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Orthotics

Peer-Review

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Development of an Orthotic Ankle Joint with a New Type of Return Spring Element

The treatment of neurologically affected patients with their individual needs presents prosthetics and orthotics with new challenges every day. It is extremely important to take a precise medical history in order to identify the patient's weaknesses and strengths and to draw up a clear plan of action for the technical fitting.

Orthotic treatment in particular requires comprehensive biomechanical knowledge, a technical understanding of mechanics and a sense of form when measuring and designing the contact surfaces close to the body. The gait mechanism is a complex process that is controlled by the interaction of muscles, joints, the nervous system and the sense of balance. Basic knowledge of the anatomical structures is also required in order to classify pathological movement patterns and design appropriate treatment strategies. The resulting mechanical requirements for an ankle orthosis joint are of great relevance to ensure adequate patient treatment.

So-called system joints from different manufacturers are typically based on known mechanical technologies and spring element concepts, which have various advantages and disadvantages.

This was the approach for the new development of the CarbonFlex (CF) system ankle joint, which aims to compensate for known weaknesses of previous designs and improve patient care. An overview of the development process and the preliminary results will be given here.

Key words: System Joint, CarbonFlex, Ankle Joint, Functional Compensation, Rolling Behaviour

The ankle joint of the human body

The three-dimensional movement of the ankle joints enables an efficient rolling movement of the foot during walking and running by allowing the joints to react to different loads and surfaces. It is important to emphasise that these movements do not take place in isolation from each other, but in a coordinated interplay.

The movements in the three main planes – the sagittal plane, the frontal plane and the transverse plane – are described in Figure 1 according to [1].

The functional compensation of orthotic ankle joint systems usually focuses on the upper ankle joint, which enables essential functions for effective locomotion. Pathological movement patterns lead to significantly reduced mobility in the affected patients.

As can be seen in Figure 2 according to [1], a distinction is made between active (internal force) and passive (external force) range of motion. According to the neutral-zero method, there is an active mobility of 20-0-40, which is not fully utilised in gait. Approximately 10° dorsiflexion and 15° plantar flexion are required in the normal gait cycle [2].

The lower ankle joint essentially has the function of shock absorption and adaptation to different surfaces. Functionality at this joint level is often significantly restricted by the structure of the orthotic restoration. In orthotics, the lower ankle joint is usually taken into account in a correspondingly partially elasticated foot shell with an elastic footbed [1].

Relevant forces within anatomical structures

In biomechanical terms, the foot has to cope with many tasks and ensures that it can bear many times the weight of the body. The foot also transmits the forces that serve to regulate balance as well as locomotion. The foot has a complex bony, muscular and ligamentous structure to fulfil the diverse requirements (Fig. 3). This allows the foot to change its position, shape and stiffness as required. The arrangement of the foot bones forms a characteristic longitudinal arched shape. The transverse arch is formed by the metatarsal bones, which is caused by muscular and fascial tension. This is primarily used to generate the required stiffness of the forefoot in the push-off phase [3].

