Comparative studies on the reduction of the risk of deep vein thrombosis by intermittent compression of the Cockett I perforating veins.

BY STEFANIE WECKESSER

1. Background

- The calf muscle pump is crucial for venous return in the lower extremity.
- This only works when the calf muscles are tensed.
- To date, there are no studies or investigations on the function of the calf muscle pump when the calf muscles are relaxed.
- From a phlebological point of view, a continuous flow would be desirable.

Reason:

The risk of DVT is reduced the more continuous and the better the flow in the deep leg veins.

1. Background

- Compression stockings or compression bandages are often used for venous disorders.

<u>Disadvantages:</u>

- Venous blood is transported only when the muscle pump is activated, not when the calf muscles relax.
- The therapy compression stockings may cause local constriction for the patient or slipping when worn for a long time.
- The therapy of the compression bandage depends mainly on the experience of the person applying the bandage.

1. Background

New principle to increase the flow in the deep leg veins

Intermittent compression of the Cockett I perforating vein (ICCV)

2. Goal of the Study

- Investigation of the new active principle (ICCV) or the newly developed teveno active socks and their effect on blood flow in the venous system of the lower extremity
- Quantification of the flow in the popliteal vein by means of color-coded Dupelx sonography while wearing the teveno active socks
- Conclusions on possible areas of application for the teveno active socks and their applicability in the treatment of CVI and its precursors.

2. Goal of the Study

Verification of the hypothesis :

By wearing the teveno active socks, the flow in the popliteal vein during heel loading is much higher than when wearing the traditional class two medical compression stockings.

3. Principle of teveno active socks

- In the ankle region, there is no system that transports blood from the superficial to the deep leg vein system.

Consequence:

- Increased venous pressure in the ankle region.
- This in turn can result in pathological skin changes such as eczema, ulceration or pigmentation.
- Intermittent compression can be used to achieve that the venous pressure on the superficial venous system is reduced by the pressure exerted on the Cockett I perforating veins.

Consequence:

- An increase in flow to the deep venous system of the leg

3. Principle of teveno active socks

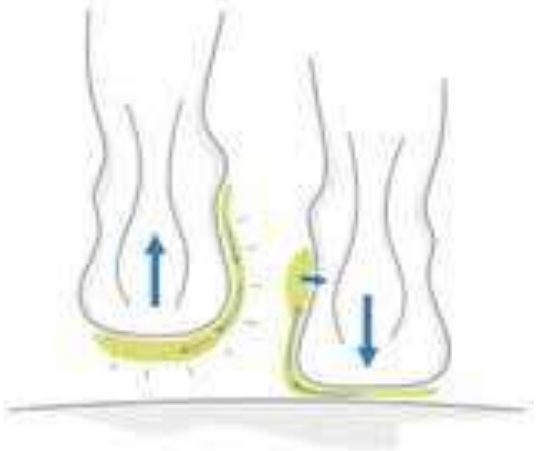
An air-filled cushion ("pad") was sewn into knitted diabetic socks.

3. Principle of teveno active socks

- The air-filled cushion (“pad”) is directly connected to an airless air cushion in the dorsal region of the medial malleolus, where an important perforating venous system is located: The Cockett I perforating veins

