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ORIGINAL ARTICLE

A novel hinged ankle foot orthosis for gait performance in chronic hemiplegic stroke survivors: a feasibility study

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Abstract

Stroke survivors with gait disturbances may use ankle foot orthoses (AFOs). However, most AFOs come in one-piece styles, which make it difficult for spasticity-affected stroke survivors to don. AFOs are also limited since they do not properly prevent ankle joint for foot drop by itself. Therefore, the present study developed a novel hinged AFO by adding a locking device to a hinged joint. We then tested its feasibility in 9 hemiplegic stroke survivors by investigating temporal–spatial gait parameters using the GAITRite in the following 3 conditions: no AFO, traditional AFO, and novel hinged AFO. There was no significant difference in spatiotemporal gait parameters among the different conditions. There were greater decreases in gait velocity, cadence, step length, and stride length in the novel hinged AFO group than in the no AFO and traditional AFO groups. This novel hinged AFO was developed to prevent foot drop. However, the AFO did not show significant differences in gait parameters because it consists of metal with extra weight and volume. Functionally, it prevented foot drop. It also improved convenience by its releasable design. Thus, further studies are needed to develop an AFO that improves gait and is convenient to use for hemiplegic stroke survivors.

Keywords Ankle foot orthosis · Hemiplegic stroke survivors · Gait

1 Introduction

Muscle weakness, increases in muscle tone, and sensory impairments that appear on the more affected side are common symptoms after stroke [1] and limit functional mobility cause a loss of balance control and an abnormal gait pattern [2, 3]. In particular, the foot drop of the more affected side caused by muscle weakness around the ankle and alterations in tone not only prevents a smooth weight shift difficult due to lacking ankle stability [4, 5], it contributes to a compensatory gait pattern [6, 7]. Reduced walking speed and alterations in temporo-spatial gait parameters with hemiplegic gait patterns may occur due to foot drop on the more affected side [8]. In the community, a walking speed of 0.8 m/s guarantees independent living, whereas a speed < 0.5 m/s may restrict daily life and participation in the community [9]. However, the walking speed of most of stroke survivors is generally < 0.8 m/s, indicating their struggle in living independent life.

For solving these problems of walking, walking aids have been used [8]. The most frequently used walking aids are a cane and ankle foot orthoses (AFOs) [10]. Previous studies have reported that more than 67% of stroke survivors prefer a cane [10], whereas more than 20% preferred AFOs [11]. A cane improves gait by reducing the burden of weight on the less affected side of stroke survivors. However, a cane limits the normal upper extremity functions of the less affected side and the cognitive function that is required to relearn gait [12]. It has been reported that AFOs, unlike cane, fixes or adjusts ankle movement to

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ensure a safer and better walking pattern [13, 14]. AFO use has been shown to improve dorsiflexion angle during the swing phase of gait and instability of the subtalar joint during the stance phase [15]. AFOs also provide stability to the ankle during the mid-stance phase, improved heel strike at the initial stance phase, and a facilitated weight shift from the heel to the toes [16]. In this regard, the use of an AFO means a positive effect not only to enhance walking speed and cadence but to improve static or dynamic standing balance [17]. It has been argued that AFO use improves gait speed, step and stride length, and dorsiflexion angle [12], and an effect on peace of mind was also reported [1]. Ryerson [15] as well as Leung and Moseley [16] concluded that both gait speed and balance ability improved when stroke survivors were equipped with AFOs. Another study showed that when stroke survivors applied AFOs, similar improvements in dynamic balance were observed on the Timed Up and Go test [1].

AFOs generally consist of lightweight polypropylene-based plastic in the shape of an "L" with the upright portion behind the calf and the lower portion running under the foot to inhibit correct foot drop. However, most previous AFOs were a one-piece style comprising approximately 26% of all orthoses in the US [18]. It is difficult to custom-manufacture individualized AFOs. Some AFOs were produced in a small size to make them easy to apply, but they were unable to correct ankle deflection. In addition, the AFO made of rigid plastic limits joint motion and causes skin problems in elderly people, in whom elasticity is reduced, and poses problems such as wearing-in and after-wearing discomfort [19]. Thus, it has been suggested that an AFO should be developed for the convenience of stroke survivors that maintains the original function.

