MANUAL VOL.1

GAITSOLUTION

Ankle Foot Orthosis Design

An ankle foot orthosis designed with smooth walking in mind.

reddot design award
winner 2006

KAWAMURA

GAITSOLUTION Design

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GaitSolution Design

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1. What Is GaitSolution Design?

GaitSolution (GS) is an orthosis developed by "pursuing natural walking." It is endowed with the functions required for ankle foot orthoses, which have been derived from the results of gait analysis of a total of more than 100 patients with hemiplegia.
The GaitSolution Design (GSD) has realized ease in the ability of the wearer to wear and remove the problem restricting wearable shoes by enhancing the design in addition to superior function as a walking aid equipped with GS.

2. Features of GSD

The features of GSD are described below in comparison with conventional orthoses. Shoehorn-type orthoses, which are currently the most commonly used, produce a braking force during both ankle plantar flexion and dorsiflexion from a certain angle. The strength of the braking force is adjusted by the material thickness or trimming, but fine adjustment is practically difficult since reversion does not work. Most orthoses with an ankle joint have a structure which allows free movement in the dorsiflexion direction by stopping ankle plantar flexion. The angle to stop plantar flexion can be adjusted by adjusting the joint part. On the other hand,
GSD has a structure which allows free movement in the dorsiflexion direction by producing a braking force at the time of ankle plantar flexion from a certain angle. In addition, the strength of the braking force and the angle at which the braking force starts to be effective can be adjusted. It is this fine adjustment for plantar flexion braking of GSD that can realize the wearer's natural walking. (Fig. 1)

In this manual, stopping joint movement at a certain angle is expressed as restriction and joint movement while putting on the brakes as "braking."

Comparison of Features of Various Orthoses

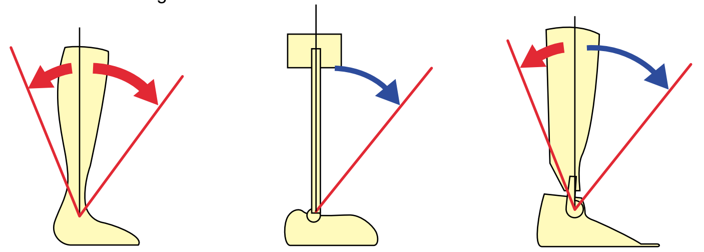


Fig. 1

3. Structure of GSD

①Titanium frame

The adoption of lightweight and durable titanium for the frame has realized lightness and strength. Since deformation does not appear in the orthosis itself as in the case with conventional plastic orthoses, the force exerted by a hydraulic damper can be transmitted directly to the lower limb.

②Rear entry (Fig. 2)

The wearer can wear the orthosis without raising a foot by tilting the frame forward and inserting his or her foot from the rear of the orthosis. Since it is engineered to prevent the frame from tilting forward, it is easy to install belts with one hand.

Fig. 2

③Small foot-ankle assembly

By keeping the shape of the foot-ankle assembly to a minimum, the wearer can wear various shoes on top of the orthoses. The need for selecting one-size larger shoes, as was the case with conventional orthoses, has been eliminated.

④ Use of water dispersion pads (Fig. 3)

By using water dispersion pads which offer superior breathability in the parts contacting the body, the wearer can obtain a comfortable wear feel. The crural area belt can be cut according to the shape of the lower limb and used as it is.

Fig. 3

⑤Small hydraulic damper (Fig. 4)

A small hydraulic damper built into the ankle joint applies the brake to the movement of plantar flexion by producing a braking force in response to the ankle movement while walking. The strength of the braking force can be adjusted by turning a screw on top of the damper.When adjusting the strength, refer to the scales on top of the damper.
A scale of "1" indicates the weakest condition while "4" indicates the strongest condition.
Since the strength can continuously be adjusted,it can be adjusted to 1.8, 2.5 or other scale adjustments. Select an appropriate strength while observing the gait of the wearer.
The brake applied to the plantar flexion promotes weight bearing on the plegic side with impact absorption, which realizes smooth walking.

