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Original Article

A super-elastic alloy hallux valgus brace – a novel orthotic device

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Abstract

Objective: Evaluate the efficacy of a new orthotic-made super-elastic alloy brace to correct hallux valgus (HV) deformity.

Methods: Five female patients diagnosed with HV deformity wore the newly developed orthotic daily for six weeks. The orthotic was developed using a super-elastic alloy brace to correct great toe lateral deviation, first metatarsal medial deviation, and fixation belts. The correction was evaluated by measuring the load at which the big toe begins to move and the distance moved by 15 gf force when pulled from the side.

Results: The orthotic was worn by all patients without causing any sleep disruptions. In the initial state, a strong force was required to move the big toe, but after two weeks, it was significantly improved to be mobile in all patients. **Conclusion:** The developed HV orthotic has a high wearability without causing pain or discomfort. Long-term use can provide a consistent and continuous correction force to the big toe, resulting in the successful release of the big toe metatarsophalangeal joint contracture within two weeks.

Level of Evidence: Level 4.

Keywords: Hallux valgus; Conservative treatment; Orthotic device; Alloy.

Introduction

Hallux valgus (HV) deformity is a common and potentially debilitating deformity. A variety of orthotics are used to correct HV. To date, effective conservative interventions have been scarce. Conservative treatments commonly used by patients include night splints, foot exercises, and use of orthotics. However, orthotic devices and night splints were no more effective than no treatment for mild-to-moderate patients(1). Furthermore, high-quality evidence for HV conservative treatments is still required(2).

When the metals deform beyond the elastic limit of ordinary metals, superelasticity in shape memory alloys exhibits a large recoverable strain and force. In the medical field, super-elastic alloys are now widely used. Ni-Ti (NT) alloys have been used as a painless method for primary orthodontic treatments(3) and as a minimally invasive method for lumen stenosis treatment(4). However, the use of NT in orthopedics has not advanced. One obstacle is the form limitation(4). Due to the difficulty of cold working, NT alloys have only been used in simple shapes, such as wires and tubes, in most commercial applications. On the other hand, the Cu–Al–Mn super-elastic alloys discovered by Kainuma et al. in the early 1990s are inexpensive and have excellent workability(5), making them easy to process into plates(6,7). A thin Cu–Al–Mn plate has been used to treat ingrowing toenails(8).

We present a new nocturnal orthotic-made super-elastic alloy brace to correct hallux valgus (HV) deformity.

Study performed at the Senen Rifu Hospital, Rifu-cho, Miyagi, Japan.

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Methods

Created orthotics

Our objective was to create a supporter-type brace that could be worn stably for long periods without disturbing the patient's sleep. The aim of this brace is to correct great toe lateral deviation and first metatarsal medial deviation.

A super-elastic alloy brace with a hinge joint covered to avoid direct contact with the foot was created. The plate measures 0.4 mm thick, 15 mm wide, 130 mm long (50 mm and 80 mm), and has rounded corners. To allow for toe movement, a hinge joint is attached to the plate (Figure 1).

The belt for the midfoot was made of elastic material and lined with ultrafine nanoparticles. The fibers were made of polyester and hook-and-loop belts to secure the supporter at the midfoot. The belt to secure the big toe was made of the same material as the midfoot. Figure 2 shows the configuration from (1) to (4) of the components of the developed brace.

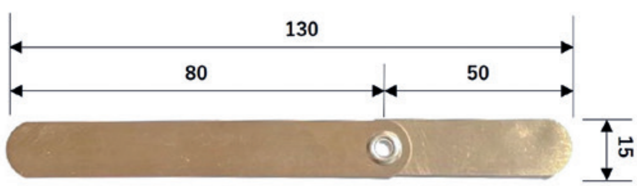

Figure 1. Super-elastic alloy brace with a hinge joint.

Figure 2. Configuration of the components of the developed brace made of ultrafine fiber.

Patients and procedures

Five female patients were diagnosed with HV deformity. The patients' age and initial HV angles are shown in table 1.