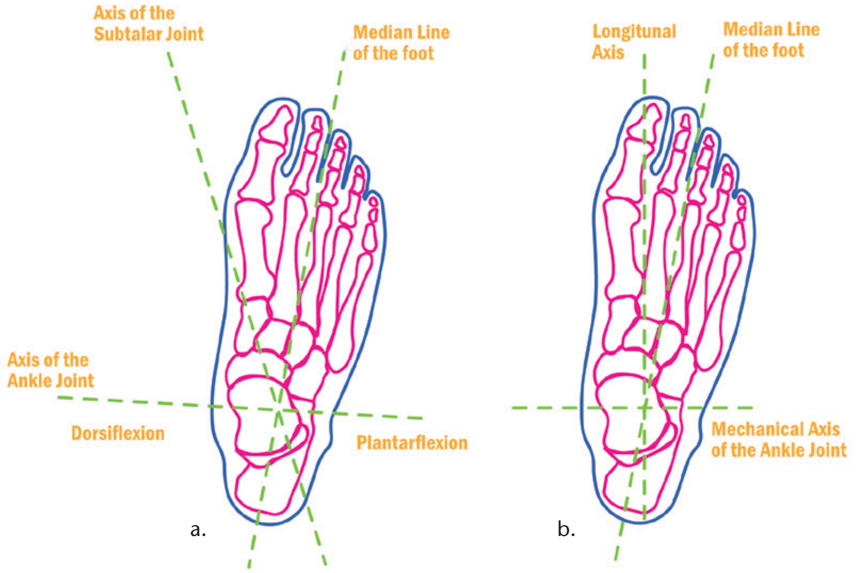

***Fig. 1a** and **b** Technical axes: overview of transverse upper ankle joint/lower ankle joint **(a)**, alignment of the technical axis of the upper ankle joint in relation to the longitudinal axis of the foot **(b)**.*

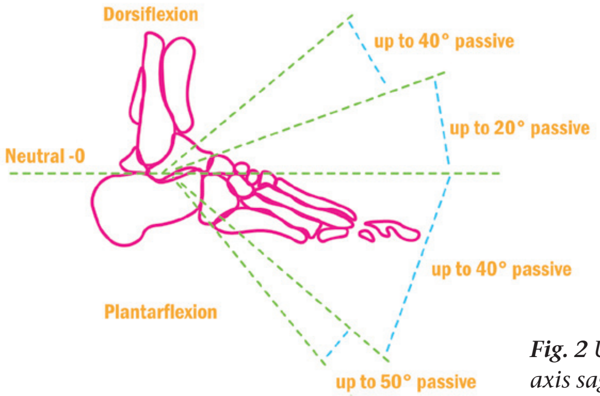

***Fig. 2** Upper ankle joint axis sagittal RoM.*

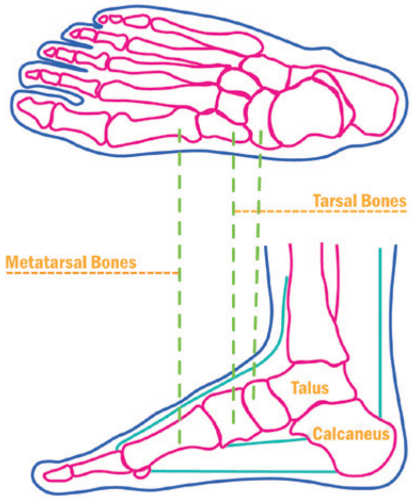

***Fig. 3** Views of the foot skeleton [3].*

The upper ankle joint and the lower ankle joint allow movement in two different anatomical axes as well as compound movements due to the structural arrangement of the bones in the midfoot. The kinematics of the foot are essentially determined by the upper and lower ankle joint. The talus has a special position here because it is involved in both joints and does not have its own muscle insertion. The muscles overstretch the talus, which is why the acting forces must be compensated by the muscles. In addition, both axes cross in the sinus tarsi, which describes the coupled functionality in the sense of an atypical cardan joint [3].

Pathological movement patterns and corresponding countermeasures

The categorisation of gait types according to the N.A.P. Gait Classification, for example, describes four different types of gait. The present talus malalignment in inversion and eversion requires a compensatory hyperextended or hyperflexed knee position of the affected patient [4]. Even if the pathological muscle functions are responsible here, it is clear that the correct static base of the talus is necessary to enable efficient locomotion. Physiotherapeutic and orthotic interventions offer good options here.

Qualified physiotherapy uses the heel tilt lever function to train natural gait patterns. In this stretch-shortening cycle, correct neuronal connections in the brain are strengthened by motor impulses and specific muscle groups are strengthened through targeted strength training.

Kinematically, the ground reaction force during the initial contact and the loading response generates a torque in the upper ankle joint, which leads to rotations in the upper ankle joint and around the heel strike point and causes passive plantar flexion of the foot. Kinetically, the tibialis anterior muscle works eccentrically against this plantar flexion, which enables controlled lowering of the foot.

Can a mechanical joint replace the missing muscle functions?