Accordingly, here we developed an tested the feasibility of an AFO that not only would facilitate the appropriate ankle position and heel strike but would also be convenient for stroke survivors.

2 Novel hinged AFO

2.1 Mechanical system

The novel hinged AFO (Fig. 1b) is an AFO with a locking hinge joint that weighs about 180 g. As shown in Fig. 1, weight and volume were increased compared to existing AFOs (Fig. 1a; DR-A015, Dr. MED, Busan, Korea). The material is the same as polypropylene, polyurethane, polyester, and nylon, but the hinge joint is made of metal, so it has increased weight compared to existing products (Fig. 1). The novel hinged AFO consists of an upper base (100), upper fixed axis (110), lower base (200), locking rings (300), locking ring axis A (310), locking ring axis B (320), fixing equipment (400), fixing equipment axis (410), and retainer torsion spring (420) (Fig. 2).

1. An upper fixed axis (110) is combined with an upper base (100) (Fig. 3a).
2. After joining a fixed equipment axis (410) to an upper base (100), a retainer torsion spring (420) is combined with the upper base and fixing equipment (Fig. 3b).
3. A locking ring axis A (310) and a locking ring axis B (320) are combined with a locking ring (300) (Fig. 3c).
4. The device combined at step (3) is joined to the device combined at (2) (Fig. 3d).
5. Finally, a lower base is added (Fig. 3e).

Nuts were fixed according to the order shown above and rotating nuts were combined to enable them to rotate.

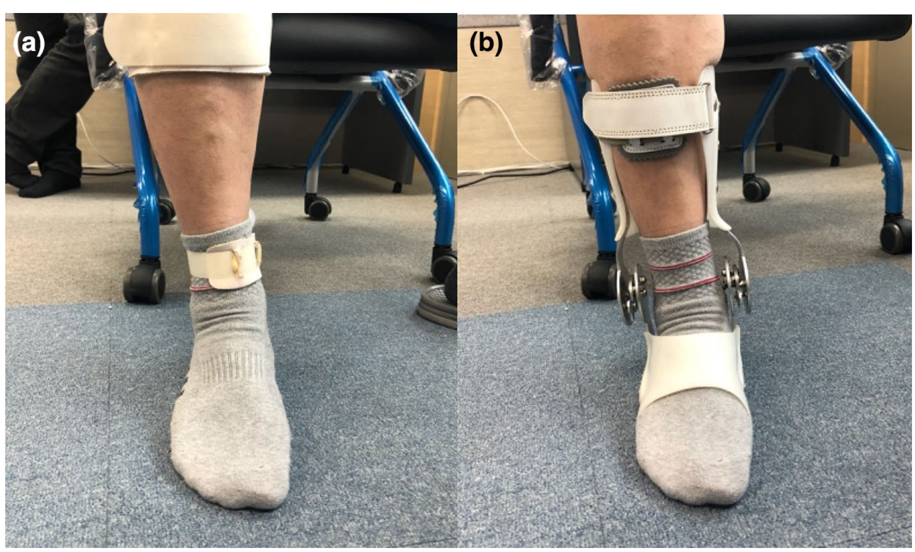

Fig. 1 Comparison of conventional ankle foot orthosis (AFO) (**a**) and the novel hinged AFO (**b**)