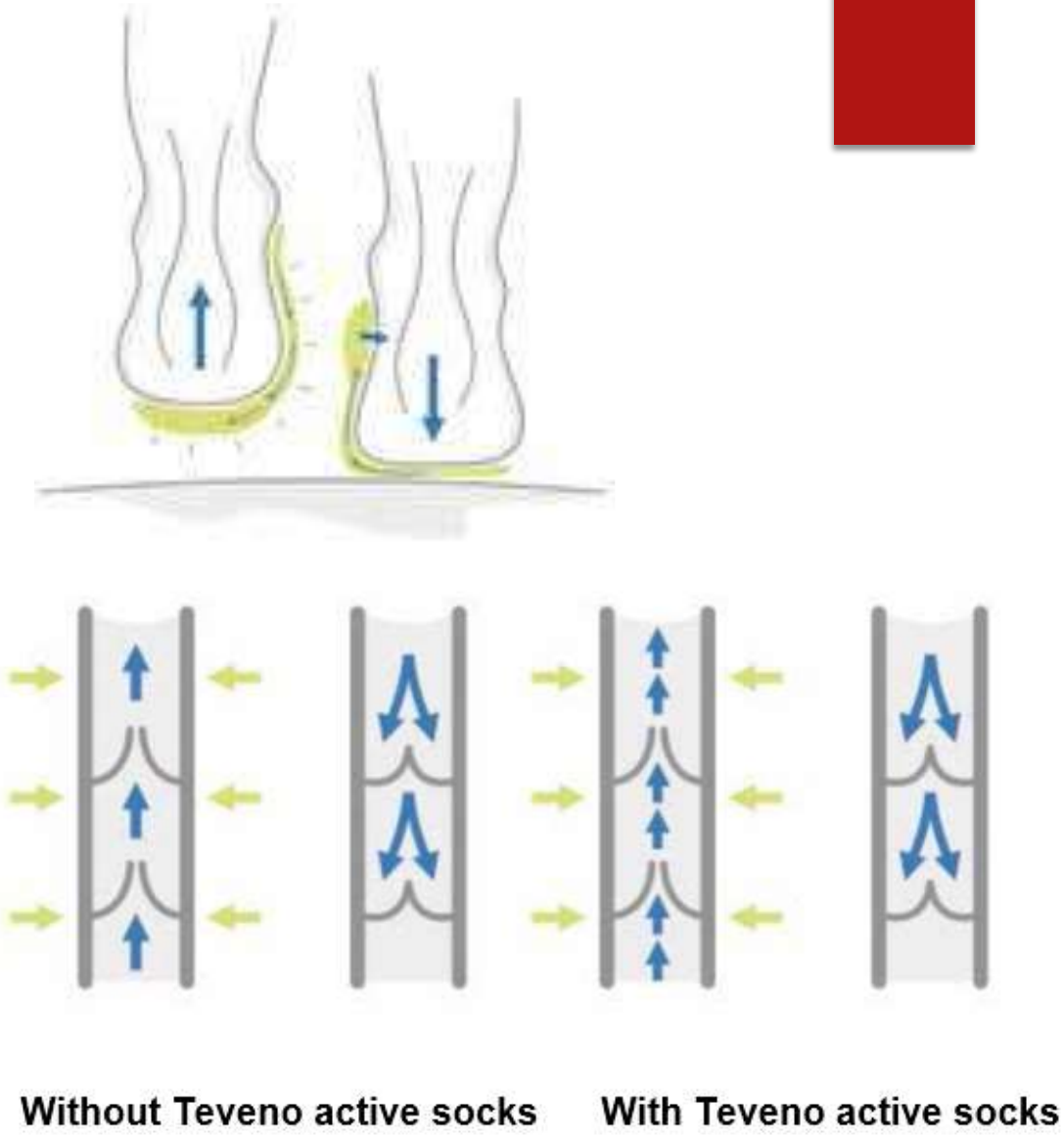
3. Principle of teveno active socks

- This is where the active principle of teveno active socks comes in.
- Every time pressure is applied to the heel cushion, the inner ankle cushion fills up.
- Our current development does not need the 2.5 cm wide plastic band to secure the pad



3. Principle of teveno active socks

- Venous blood is actively transported from the superficial leg vein system via the Cockett I perforating veins into the deep leg vein system.
- Each pressure pulse promotes and increases the active return flow of venous blood from the legs.



4. Study subjects

- Number: 100.
- Employees and patients of the accident surgery and orthopedic department of the clinics Dr. Erler Nuremberg as well as test persons from the practice for general and vascular surgery of Prof. Dr. med. H.-J. Günther (Nuremberg)
- Age : 17-69 years
- Average age at the time of the examination : 43.3 years

4. Study subjects

- 34 male subjects (average age 53.4 years)
- 66 female subjects (37.8 years)

Selection criteria:

- Obtain a broadly diversified collective of test persons
- Consideration of certain inclusion or exclusion criteria

4. Exclusion criteria

- Polyneuropathy
- Deep vein thrombosis of the right leg within the last three months
- Currently after surgery in the area of the veins in the area of the right leg within the last three months
- Presence of allergies to the material used for the compression stockings or the teveno® active socks
- Presence of a PAD
- if you have severe heart disease
- Presence of severe renal insufficiency
- Diabetes mellitus with micro- or macroangiopathies
- acute eczematous skin changes as a result of chronic dermatoses
- Leg edema that is not due to chronic venous insufficiency
- Presence of pregnancy
- Immobility
- Dementia
- Participation in another study

4. Inclusion criteria

- Age of at least seventeen years
- Study participants of both sexes
- Declaration of consent of the test persons
- Willingness of 48 further test persons to wear the teveno® active socks for another four weeks and thus participate in a follow-up examination on a voluntary basis

5. Methodology

- For anonymization, each test person was assigned a number from 1-100.