In everyday movement, concentric and eccentric contractions work together alternately to enable complex and precise movements. The terms "concentric", "isometric" and "eccen-

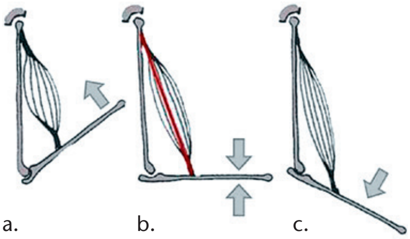

***Fig. 4a-c** Principle of the different forms of contraction [6]: concentric **(a)**, isometric **(b)** and eccentric **(c)**.*

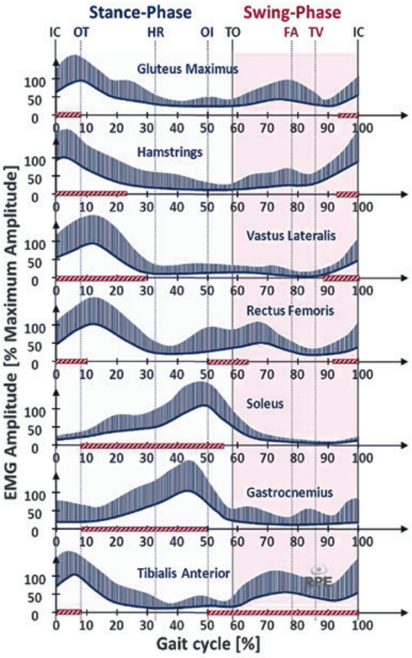

***Fig. 5** Overview of EMG Gait Cycle [7].*

tric" refer to different phases of muscular contraction and stretching during movement (Fig. 4).

Concentric muscle contraction: Concentric contraction occurs when the muscle actively shortens to perform a movement. In the case of the lower leg muscles, especially the calf muscles, this happens during active plantar flexion in terminal stance/pre swing. During this movement, the muscle fibres contract and the muscle becomes shorter [2].

Isometric muscle contraction: Isometric muscle contraction occurs when the muscle contracts statically and the adjacent body parts do not change angle. Strength is therefore built up without changing the length of the muscle. This occurs, for example, during the co-contraction of the lower leg muscles in a stable stance under load.

Eccentric muscle contraction: Eccentric contraction occurs when the muscle continuously lengthens while resisting a load. In the case of the pretibial musculature, this occurs when the foot is lowered during the inital contact/loading response [2].

Relevant muscle activities in the human gait cycle

The overview of the EMG amplitudes with the peak values of the relevant muscle groups in Figure 5 provides a good overview for the overall assessment of the concentric and eccentric muscle functions that occur. In order to develop an appropriate care strategy, the pathological muscle deficits define the technical requirements for patient care.

As an example, dorsiflexion of the upper ankle joint in mid stance/terminal stance is initiated by external ground reaction forces. The strongest moments in the upper ankle joint occur before the so-called push-off in the terminal stance phase (Fig. 6). This is countered by the compensatory forces of the lower leg muscles (muscle contraction), which are shown in the performance diagram (Fig. 7). This shows that a corresponding torque always requires an antagonistic counterforce in order to restore the necessary balance of forces.

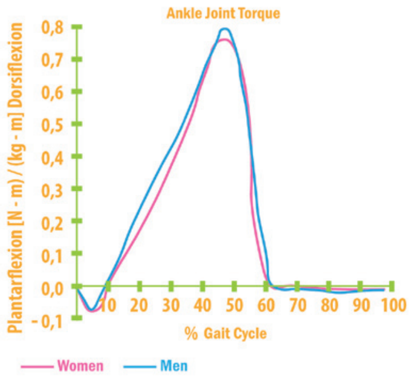

***Fig. 6** Calculated torque for upper ankle joint [8].*

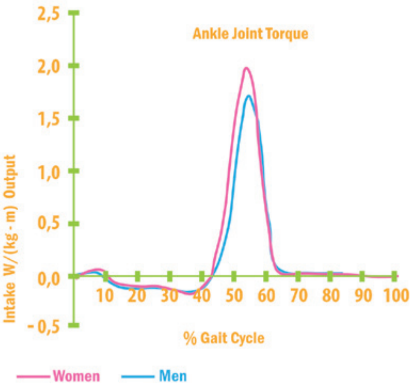

***Fig. 7** Calculated muscle power [8].*

Interim conclusion

Current mechanical orthotic joint systems can provide good support for eccentric muscle function and limit pathological movement deflections. However, these reach their limits when balancing concentric activity. By design, the dynamic return always goes back to the set zero point of the joint, which is not physiological in certain gait phases. One example of this is the terminal stance phase. The concentric function of the calf requires an angular change in the ankle joint from 10° dorsiflexion to 15° plantar flexion in the normal range in order to generate the necessary push-off.