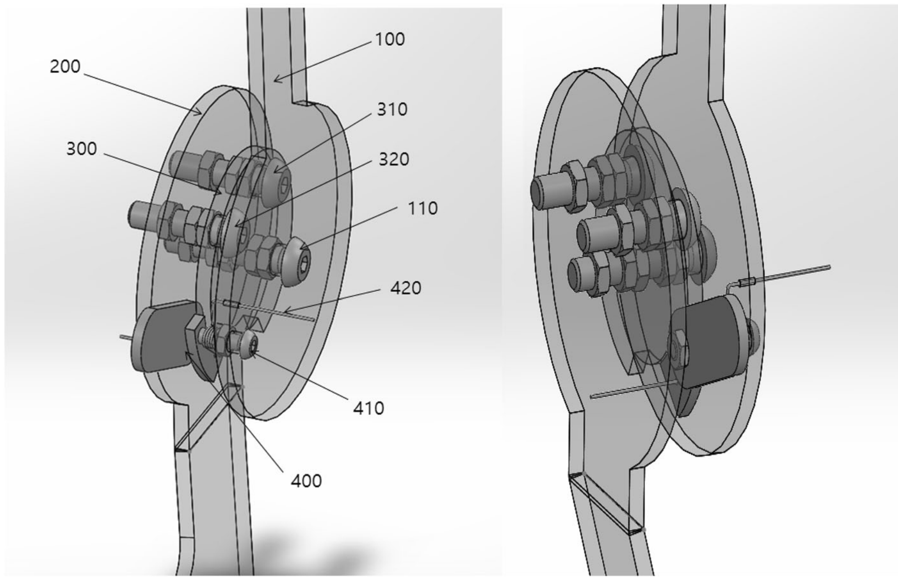

Fig. 2 Mechanical system of the novel hinged ankle foot orthosis

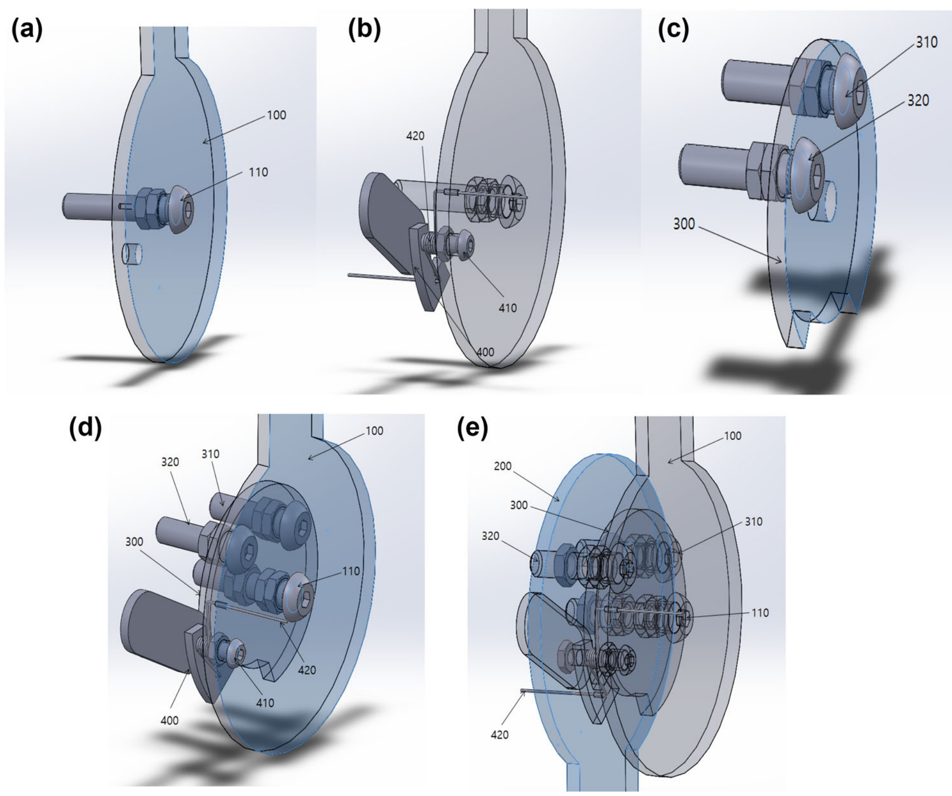

Fig. 3 Design of the novel hinged ankle foot orthosis

2.2 Controls and algorisms

Figure 4 demonstrates the rotation of the fixing equipment. Figure 4a, b show the fixing equipment (400) hanging on a locking ring (300) and illustrates that only a clockwise rotation is possible. Figure 4c, d show the fixing equipment (400) not hanging on a locking ring and illustrates that both clockwise rotation and counterclockwise rotation are possible.