Adjustment of Hydraulic Damper

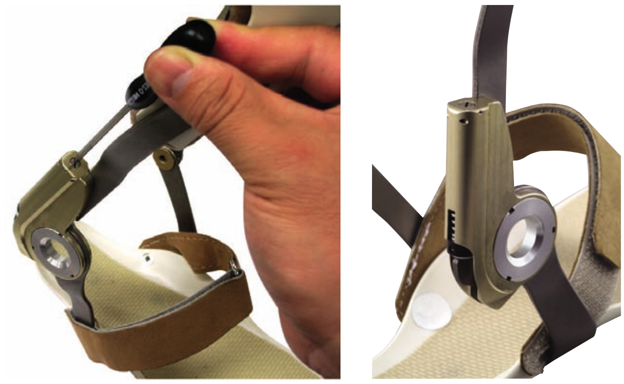


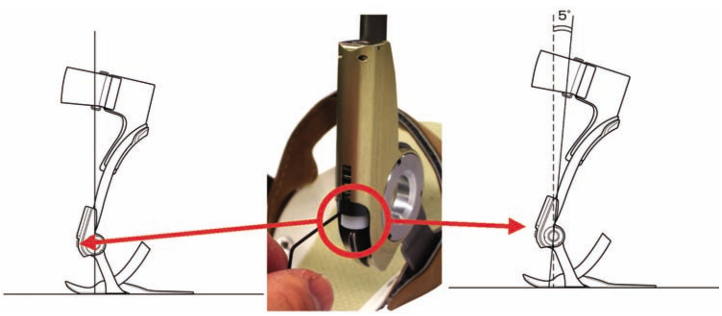
Fig.4

⑥Ankle angle adjustment mechanism (Fig. 5)

The angle at which a braking force of the hydraulic damper starts to be effective can be adjusted by replacing an ankle joint part. This angle corresponds to the initial ankle angle using conventional orthoses. The angle is normally set at the neutral position (0 degrees). In addition to this, a part with dorsiflexion of 5 degrees has been prepared.

Adjustment of Initial Angle

The initial dorsiflexion angle can be changed to the following 2 variations (0 and 5 degrees):



Adjustment cap: 0 degrees (When the thin type is used)

Adjustment cap: 5 degrees (When the thick type is used)

Fig.5

⑦Three color variations

GSD has the three color variations: the Standard type of quiet color arrangement, the Urban type of sophisticated color arrangement, and the Sport type of active color arrangement.
(*Refer to page 1 of this manual.)

4. Why Does GS Realize Smooth Walking?

Since patients with hemiplegia have difficulty in ensuring the toe clearance during the swing phase due to resistance in separating the toe from the floor during the late stance phase while walking, conventional orthoses are used to assist this point. On the other hand, GS is an orthosis developed with the assistance of the stance phase as its primary purpose. Improving the stance phase can improve the entire gait including the swing phase.

Normal Gait Stance Phase: Three Rocker Functions

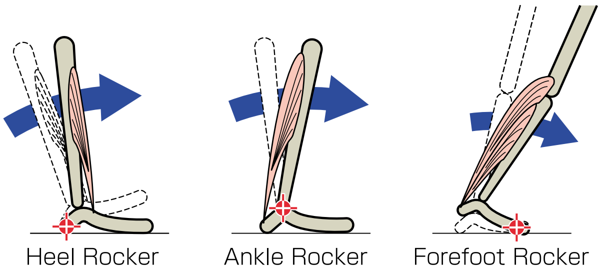


Fig.6

In normal gait the body rotates around the weight-bearing foot during the stance phase. At this time, the center of rotation shifts from the heel during the initial stance phase through the ankle during the mid stance phase to the forefoot during the late stance phase. Such rotations are called rocker functions while walking since they resemble the movements of a rocking chair (J. Perry, 1992). (Fig. 6)

Vertical Movement of Center of Gravity during Normal Gait

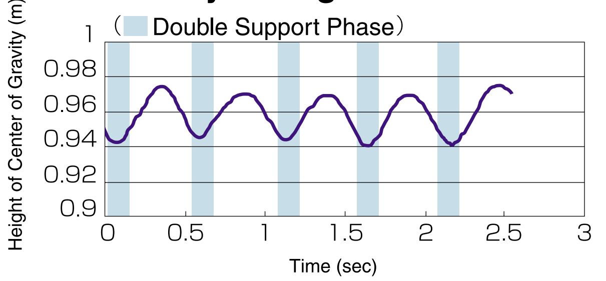


Fig.7

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With these 3 rocker functions, the center of gravity while walking exhibits movement resembling a sine curve on which it becomes high during the single support phase and low during the double support phase. The sine -curve-like movement of the center of gravity realizes an efficient gait by use of gravity. (Fig. 7)