Development of a new type of orthotic joint

State of the art

The development of a new type of orthotic joint was initiated as part of the joint research project “FlexOr” (ZF 4451701AK7) of the Central Innovation Programme for SMEs (Zentrales Innovationsprogramm Mittelstand, ZIM), funded by the German Federal Ministry of Economics and Climate Protection (Bundesministerium für Wirtschaft und Klimaschutz, BMWK). Firstly, the state of the art was analysed.

With a few exceptions, the most common ankle joint constructions

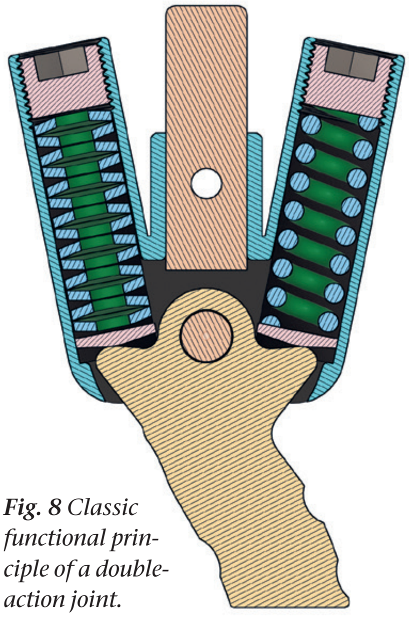

***Fig. 8** Classic functional principle of a double-action joint.*

are used to compensate for functional disorders in the upper ankle joint. As is well known, this is where the greatest forces and angular changes occur, which are decisive for effective propulsion in the gait cycle. The designs are so-called double-action joints, in which movement deflections and the load resistances can be adjusted independently in both directions of movement (Fig. 8).

In conventional joint systems, the spring assemblies are each arranged at a specific angle to the system stirrup to ensure optimum absorption of the forces. During the gait cycle, the foot stirrup compresses the corresponding spring elements in the stance phase and releases the stored energy when the load is released.

The following features of existing joint systems were identified:

- **High mass and large installation space:** current orthosis joints have a high structural mass and a comparatively large installation space. This results, among other things, from the biomechanical requirements, such as achieving a high restoring force. Due to the predominant use of sometimes solid helical or disc springs made of steel, correspondingly large installation spaces are required, resulting in a high component mass.
- **Noise-intensive use:** current orthosis joints have acoustically perceptible operating noises due to their design. This is a major limitation, particularly with regard to patient acceptance (compliance).
- **Complex designs:** the use of disc and coil spring concepts requires complex design implementation. This in turn requires the use of experts for the sometimes complex and time-consuming assembly and adjustment of existing systems. This means that adjustments to existing systems can sometimes only be achieved by adjusting the spring unit, which can favour incorrect adjustment of the components.

Requirements for a new spring joint

The following objectives were derived from this for the development of a new joint approach:

- **Improved compliance:** improved acceptance by leg orthosis wearers should be achieved by minimising the installation space and structural mass. At the same time, a new joint should minimise noise emissions.
- **Simple design:** the new joint mechanism should be as easy to install as possible, require little maintenance and ideally be easy to adjust. The number of necessary components should be reduced to a minimum. The current standards regarding the avoidance of clamping hazards and the use of established system widths should also be complied with.
- **Desired range of functions:** the new joint should have full spring force with full range of motion wherever possible. This means that a deflection of 20° in each direction of movement (plantar flexion/dorsal extension) should be possible regardless of the spring force. It should also be possible to restrict the manoeuvrability at a later date with adjustable stops. In addition, the joint angle (range of motion) should also be adjustable up to complete blocking of the movement deflection. This is necessary in order to be able to make adjustments in the event of a change in status or a minor position correction, but without pretensioning the springs differently so that the maximum spring travel is always available.

Design description of the innovative ankle joint

Initially based on a coil spring approach, a design principle based on leaf springs proved to be advantageous in the course of development. Leaf springs can be realised both in a space-saving manner and using alternative materials, which can significantly reduce installation space and structural mass.