Among stroke survivors, it can be difficult to apply AFO fixed at 90°. Therefore, as shown in Fig. 4d, making the shape of an AFO in plantar flexion, the researchers designed it as convenient even for stroke survivors with severe spasticity. Even after standing up after putting the foot in and fixing it in a state as shown in Fig. 4d, the angle

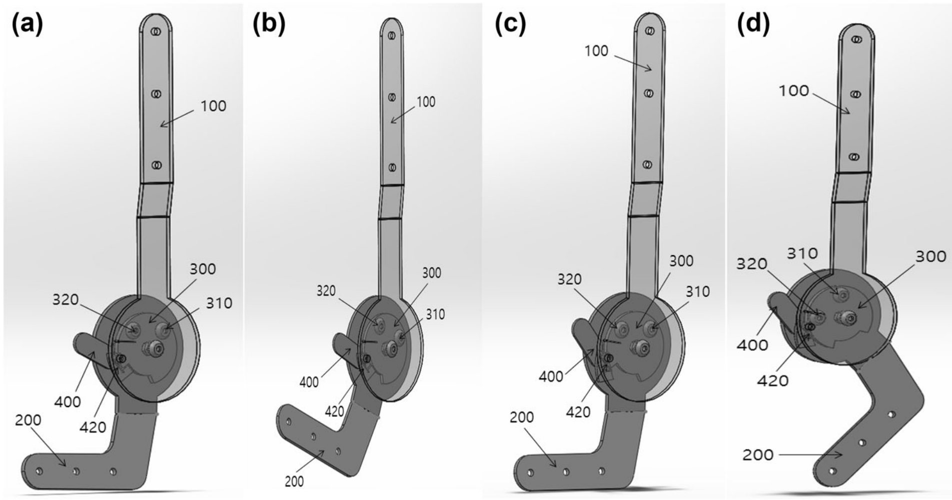

Fig. 4 Controls and algorithms of the novel hinged ankle foot orthosis

of the AFO can be maintained at 90° by the support of weight as shown in Fig. 4c. As shown in Fig. 4c, a locking ring is combined into a lower base (200) by a locking ring axis A (310) and a locking ring axis B (320), while a lower base (200) is driven by clockwise or counterclockwise according to the foot movement. In the cases of hemiplegic stroke survivors, however, a foot needs to be fastened not to droop to prevent foot drop. To address this, a locking ring should be fixed using the fixing equipment (400) and the retainer torsion spring; further, a lower base (200) combined into the locking ring (300) should be fixed. This prevents foot drop of stroke survivors and provides support for comfortable walking.

Moreover, if fixing equipment (400) is hung on to a locking ring (300), it might be difficult for the hemiplegic stroke survivors to remove the AFO because it does not rotate counterclockwise. The fixing equipment (400) was always joined by a retainer torsion spring (420) such as that when pulling the lever with the hand in a clockwise direction, so a locking ring (300) and a lower base were devised to rotate in a counterclockwise direction. Taking this into account as in Fig. 4a, the fixing equipment (400) is always fixed by an equipment torsion spring, and when the user draws the handle of the fixing equipment (400) clockwise with the hand as shown in Fig. 4 (d), the locking ring (300) and lower base (200) easily rotate counterclockwise (Figs. 5 and 6).

3 Feasibility test

3.1 Participants

The feasibility test was performed for stroke inpatients at a rehabilitation center in South Korea. The participants were recruited through the public bulletin in the center. Twelve stroke patients volunteered; among them, 9 were included in the feasibility test. The inclusion criteria were as follows: hemiplegic stroke patient; ability to walk > 10 meters with or without assistance; modified Ashworth Scale (MAS) score < grade 2 for the ankle plantarflexor; and ability to understand the researcher's instructions. Patients with musculoskeletal, neurological, or cerebrovascular problems or who were medically unstable were excluded from the test. The participants were informed of the purpose and procedures of the feasibility test and voluntary signed an informed consent form. The participants' characteristics are shown in Table 1.

3.2 Procedures

The feasibility test was performed of 9 stroke survivors. Each participant walked without an AFO, with a traditional AFO, and with a novel hinged AFO. As the participants walked, gait parameters including gait velocity, cadence, step length, stride length, single support time, and double support time using the GAITRite system were collected. Participants walked on the GAITRite system three times for each condition (9 times total) with a 5-min break between trials. The participants were asked to walk on and pass the GAITRite system at a comfortable pace starting from 2 m before the request. A research assistant was prepared to provide safety support in case of any accident while maintaining a distance from the participants to not affect the test.

