 15 %/min limiting outflow value
- Pathological: VO < 15 %/min outflow impediment

Following values result for venous capacity VC:

- Normal: VC > 5 %
- Pathological: VC < 5 %
  VC > 10 % Varicosis (primary / secondary)

Note This graduation applies only for evaluating O-VOP parameters.

Medical notes on Measuring Results

Even if O-VOP diagnoses are easily established, never disregard clinical results.

The smaller the parameters the more pronounced the haemodynamic disorder. Only the “venous (out)flow” has been internationally standardized up to now but you will have determined your standard for the other parameters soon.

Repeat measurements where there is a large discrepancy between your clinical results and the measuring results obtained.

8.4 Medical Application Fields

Application fields for venous occlusion testing

General

Diagnostic investigation of haemodynamically effective outflow impediments

- Acute thrombosis
- Postthrombotic occlusions
- Venous stagnation by space requirement
- Haemodynamic follow-ups
- Thrombolysis
- Thrombectomy
- Rethrombosis

Pelvic plane

O-VOP is dependably suitable for diagnosis of pronounced pelvic vein thrombosis.

Femoral plane

O-VOP is dependably suitable for diagnosis of pronounced femoral vein thrombosis.

Crural plane

There are characteristic curves for haemodynamically relevant crural thrombosis i.e., occlusion of several crural veins up to v. poplitea. However, if only one crural vein or calf muscle sinus is occluded then there won’t be a definite curve shape and therefore no definite diagnosis can be made.

Determining haemodynamic parameters

- Venous capacity
- Venous (out)flow
- Arterial inflow

Application fields for filtration test

In addition to venous occlusion testing, following parameters are determined through the filtration test (filtration = venous tightness):

- Differential capacity from 4th minute to 3rd minute

- Differential capacity from 5th minute to 3rd minute
- Differential capacity from 6th minute to 3rd minute

These parameters inform whether and how filtration through venous wall takes place. This would allow, e.g. within the scope of follow-ups, how effective a medicament is that should seal the venous wall.

8.5 Scientific Basics on Measuring Method

General

Application of optical measuring methods on skin has been known to the medical world ever since 1930. CARTWRIGHT used infrared beams for measuring blood circulation fluctuations. In 1938, HERTZMAN found a connection between intensity of skin light reflection and its blood content: He called the apparatus “photoelectric plethysmograph”. Ever since photoplethysmographs have been employed for recording acral or dermal arterial pulsation i.e., for measuring skin perfusion.

The O-VOP sensor (D-PPG sensor) features in-depth optimization using an appropriate wavelength of light and radiation geometry at simultaneous suppression of surface reflection and stray light thus enabling safe sensing of the entire venous cutis plexus.

As opposed to all systems used hitherto, the O-VOP system contains a self-calibrating amplification system by which the reflected input signal is calibrated. During this process, all essential components including the optical sensor are within a microprocessor-controlled loop. This arrangement grants standardized and reproducible measurements independent from skin structure and skin pigmentation. This allows QUANTITATIVE PLETHYSMOGRAPHY for the first time.

Biophysical basics

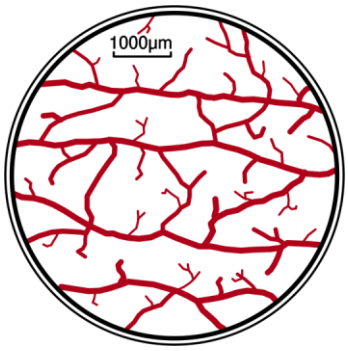

Fig. 8.5.1: Measuring window under the O-VOP sensor

Indicated here are the typical reflection and extinction properties of the human skin. It is known that a particularly favourable “measuring window” for optical sensing is in the 940 nm range of invisible rays. The radiated light is insignificantly absorbed by the epidermis (approx. 15 %). Furthermore, there is a big difference between reflection of bloodless skin and reflection of blood vessels.