Based on a patient questionnaire, the following parameters were collected during anamnesis:

- Gender and age of the subjects
- DVT in the past and /or ulcus cruris or DVT with pulmonary embolism in consequence
- Existing varicosis
- Varicose vein surgery
- Heart failure
- Existing chronic lip or lymphedema
- Orifice valve insufficiency of the great saphenous vein or of the great saphenous vein and the saphenous vein parva

5. Methodology

- Color-coded duplex sonography under different conditions
- Duplex sonography on the right leg
- First, the function of the orifice valve of the great and small saphenous veins was visualized.

5. Methodology

The flow in the popliteal vein (deep leg vein system) was then examined using color-coded duplex sonography in 100 subjects under the following examination conditions:

- Flow in standing position
- Flow with heel load after toe position
- Flow at heel load after toe stand with compression stocking Class two
- Flow during heel load after toe position with teveno® active socks

5. Methodology

- Following the color-coded duplex sonography, in which the medical effectiveness of the teveno® active socks could be verified, a further application observation over four weeks took place in 48 test persons.

The following parameters, among others, were recorded:

- Comfort of wearing/handling of the socks, including during sports activity
- Comprehensibility of the instructions for use
- Change in the tendency to swell in the lower leg/ankle region
- Overall satisfaction with the product

6. Results

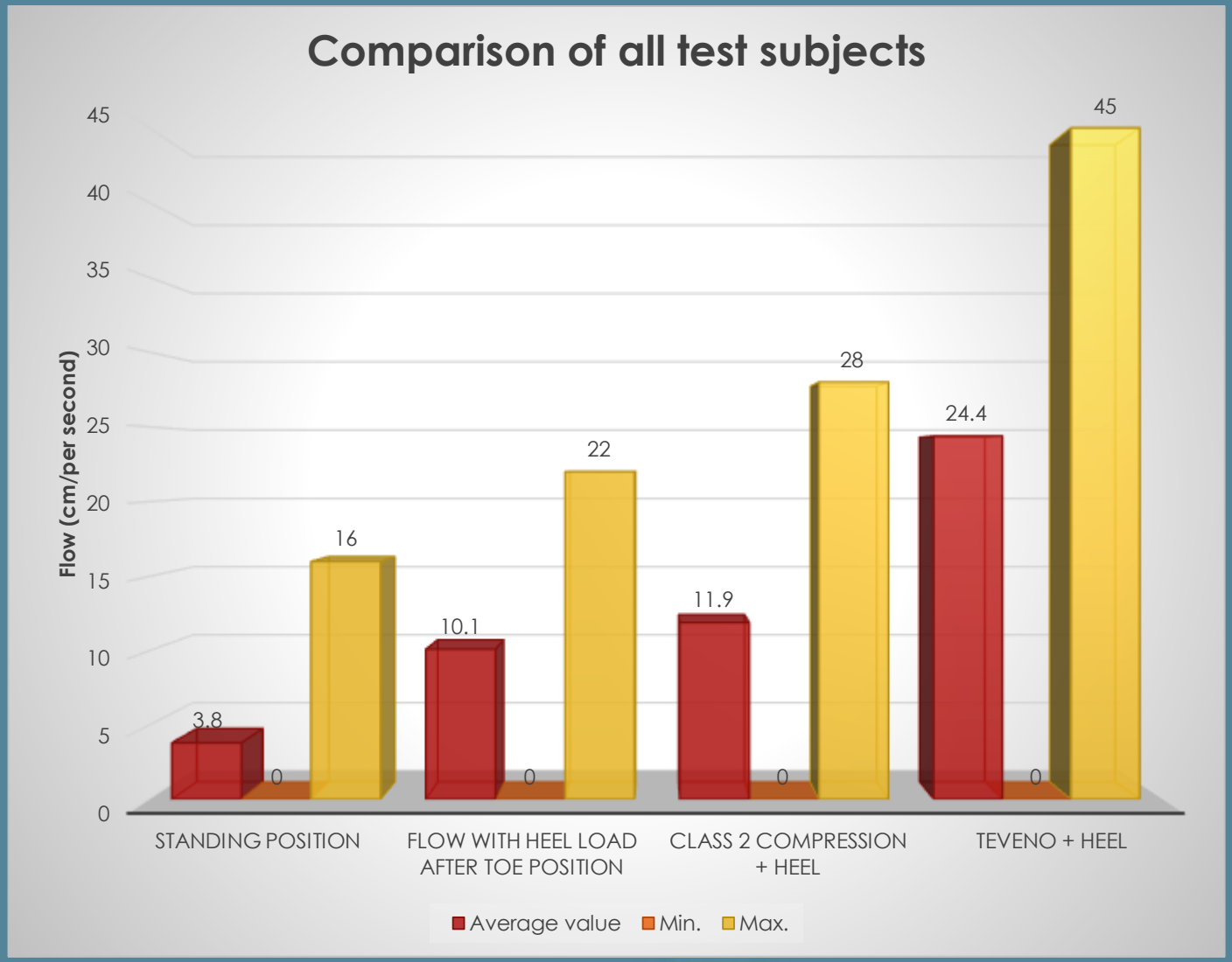
6.1 Secondary diagnoses

History of DVT	6 subjects (6%)
History of Ulcus cruris	1 subject (1%)
Varicosis	21 subjects (21%)
Varicose vein surgery	21 subjects (21%)
Chronic edema	1 subjects (1%)
Valve insufficiency	
of the great saphenous vein	18 subjects (18%)
great and small saphenous veins	7 subjects (7%)

6.2 Measurement flow in V. Poplitea

6.2.1 Comparison of all test subjects

- A total of 100 volunteers participated in the study (34 male / 66 female)



6.2 Measurement flow in V. Poplitea

6.2.1 Comparison of all subjects

The results show that the flow in the popliteal vein when the heel is loaded, i.e. in the "passive phase" after the toe position (calf muscle pump),

- is about 100% higher when compared to normal conditions and
- more than 70% higher when using class 2 medical compression stockings.

Result:

- This means that venous blood is transported towards the heart with every movement of the leg.
- The risk of deep vein thrombosis can thus be significantly reduced with teveno® active socks.
- There is also a significant reduction in edema in the distal lower leg and ankle area. Slag is more quickly removed from the muscles.