Material selection: metals and composites

Steel has established itself as a material for engineering tasks involving highly stressed components, as it has outstanding mechanical properties. However, steel and light metal alloys

Material characteristic value	**Spring steel (1.4310)**	**Aluminium alloy (EN AW 7075-T6 T651)**	**CFRP (HTS40/EP resin, 50% fibre volume content, data in fibre direction)**	**GRP (E-glass/EP resin, 50% fibre volume content, data in fibre direction)**
Density [g/cm³]	7.9	2.8	1.5	1.9
Modulus of elasticity [GPa]	185	72	121	37
Specific modulus of elasticity [GPa/(g/cm³)]	23	26	62	20
Tensile strength [MPa]	up to 2500	524	2200	1976
Specific tensile strength [MPa/(g/cm³)]	316	186	1472	992

***Table 1** Mechanical properties of selected construction materials according to [9, 10].*

are increasingly being replaced by composite materials consisting of a reinforcing fibre and a plastic matrix, such as carbon fibre reinforced plastic (CFRP) or glass fibre reinforced plastic (GFRP). The mechanical parameters for rigidity and strength play a decisive role, especially in lightweight construction applications. In relation to the material density, these so-called specific characteristic values exceed the stiffness (modulus of elasticity) of spring steel by more than two and a half times when looking at the material in the fibre direction, for example for CFRP. In terms of load-bearing capacity (tensile strength), this value is even exceeded by a factor of four and a half (Table 1). This property profile can be used specifically to significantly reduce the component mass. In addition, composite materials offer further advantages over steel and aluminium alloys, such as significantly better corrosion resistance and, in certain cases, even resistance to material fatigue.

However, the use of composite materials also presents users with special challenges. A comparatively low hardness favours abrasion. In addition, extensive knowledge of the highly anisotropic (direction-dependent) material behaviour, processing and recyclability of the material is required.

For this reason, leaf spring concepts based on both metals and composite materials are being investigated. Due to the design principle, it is even possible to realise a combination of different materials within a leaf spring package.

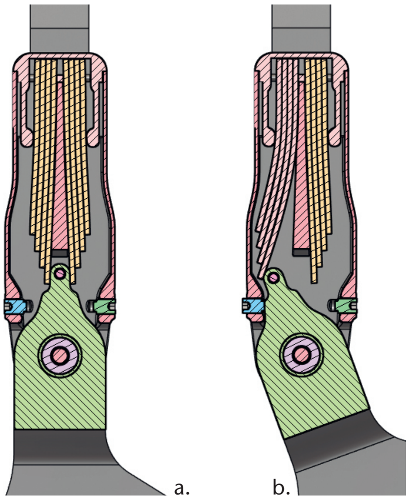

***Fig. 9a** and **b** Leaf spring construction in neutral position **(a)** and in 20° deflection **(b)**.*

The innovation: leaf spring versus coil and disc spring

The newly developed orthosis joint was given the name CarbonFlex (CF), which refers to the possible use of carbon springs. With the innovative spring system, the foot stirrup functions like a pendulum that deflects the pre-tensioned leaf springs. The spring leaf stacks absorb kinetic energy and release it again when the load is released.

By arranging the leaf springs along the system rails, the joint can be made significantly narrower. The pre-tensioning of the spring stacks also ensures a harmonious transition in the loading and unloading phase of the gait, which also leads to a reduction in noise. Figure 9 shows sectional views of the CF joint for two different deflections.

The stiffness of the spring assemblies can be customised by combining different CFRP, GFRP and metal springs and depends on the patient's requirements. Distally positioned screws can be used to restrict the range of motion in the upper ankle joint until the respective direction of movement is blocked.

When the adjusting screws are completely removed, a maximum deflection of 20° in each direction of movement is possible. This is limited by the stiffness of the spring assemblies used.

The actual body of the joint is made of a titanium alloy and consists of only two parts (Fig. 10). The mass of the enclosure was significantly reduced with the help of FEM (finite element method) simulation-based topology optimisation and an additive manufacturing process. The lid and enclosure together weigh only around 90g.