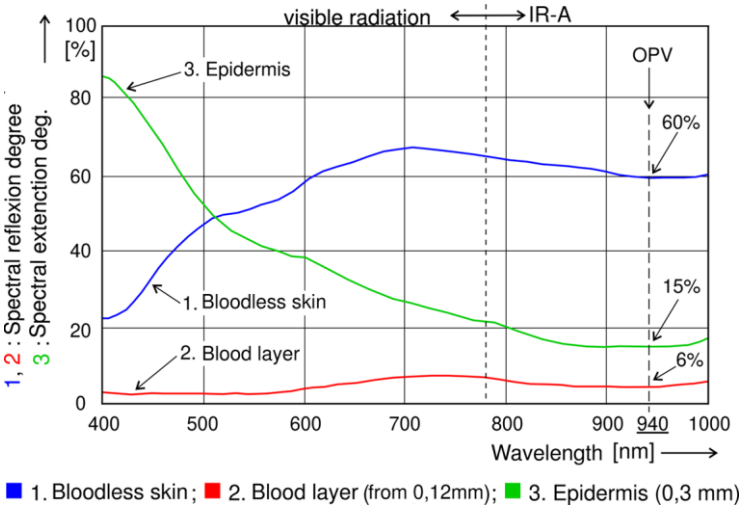

Fig. 8.5.2: Optical characteristics of biological samples in the visible and infrared range

This figure shows a schematic view of skin's vascular system under the O-VOP sensor. Since the filled blood vessels reflect light about 10 times less than bloodless skin tissue would they appear as dark lines against a relatively light surround.

Blood congested by occlusion causes peripheral venous pressure to rise and surface of the elastic, capacitive vessels to enlarge. This reduces mean measuring window reflection recorded by rise of the OVP curve. So the OVP optoelectric measuring principle is based on acquisition of reflection fluctuations of subepidermal skin layers, before and after occlusion, where the changes are caused by filling fluctuations in the skin vessel plexus.

The Tourniquet cuff manages to tie the surface venous system haemodynamically stronger to the deep venous system.

Following biophysical laws are used

There is a direct and immediate connection between the deep venous system filling states of the lower extremities and the degree of filling of the cutis vessels sensed by the O-VOP system.

Any change of pressure in the venous vessel system causes a change of vascular surface and thus change of O-VOP signal.

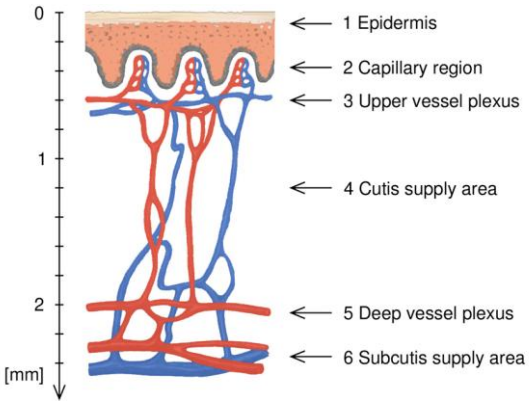

Fig. 8.5.3: Topography of the skin vessels in the lower leg (schematic)

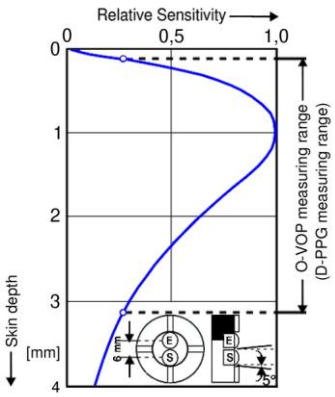

Fig. 8.5.4: Relative sensitivity of O-VOP sensor as a function of skin depth

Besides transmitting diode S and detector diode D there is a micro signal amplifier inside the O-VOP sensor. The O-VOP sensor measuring range is defined by 1/e decay of maximum sensitivity. It is approx. 0.1 to 3.1 mm enabling safe reaching and evaluation of the cutis vessel plexus.

8.6 Technical Information on Measuring Method

O-VOP sensor (D-PPG sensor)

The O-VOP sensor (D-PPG sensor) is directly connected to the equipment through a non-buckling cable. It contains two optoelectronic measuring elements with integrated lenses. The transmitter sends infrared waves into the skin and the receiver picks up the reflected light waves.

Measuring process

The O-VOP measuring process consists of five execution phases all of which being microcomputer-controlled and running fully automatic. Below figure shows the automatic measuring process and illustrates the individual program steps.