Workings of Muscles in Heel Rocker

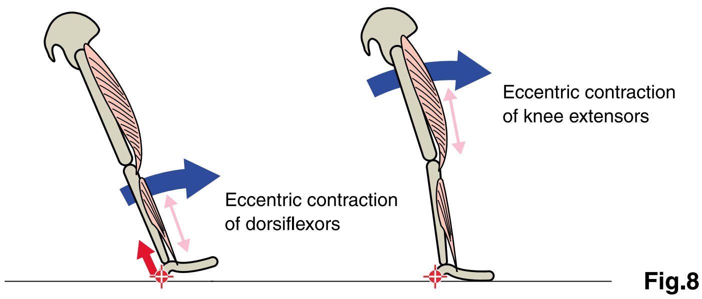

Fig.8

Fig. 8 shows the workings of muscles in the heel rocker. The floor reaction force produced in the heel by heel contact works in the ankle plantar flexion direction. At this time, ankle dorsiflexors such as the pre-tibial muscles work to ensure tibial progression while applying the brake to plantar flexions by eccentric contraction.Moreover, the knee extensors work to pull the thigh foward.

By such muscle activities, the body rotates upward and forward towards foot flat.

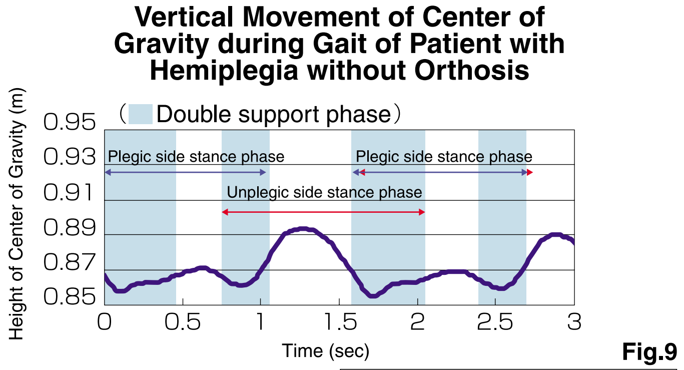

Fig.9

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With regard to the gait of a patient with hemiplegia, the forward body rotation cannot be obtained due to the difficulty of heel contact and insufficient activities of ankle dorsiflexors and knee extensors in plegic side. Fig. 9 shows the vertical movement of the center of gravity in the gait of a patient with hemiplegia without orthosis. It is found that the time is long and the center of gravity does not go upward during the double support phase for the plegic side. (Fig. 9)

The analysis of the gait of more than 100 patients with hemiplegia using orthoses has revealed that the purpose of ankle foot orthoses is to assist the eccentric contraction of ankle dorsiflexors in the heel rocker. By performing ankle plantar flexion braking and tibial progression in the heel rocker using the orthoses, weight bearing on the plegic side is facilitated to allow forward body rotation.

GS does not assist the ankle rocker to apply the brake to the ankle dorsiflexion during the mid stance or later phase. From this, it is assumed that GS is suitable for patients who are capable of heel contact and forward rotation of the center of gravity with the assistance of plantar flexion braking.

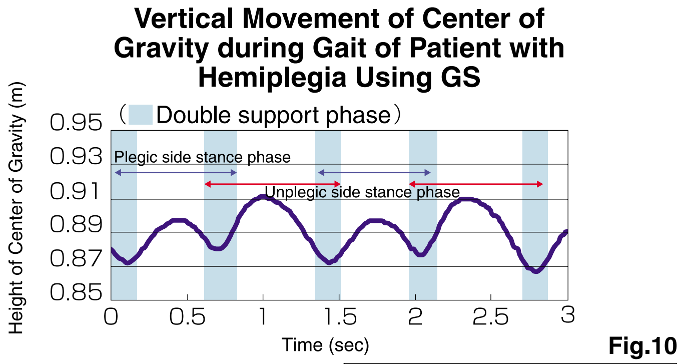

Fig.10

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Fig. 10 shows the vertical movement of the center of gravity in the gait of the same patient as in Fig. 9 using GS. It is found that the center of gravity in the gait using GS exhibits movement resembling a sine curve by going upwards even during the plegic side stance phase, although a difference between the plegic side and unplegic side remains.