Production is additive and virtually waste-free using the DLMS (direct metal laser sintering) process, a laser-based powder bed sintering process. Excess material is collected and reused.

Mechanically, the enclosure has a receptacle for the distal foot stirrup and the proximal system anchor. The system springs are inserted into the body using the metal cover and fixed in place under pre-tension.

There is an eccentric adjustment on the back of the joint construction, which allows the position of the heel height to be subsequently adjusted without compressing the spring assemblies. This means that alignment errors or shoe changes can be compensated for with a maximum adjustment range of 10° in any direction of movement. The system anchor is additionally secured by two grub screws once the angle has been set.

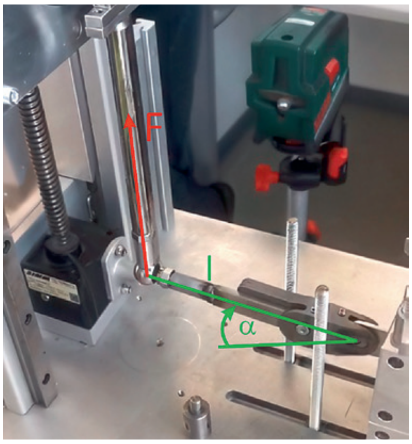

Fig. 11 *Calibration test stand with CarbonFlex joint inserted: test force F, lever length l and angle of rotation α.*

Examination of the property profiles of different joint systems

In order to evaluate the mechanical behaviour of the newly developed leaf spring joint and compare it with the concepts available on the market, translational measurements were carried out along the sagittal plane of motion. A test stand specially developed for the calibration testing of orthosis joints was used for this purpose (Fig. 11).

In addition to the CarbonFlex joint with a medium restoring force, other double-action joints, as described above and shown schematically in Figure 11, with restoring forces ranging from "extra strong" to "extra soft" were investigated experimentally. The deflection took place in the positive and negative direction up to a maximum specific force of approx. ± 12 N/Nm or a maximum angle of rotation of ± 15° – depending on the rigidity of the joint system.

The diagram in Figure 12 shows the qualitative behaviour using characteristic curves of the measured specific force and the angle of rotation for one double-action joint with coil spring (soft) and one with disc spring (strong) as well as the CarbonFlex joint with medium-strong restoring force. All three joint variants exhibit clear hysteresis effects after a start-up behaviour not shown here. This means that part of the potential energy stored in the springs is converted into heat during the return phase. This energy conversion is most likely the result of design-related friction effects of the spring elements or actuators used.

However, one notable difference between the joint types analysed is that the variants with leaf springs exhibit a global hysteresis. A less pronounced hysteresis, but one that occurs around the zero position of the joint, can be observed in joint types with spiral springs. On the other hand, these behave linearly or with only a slight hysteresis at larger deflections. In contrast to this, the CarbonFlex system joint with leaf springs exhibits primarily linear behaviour, especially at zero crossing, and only tends towards non-linear behaviour in conjunction with energy dissipation at larger deflections.

Fig. 10 *Prototype of the CarbonFlex joint.*

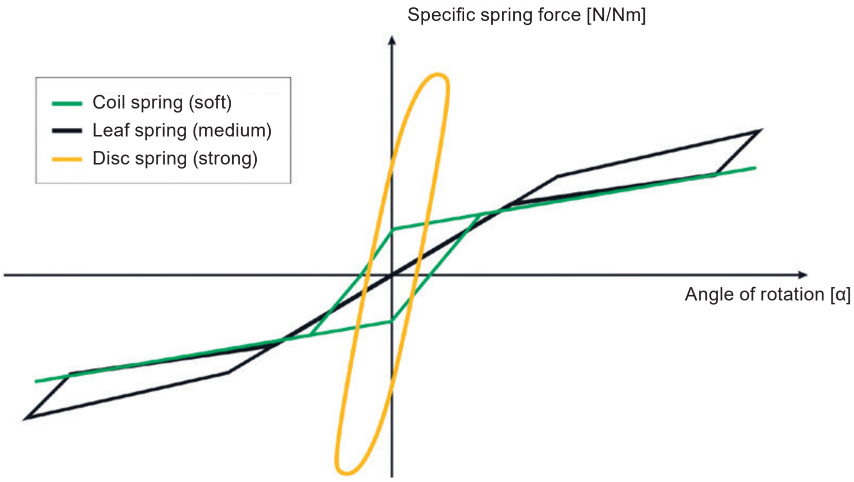

Fig. 12 Exemplary characteristic curves of the specific spring force as a function of the angle of rotation of various joint systems.