3.3 Outcome measures

The GAITRite System (CIR systems Inc, USA) was utilized to collect data on quantitative gait parameters on gait pattern. The gait analysis device is a 366-cm-long and 61-cm-wide electronic board to which 13,824 sensors are

Fig. 5 Putting on process of a conventional ankle foot orthosis

Fig. 6 Putting on process of a novel hinged ankle foot orthosis

Table 1 Participants' characteristics

Variables	
Gender (male/female)	7 (77.8%)/2 (22.2%)
Age (year)	57.11 (11.90)
Height (cm)	160.89 (5.51)
Weight (kg)	60.33 (9.50)
Duration (month)	25.11 (22.23)
Etiology (infarction/hemorrhage)	4 (44.4%)/5 (55.6%)
Affected side (Lt/Rt)	0 (0%)/9 (100%)
MMSE	21.22 (3.90)
MAS (0/1/1^{+})	3 (33.3%)/3 (33.3%)/3 (33.3%)

Data are presented as mean (SD) or mode

MMSE mini-mental state examination, *MAS* modified Ashworth scale

attached that collects spatiotemporal gait parameters at a sampling rate of 80 Hz per second. The collected data are sent to a computer connected to a serial interface cable for analysis. Data including gait velocity, cadence, step length, stride length, single support time, and double support time were collected and analyzed.

3.4 Data analysis

The data analysis was performed using SPSS Window version 18.0. The Kruskal–Wallis H test was conducted to compare gait parameters among 3 different conditions (with no AFO, with a traditional AFO, and with a novel hinged AFO). The statistical significance level was set at $\alpha = 0.05$.

3.5 Results

There was no significant difference in spatiotemporal gait parameters among the 3 different conditions (with no AFO, with a traditional AFO, and with a novel hinged AFO) (Table 2). However, in the novel hinged AFO condition, there were more pronounced decreases in gait velocity, cadence, step length, and stride length than in the conditions with no AFO or a traditional AFO (Table 2).

Table 2 Comparison of gait parameters among the 3 different conditions

Gait parameters		Without an AFO	With a traditional AFO	With a novel hinge AFO	*P*
Velocity (cm/s)		69.02 (28.20)	71.91 (27.99)	62.57 (26.61)	0.79
Cadence (step/min)		94.02 (18.64)	95.98 (17.42)	90.29 (15.65)	0.62
Step length (cm)	Lt	41.72 (11.75)	42.32 (12.70)	38.10 (12.92)	0.59
	Rt	44.49 (11.16)	45.41 (10.69)	42.89 (10.34)	0.85
Stride length (cm)	Lt	86.46 (21.65)	87.87 (22.22)	81.24 (22.70)	0.73
	Rt	87.32 (21.93)	88.38 (22.54)	81.61 (22.56)	0.73
Single support time (s)	Lt	0.48 (0.10)	0.47 (0.09)	0.51 (0.12)	0.51
	Rt	0.40 (0.10)	0.39 (0.09)	0.38 (0.09)	0.94
Double support time (s)	Lt	0.44 (0.15)	0.43 (0.15)	0.47 (0.16)	0.82
	Rt	0.45 (0.15)	0.43 (0.15)	0.47 (0.16)	0.78

Data are presented as mean (SD) or mode

AFO ankle foot orthosis

4 Discussion

In the present study, to overcome the limitations of the traditional ankle aids, we devised a modified ankle aid and developed a novel hinged AFO. We also performed the feasibility test of the novel hinged AFO in hemiplegic stroke survivors. As a result, there was no significant difference in gait parameters among the different conditions (with no AFO, with a traditional AFO, and with a novel hinged AFO).

Foot drop is a common gait impairment that affects nearly 20% of stroke survivors [20]. AFO use is suggested to overcome such problem. Sankaranarayan et al. [21] conducted a study of the gait of 26 stroke survivors with spasticity who applied AFOs. The study findings showed that using an AFO could positively influence the walking speed of hemiplegic stroke survivors. Besides, Bouchalová et al. [22] reported significant improvements in single support time, double support time, and step length of the more affected side in mild hemiplegic stroke survivors. However, these studies also suggested that it might not be easy for stroke survivors with strong plantarflexion spasticity to apply a plastic AFO.