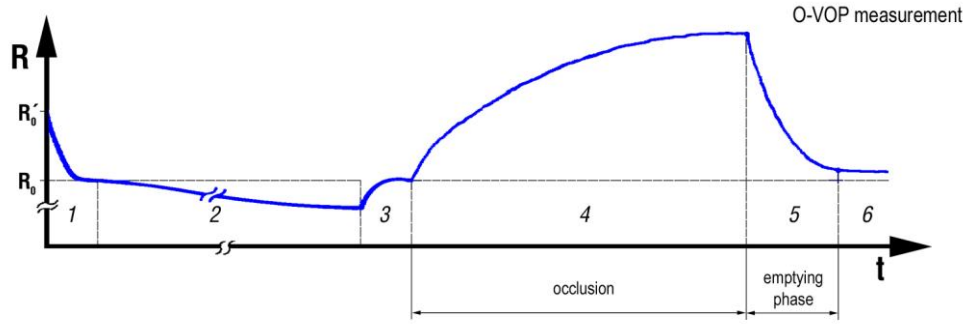

Fig. 8.6.1: Automatic measuring process of O-VOP measurement procedure

1. **Automatic calibration**

   Individual measuring value R_0 is calibrated against specified initial value R_0 (baseline of O-VOP curve).

2. **Determination of stationary resting flow**

   The quiescent value is reached when two subsequent average values do not have great difference for 4 seconds. 30 seconds latest after, however, measurement will start anyway.

3. **Further calibration**

   A further calibration will correct possibly occurred drift.

4. **Stagnation phase**

   Execution of venous occlusion for selected stagnation time

5. **Outflow phase**

   The examiner can view the resistance changes generated by venous outflow on the display.

6. **Evaluation**

   The haemodynamic parameters are automatically calculated after end of measurement.

9 Intended Use

O-PO

In pulse oscillography, arterial pulsation is acquired with aid of optical sensors. This can be made at different application locations (fingers, toes, or other skin areas). In this process, arterial pulsation on fingers, toes, or other skin areas is evaluated in order to gain information on circulatory disorders. Depending on type of sensor, only superficial or also the deeper vessels are sensed.

O-AP

In acral blood pressure measurement, optical sensors sense arterial pulsation. Using inflatable stagnation cuffs, acral vessels (fingers or toes) are compressed such that systolic blood pressure can be determined by change of pulsation curve. It also allows statements on patency of major arteries lending itself to screening method owing to simple and fast practicability.

P-SPO

In segmental pulse oscillography, inflatable stagnation cuffs are compressor-controlled such that cuff pressure is changed starting from high cuff pressure in freely adjustable pressure increments. Inflatable stagnation cuffs themselves serve acquisition of pulsation on extremities (arms or legs) at the same time. Segmental pulse oscillography serves for documenting pulse palpation result and localization of arterial occlusions (also by side-by-side comparison). Segmental pulse oscillography serves acquisition of haemodynamically effective stenoses after patient's exercise.

D-PPG

Diagnostic venous function investigation with optical sensors is performed at D-PPG (LRR) application. Venous pump power is generated by patient's dorsal extensions or tiptoe standings. Refilling time and venous pump power allow evaluation of venous haemodynamic.

PDM

The absolute venous pressure is acquired when phlebodynamometry is performed. Venous pressure is changed by patient's dorsal extensions or tiptoe standings. Evaluation of static pressure, differential pressure, minimum pressure, and venous refilling time allow evaluation of venous haemodynamic.

SG-VOP

Performing a venous occlusion test, venous blood is build up under a stagnation maneuver. The inflatable stagnation cuffs are quickly deflated at the end of stagnation time. Under SG-VOP, strain gauge sensors are used for recording circumferential changes of patient's legs. Dynamic of venous flow is used for detecting outflow impediments (thromboses, etc.) SG-VOP application fields are:

- Diagnostic investigation of haemodynamically effective outflow impediments
- Diagnosis of pelvic vein thromboses, popliteal vein thromboses, and calf vein thromboses

SG-AR

Supporting determination of arterial reserve (reactive hyperaemia), an inflatable stagnation cuff generates interruption of arterial blood supply. The inflatable stagnation cuffs are quickly deflated at the end of stagnation time. Under SG-AR, strain gauge sensors are employed. After that, a further outflow and stagnation maneuver will follow in rapid succession.

Time course of arterial inflow generates the evaluation parameters for arterial reserve.

O-VOP

Performing a venous occlusion test, venous blood is build up under a stagnation maneuver. The inflatable stagnation cuffs are quickly deflated at the end of stagnation time. O-VOP uses an optical sensor. Dynamic of venous flow is used for detecting outflow impediments (thromboses, etc.) O-VOP application fields are:

- Diagnostic investigation of haemodynamically effective outflow impediments
- Diagnosis of pelvic vein thromboses, popliteal vein thromboses, and calf vein thromboses