This is probably due to the design of the leaf spring assembly, in which the external springs are also stressed and deflected with increasing deflection, which causes increasing friction. The clearly pronounced linear increase during the load change from one leaf spring assembly to the other can be assumed to be one of the reasons for the lower noise development when using the CarbonFlex system joint.

Summary

The innovative CarbonFlex orthosis joint shown in Figure 13 is based on a new leaf spring principle for orthosis joints. By using lightweight composite materials for the leaf springs and a numerically optimised housing design, mass savings of up to 50% can be achieved compared to products already established on the market.

Noise levels have been significantly reduced. This behaviour can very probably be explained by a change in the behaviour when charging the leaf spring assemblies at zero crossing compared to known systems.

The closed design, which minimises the number of components, provides protection against dirt particles. The foot stirrup runs between two Teflon discs to reduce wear to a minimum. The spring assemblies, bolts and sliding discs currently have to be replaced after approx. six months due to the heavy load on the functional components.

The slim design, which is made possible by the innovative spring construction, significantly improves the wearing properties of the tailored footwear. The joint was designed analogue to known systems, primarily on a system width of 16mm. Further system widths are currently being developed.

Installation is simple, quick and reduces potential installation errors. The spring assemblies are supplied pre-assembled and can be inserted into the system as required.

Subsequent adjustment via the eccentric works perfectly, especially during dynamic fitting. Even if the angle change does not take place at the centre of rotation of the ankle joint, there is no shifting in the area of the contact surfaces of the orthosis close to the body. The eccentric must be fixed again after adjustment and should be in the neutral position in the definitive care if possible.

The body allows the joint angle to be deflected by 20° in any direction of movement. The maximum change in angle depends heavily on the stiffness of the respective spring assemblies. The bending behaviour is very dynamic and is perceived positively by patients.

The development of the joint's spring elements presented the greatest challenge overall. Different leaf spring variants are currently being investigated with regard to their maximum stiffness and deflection behaviour and various wear and fatigue strength tests are being carried out.

Conclusion and outlook

The newly developed CarbonFlex orthotic joint is characterised by a moderate component size, low mass, a simple design principle and harmonious properties of the leaf spring technology used. It can be worn in most tailored shoes without any problems. The design principle offers great potential for developing different joint sizes, variants with different restoring forces and waterproof component groups.

Further developments will focus on achieving high spring resistances, as previously achieved by other system joints, as well as increasing the maximum possible deflection angle. Various solutions already exist for the leaf spring design, which are currently being evaluated in static and dynamic tests.

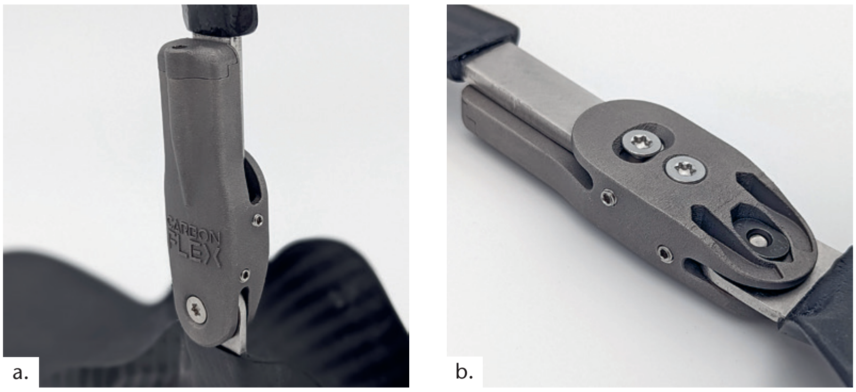

*Fig. 13**a** and **b** View of the CarbonFlex joint: on the outside, sideways, **(a)** and from the inside **(b)**.*

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Conflict of interest:

The author Norman Fittkau works for the manufacturer of "CarbonFlex".

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