6.2 Measurement flow in V. Poplitea

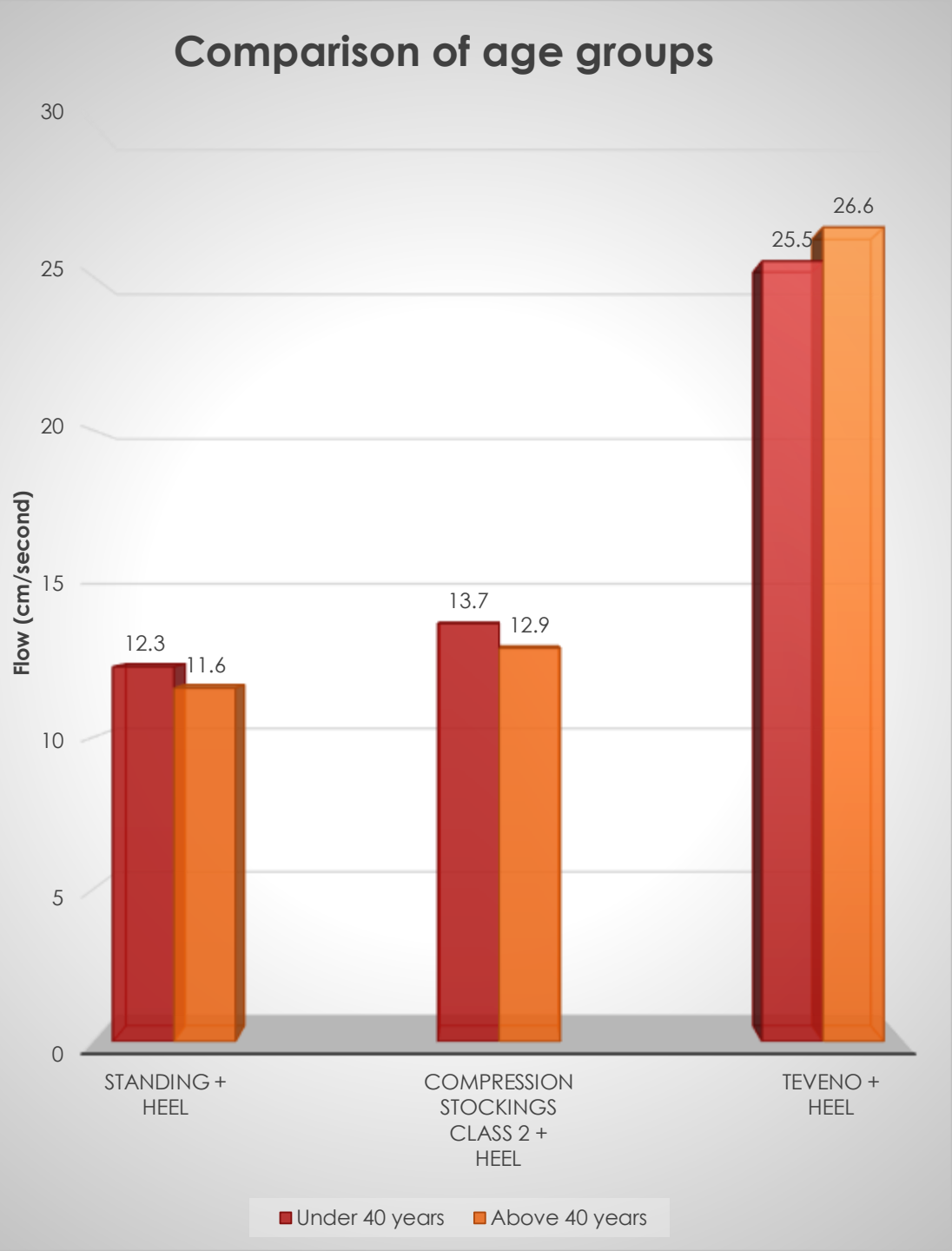
6.2.2 Comparison of age groups

- The age of the test persons ranged from 17 to 69 years at the beginning of the study
- The average age was 43.3 years
- 40 subjects had an age below forty years at the beginning of the study
- 60 subjects had an age below forty years at the beginning of the study

6.2 Messung Flow in V. Poplitea

6.2.2 Comparison of age groups

- Measurement of flow in the popliteal vein in the selected age groups (under or over 40 years).