5. Adjustment of GS Functions

Effects of Plantar Flexion Braking by Orthoses in Heel Rocker

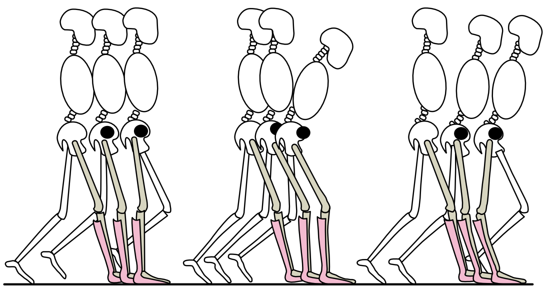


Fig. 11

GS realizes plantar flexion braking in the heel rocker with a braking force by a hydraulic damper. The strength of braking is very important and it is required to adjust it while observing the gait of a wearers. When plantar flexion braking is satisfactry, the trunk approaches an upright posture and the center of gravity is facilitated to moving upward and forward. When braking is excessive, the knee is pushed forward with the movement of the foot-ankle assembly and the trunk forward lean or backward rotation of the pelvis may be observed in compensation for the above. The wearer may have distaste for being pushed from behind and walk pulling back the hips, while feeling "being pushed from behind due to the hard orthosis." The same phenomenon occurs even in orthoses which stop the plantar flexion of an ankle joint. On the contrary, when plantar flexion braking is insufficient,the knee stays back and becomes hyperextended. At this time, compensation may be seen such as the trunk forward lean. The wearer gets a "sensation that the orthosis is too soft with the same feeling as if not wearing." (Fig. 11)

Flow Chart for GS Adjustment of Plantar Flexion Braking

Initial stance
- Long time from heel contact to foot flat
- No excessive knee bending

→ Do not change the amount of plantar flexion braking.

Initial stance
- Short time from heel contact to foot flat
- Toe contact
- Pelvis located at the rear of the foot-ankle assembly

Mid stance
- Knee hyperextension
- Trunk forward lean
- Small upward movement of the center of gravity

Late stance
- Short stride on the unplegic side
- Difficult to remove the toe from the floor

→ Increase plantar flexion braking.

Initial stance
- Short time from heel contact to foot flat
- Knee flexion
- External rotation occurring around the heel

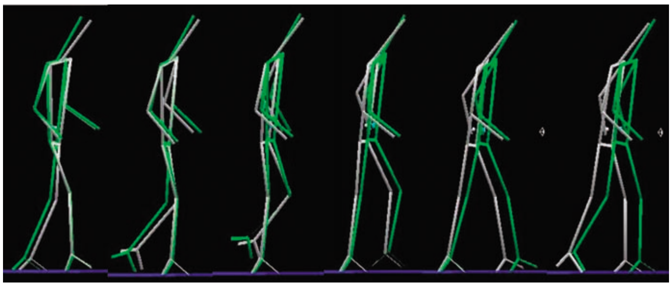
Mid stance
- Knee flexion position
- Trunk forward lean
- Small upward movement of the center of gravity

→ Decrease plantar flexion braking.

 Fig. 12

Adjust plantar flexion braking while observing the entire body, mainly on the knee and the trunk movements, during the plegic side stance phase. For adjustment, the opinions of the wearer is also important. Fig. 12 shows a flow chart for adjustment for your reference. It is recommended to check the braking every one or two weeks during period of initial use of GS since the appropriate strength of braking varies during this time. Especially for the wearer in the recovery phase, adjust plantar flexion braking frequently by paying attention to changes in his or her gait.
GS also allows adjustment of the initial ankle angle. Adjust the initial angle while observing the plegic side contact.Adjustment of the angls to dorsiflexion coincides with the increase of braking and to planterflexion with the decrease of breaking.