Various AFOs can be provided to stroke survivors with foot drop [23]. The two adjustable gas springs are attached to the posterior side of the AFO to provide plantarflexion resistance [24]. The solid material of the AFO might limit dorsiflexion when standing and performing some of the items of Timed Balance tests [23]. Therefore, the solid material of the AFO can be useful to stroke survivors for whom substantial stability should be provided [23]. However, the solid material of the AFO has advantage that it fixes the ankle in dorsiflexion; on the contrary, AFOs are bulky and difficult to wear. Recently, new AFOs have been developed that are less bulky and easy to wear and easy to custom-make. Such flexible material of AFOs is normally used to calibrate walkers to flexible material and foot drop at the swing phase [23]. Even though it is convenient to wear, the function of fastening the ankle into the neutral position should be improved. In addition, according to recent studies, an AFO has been suggested that an optimal match needs between the stiffness or rigidity of the device and the stroke survivors [25]. Because a very rigid AFO may help maximize efficiency during flat walking, stroke survivors may prefer a less rigid device for ascending and descending stairs [24]. Existing AFOs are used to solve problems such as foot drop. However, stroke survivors with high muscle tone and spasticity of the ankle plantarflexor find it difficult to independently apply fixed AFOs. Therefore, this study focused on providing AFO wearing convenience and independence. The novel hinged AFO was designed to induce angular movement by adjusting the hinge at the ankle joint; after releasing the hinge, it is convenient to move the ankle to the neutral position and lock it, even in the foot drop state.

In this regard, to overcome the disadvantages of previously mentioned AFOs, the present study aimed to develop a new AFO with satisfactory convenience and functionality. The novel hinged AFO devised in this study consists of joints made up of a plastic and metal body. This hinged AFO was devised to provide the advantage of fastening to the ankles of stroke survivors with strong spasticity to the neutral position with ease. In addition, the wear time was about 41 s for the existing AFO, while the newly developed AFO took about 26 s. However, on the feasibility test, there were no significant differences in spatiotemporal gait parameters among the 3 different conditions (with no AFO, with the traditional AFO, and with the novel hinged AFO). The result might be due to the increased weight and volume of the metals, although the device developed by the present study was made to prevent foot drop. The verification of its effectiveness and endeavors for the development of new AFOs have been performed. Leung and Mosely [16] mentioned the effectiveness of AFOs in gait speeds and patterns and stated that AFOs are most suitable for overcoming gait disturbances in relation to ankle instability [13] and useful for patients who must apply an AFO every day after stroke, especially in the presence of gait disturbances [1]. Besides, it has been established by several studies that gait stability and confidence were also improved [1, 10, 23]. In particular, in a recent study, 65% of the participants reported a low degree of difficulty and 70% reported psychological stability, which was considered a significant outcome [10]. Stroke survivors with rather than without an AFO displayed equal weight-bearing [17, 26], and this effect indicates an improved ability for static and dynamic standing balance that resulted from the increase in stability on the supportive surface [27]. Furthermore, in the participants putting on an AFO, the onset period was shorter and an increase in the number of steps per minute was observed [17]. Chen et al. [26] maintained that as stroke survivors wore an AFO, gait speed improved, as did the weight shift to the forefoot during heel strike. However, in the study by Gök et al. [13] that analyzed gait variables such as without an AFO using a plastic AFO and a metal AFO targeting chronic stroke survivors, no meaningful effect was observed in gait velocity, single support time, or double support time. Thijssen et al. [28] performed a study analyzing gait patterns such as not putting an AFO on, wearing it immediately after manufacture, and wearing it during 3 weeks and found no significant difference in velocity. This study also showed that when the novel hinged AFO was worn, the gait pattern was not improved. That is why it has not improved the weight and volume of AFOs that directly affect walking because it focuses on the application and removal convenience for patients who have difficulty wearing them independently due to high tension of the plantarflexor or foot drop. The new AFO is easily worn with plantarflexion of the ankle; after it is removed, it plays a role in fixing the ankle with natural dorsiflexion. Therefore, stroke survivors who have difficulty wearing existing AFO due to an abnormally high muscle tone and ankle spasticity have the advantage that they can be easily worn because there is no passive ankle dorsiflexion to resist high muscle tension or stiffness. However, the addition of a locking device for the hinge joint resulted in increased weight and volume, which was not effective at improving walking parameters. Therefore, to be a supplementary tool that can have a positive effect on walking in stroke patients, it is necessary to try to decrease the weight and volume by changing the material and the design of the hinge joint.

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Compliance with ethical standards

Conflict of interest The authors declare no conflicts of interest.

Ethical approval This study was conducted after the approval of the Institutional Review Board of Kyungnam University.

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