6.2 Measurement flow in V. Poplitea

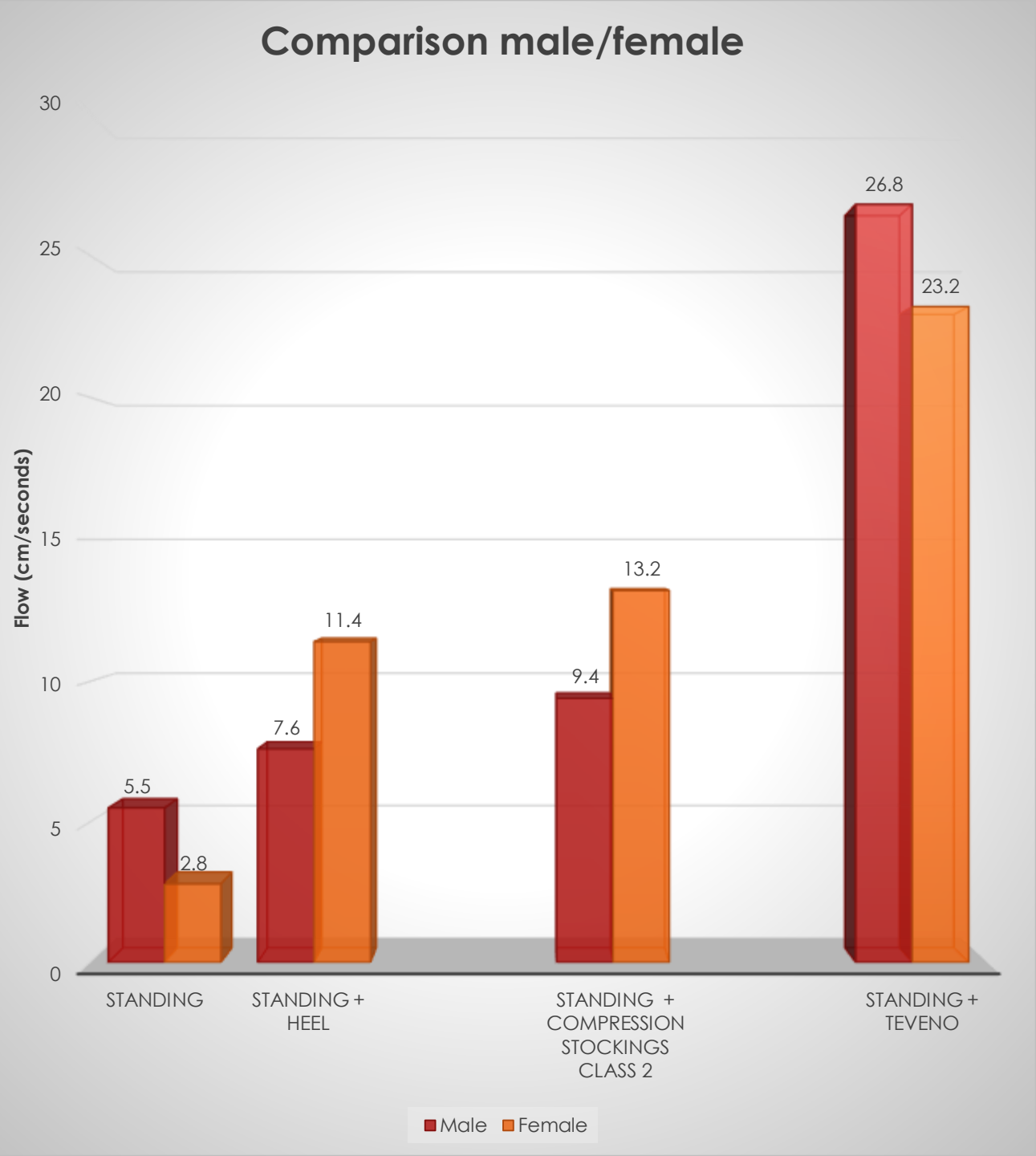
6.2.2 Comparison age groups

- Flow in the popliteal vein is almost 100% higher when teveno active compression socks are worn.

6.2 Measurement flow in V. Poplitea

6.2.2 Comparison male/female

- 66 female and 34 male subjects participated in the study.



6.3 Evaluation of the application observation

- The socks were worn for an average of 8 hours (2.5-12 h) per day
- The teveno active socks were worn exclusively during the day.
- The socks were worn at work, during sports or everyday situations.

Scale of 1 (very good) to 6 (unsatisfactory).

- Understanding of the instructions for use: grade 1.7
- Putting on the socks: Grade 2.1
- Wearing comfort of the socks: Grade 2.3
- Reduction of the swelling in the lower leg and ankle area: grade 2.3
- Wearing during sports: grade 2,4
- Overall satisfaction: grade 2.2

7. Discussion

- In recent years, medical compression stockings (MCS) (9)(4) or, less frequently, intermittent pneumatic compression (IPC) (5) (6) (7) have proven to be the most effective for acute or chronic symptoms of chronic venous insufficiency.

By definition, the medical compression stockings (MSC) class 2 ensures a:

- Reduction of the vein cross-section to accelerate venous and lymphatic return flow
- Improvement of venous valve function
- Reduction and prevention of limb edema

7. Discussion

Absolute contraindications for compression therapy are:

- advanced peripheral arterial occlusive disease
- decompensated cardiac insufficiency
- septic phlebitis
- Phlegmasia coerulea dolens

In addition, there are relative contraindications for:

- Pronounced weeping dermatoses
- Intolerance to compression (stocking) material
- Severe sensory disorders of the limbs
- Advanced peripheral neuropathies (e.g. Diabetes mellitus)
- Primary chronic polyarthritis

7. Discussion

Consequences of improper handling of medical compression stockings:

- Skin necrosis
- Pressure damage to peripheral nerves

- Since there are often difficulties in putting on the medical compression stockings, this results in poor compliance.
- The IPC is of limited use in everyday life due to the high cost factor and the special construct features.

7. Diskussion

Due to new active principle of intermittent compression of the Cockett I perforating veins

- Venous blood is actively transported from the superficial leg vein system via the Cocket I perforator veins into the deep leg vein system
- Due to the active principle of action, compression of the leg is no longer necessary

Result:

- Thus, there are no contraindications for diabetics and patients with peripheral arterial disease
- Nerve damage is avoided

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