6. Comparison with Other Orthoses



Comparison between GS and Shoehorn-type Orthosis
Green: GS, White: Shoehorn-type Orthosis
Male (77 yrs. old), right hemiplegia due to a cerebral infarction
Lower limb (Brunnstrom) stage IV, 12 months after onset

Fig. 13

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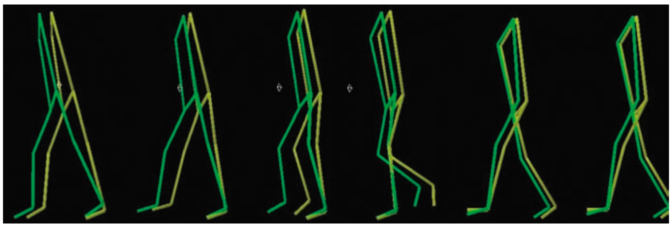
In Fig. 13, the movements of the same patient as in Fig. 9 and Fig. 10 measured using GS and the shoehorn-type orthosis during the plegic side stance phase are superimposed.The movement of the patient wearing the shoehorn-type orthosis reveals that there is restriction of smooth lean of the shank and the other foot is difficult to move forward.



Comparison between GS and Orthosis with restriction of Plantar Flexion
Green: GS, Yellow: Orthosis with restriction of plantar flexion
Female (66 yrs. old), left hemiplegia due to a cerebral infarction
Lower limb (Brunnstrom) stage IV, 1.5 months after onset

Fig. 14

Fig. 14 shows a comparison between GS and orthosis which restricts plantar flexion. The movement of the patient wearing the orthosis which restricts plantar flexion reveals that the forward body movement during the stance phase is inhibited since the body has been pulled backward from before the pregic-side contact.

7. Results of Monitor Use Evaluation

From January 2004 through May 2005, GS orthoses for monitoring were used at 34 facilities in Japan (Table 1). We lent GS of plastic types and metal upright types for monitoring to each facility and had medical experts answer questionnaires. Subjects who filled in questionnaires were patients with hemiplegia who use or are regarded as requiring use of orthoses in their daily life. We received the cooperation of 99 patients with hemiplegia (55 patients in the recovery phase within 180 days, 44 patients in the maintenance phase of 181 days or more).

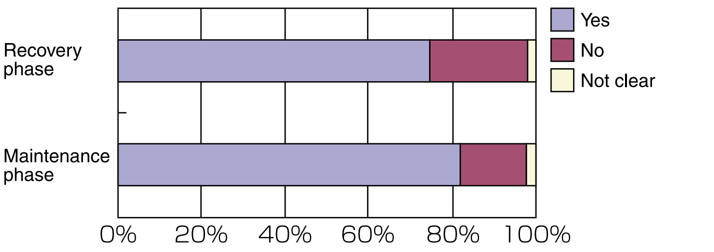
List of Cooperating Facilities in Monitoring Use of GS

Japanese Red Cross Iiyama Hospital
Eisei Hospital Rehabilitation Center
Mori Hospital, Eiseikai Health Corporation
Okazaki City Hospital
Kagoshima University Hospital, Kirishima Rehabilitation Center
Kasai Cardiology & Neurosurgery Hospital
Keio University Tsukigase Rehabilitation Center
Saiseikai Kanazawa Hospital
Sapporo Shuyukai Hospital
University of Occupational and Environmental Health,
Japan University Hospital
Jiseikai Hospital (Division of Physical Therapy)
Seiai Rehabilitation Hospital
Nagano Red Cross Hospital
Nakaizu Rehabilitation Center
Institute of Brain and Blood Vessels, Mihama Memorial Hospital
Hatsudai Rehabilitation Hospital
Yokohama Rehabilitation Center
Yokohama Shin-midori General Hospital

16 other facilities

Table 1

a) Question: Could he or she recognize the ankle plantar flexion from heel contact to foot flat which is the function of GS?



b) Question for those who could recognize the effect: Did his or her gait improve compared with his or her own orthoses?Those who did not recognize the plantar flexion in the previous question do not give answer.

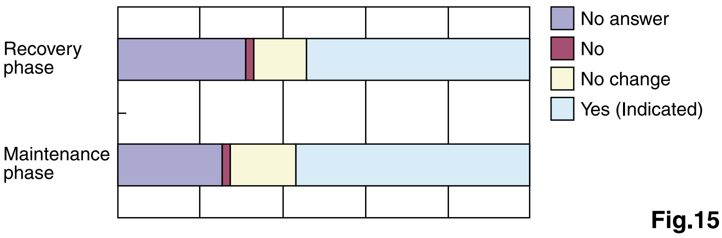


Fig.15

In response to the question "Could he or she recognize the ankle plantar flexion from heel contact to foot flat which is the function of GS?" approx. 80% of wearers answered "Yes." Approx. 60% of all those who recognized plantar flexion answered "Yes" to the question: "Did his or her gait improve compared with his or her own orthoses?" (Fig. 15)

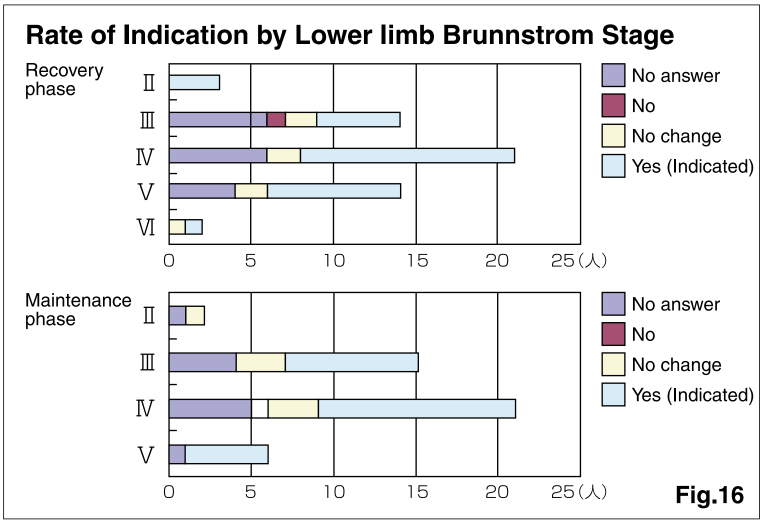


Fig.16

Judging that GS is indicated for the wearers who improved their gait in recognition of ankle plantar flexion, the rate of indication is shown by the lower limb Brunnstrom stage.
The rate is high for wearers in stage IV and V. However, the result shows that GS is indicated even for nearly half of all wearers in stage III. (Fig. 16)

Free Comments in Questionnaire (original text)

- Improvement of support properties during the stance phase. Heel contact was clearly made.It was possible to shift from toe off to swing phase without varus. (Maintenance phase,Brunnstrom stage III, small plastic orthosis used)
- Plantar flexion braking was more moderate than orthosis with metal uprights and adjustment could be made at a timing which resists knee hyperextension. Accordingly, the following were observed: a decrease the knee rocking, an increase in weight bearing, a decrease in abdominal tone, and a decrease in dragging during the swing phase. (Recovery phase, Brunnstrom stage IV, metal uprights used)
- The trunk forward lean was recognized with Shoe horn type orthosis during the stance phase while the upright position could be maintained with GS. Hip extension increased during the late stance phase and gait approached automaticwalking. (Maintenance phase, Brunnstrom stage V, shoehorn-type orthosis used)
- Very walkable. After walking using GS, a feeling of easy-to-walk even with bare feet lingered.(Maintenance phase, Brunnstrom stage IV)
- It is considered that GS can used as part of training (rising exercise, gait exercise) rather than as daily use. GS may be used as part of the introduction of weight support or weightshifting. (Recovery phase, Brinnstrom stage IV)

8. Literature

Articles

Yamamoto S, Ebina M, et al., Comparative Study of the Mechanical Characteristics of Plastic AFOs, Journal of Prosthetics and Orthotics, Vol.5, No.2, 59-64, 1993

Yamamoto S, Ebina M, et al.,Quantification of the Effect of Dorsi/plantar flexibility of Ankle-Foot Orthoseson Hemiplegic Gait, A preliminary Report,　Journal of Prosthetics and Orthotics, Vol.5, No.3, 88-94, 1993

Yamamoto S, MiyazakiÅ@S, et al.,Quantification of the Effect of the Mechanical Property of Ankle-foot Orthoses on Hemiplegic Gait,　Gait & Posture, Vol.1, No.1, 27-34, 1993

Yamamoto S, Ebina M, et al., Development of a New Ankle-Foot Orthosis with Dorsiflexion Assist, Part1 Desirable Characteristics of Ankle-Foot Orthoses for Hemiplegic Patients, Journal of Prosthetics and Orthotics, Vol.9, No.4, 163-167, 1997

Yamamoto S, Hagiwara A, et al., Development of an ankle-foot orthosis with an oil damper, Prosthetics and Orthotics International, 29(3), 209-219, 2005

BOOKS

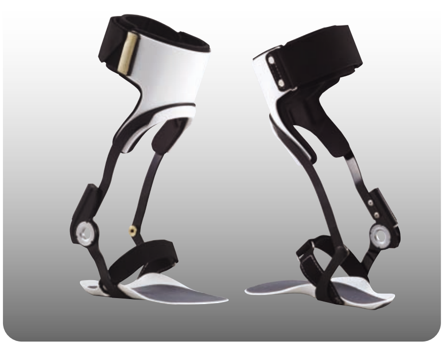
J. Perry: Gait Analysis, SLACK, 1992

Color Variations

● **Standard** （L 69500001/ R 69500002）

Quiet color arrangement which matches surroundings by a warm cast

● **Urban** （L 69500003/ R 69500004）



Sophisticated monotone color arrangement which gives an urban impression

● **Sport** （L 69500005/ R 69500006）

Sporty color arrangement with orange as the key color which cannot be ignored

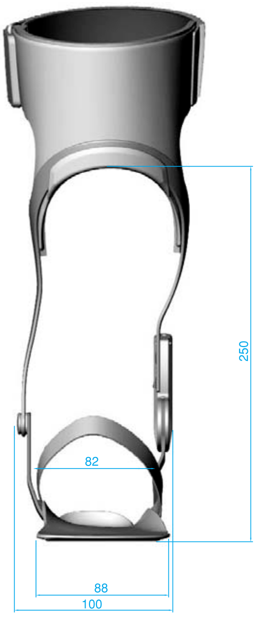
*These specifications and equipment are subject to changes without prior notice.
The body color may appear differently from the actual color in relation to exposure or printing ink.

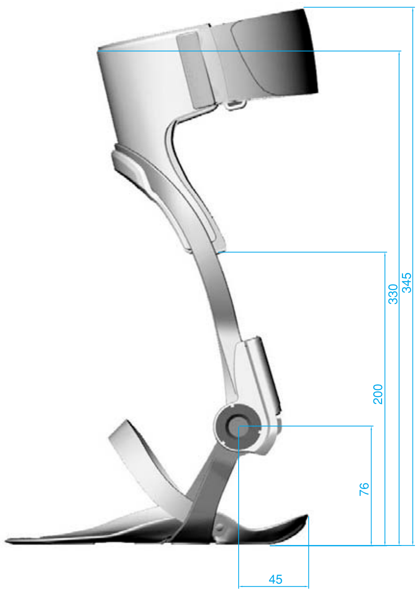
Specifications

GAITSOLUTION Design

Functions

- Braking range: From the neutral position, setting 15 degrees of plantar flexion is possible. No braking for movement of dorsiflexion.
- Braking force adjustment range: Non-step adjustment from 2 Nm to 20 Nm.
- Initial angle range: Changeable for 2 positions of 0 or 5 degrees of dorsiflexion by exchanging parts
- Weight: 370 g





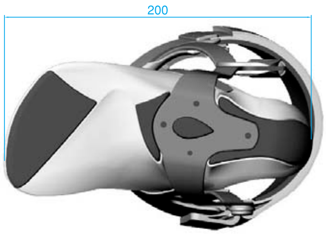
Dimensions

- Circumference of crural area: 260 mm - 400 mm *1
- Foot length: 230 mm - 260 mm *2

*1: For the crural area belt and the foot belt, special belts cuttable to any appropriate length are used.
*2: If there is excessive deformity or the length is out of the range above, use the GaitSolution of the plastic or metal strut type manufactured by order.

Indications

- Hemiplegia, peroneal paralysis, etc.
- Weight limit: 70 kg



Incompatible conditions

- When a correction force by an orthosis is required for significant spasticity or deformity
- Significant sensory disturbance
- Extreme back knee

* A therapist or prosthetist & orthotist (P&O) should select an orthosis under the guidance of a doctor after confirming the technical data.

Manufacturer

KAWAMURA

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Theory of Human Gait: Prof. Sumiko Yamamoto, International University of Health and Welfare/Graduate School
Design: GK Dynamics Inc.
This research was conducted by a grant from the New Energy and Industrial Technology Development Organization.

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