The patients were asked to record their daily brace wearing time (Table 1). The correction was evaluated every two weeks after wearing the device in the following manner.

The affected barefoot was placed on a tracing sheet on the measurement table in a sitting position, and the foot shape was traced to evaluate the correction of the big toe metatarsophalangeal (MTP) joint lateral contracture. A loop was attached to the big toe, the big toe was pulled medially, and the force at which the big toe began to move (initial movement value) was measured, as shown in Figure 3.

The same posture was used to pull the big toe until a tensile force of 15 gf was reached, and the distance that the big toe tip moved (traction value) was measured, as shown in Figure 4.

Table 1. Patients and wearing time

Monitor	Age	HV angle (degree)	Daily wearing time (h)
A	50s (F)	34	6.4
B	60s (F)	48	5.5
C	20s (F)	36	13.0
D	60s (F)	29	7.4
E	50s (F)	28	10.2

HV: Hallus valgus; h: hour

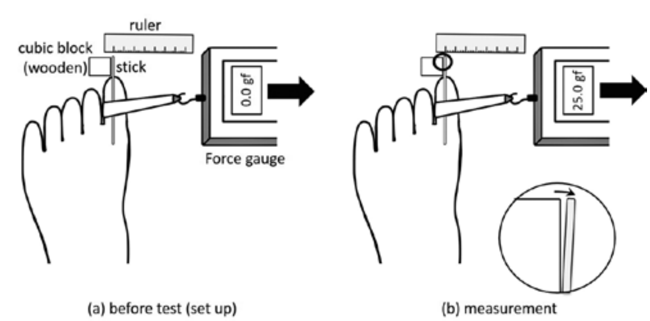

Figure 3. Initial movement value test is shown schematically.

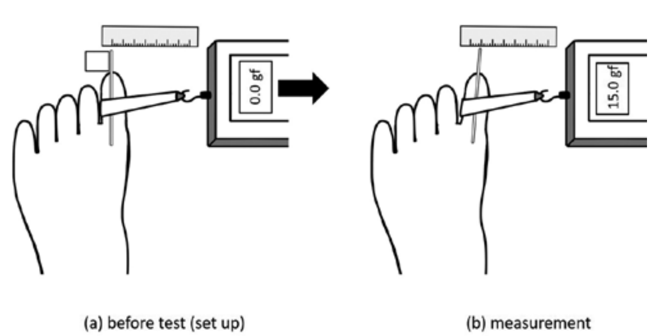

Figure 4. The traction value test is shown schematically.

Results

Wearing period

All patients were able to sleep normally while wearing the brace. The brace received no complaints about steaminess. Although there was some discomfort for about a week after wearing the device, there was no significant discomfort after that, and some patients even forgot they were wearing it.

The force of the initial response

Figure 5 shows the load when the patient's big toe begins to move after two weeks of wearing it. The initial movement values of all patients dropped dramatically two weeks after wearing, and there was no significant change after that. These findings indicate that the brace improves big toe flexibility in the first two weeks.

Toe movement distance when loaded with 15 gf

Figure 6 shows the toe movement distance under 15 gf tensile loading two and six weeks after wearing it. As shown in Figure 6, all patients' big toes did not move under 15 gf tensile loading before brace application, but they did after two weeks. Although there was some variation among patients, in three cases, the greater the movement of the big toe, the longer the patients wore the brace.

Discussion

Hallus valgus can be corrected with a variety of orthotics. Many nocturnal varieties have a rigid inner brace to which the big toe is secured with a belt. Although mechanically effective, they can cause pain when worn by forcibly widening the contracted big toe MTP joint. It is assumed that the greater the HV angle, the greater the pain because the generating force increases linearly due to the linear relationship of the stress-strain response in the normal elastic deformation. Furthermore, most current nocturnal orthotics used for conservative treatment are injection-molded from plastic materials easily formed into three-dimensional shapes. Because of their three-dimensional shape, existing orthotics are rigid and almost nondeforming. As a result, it is easy to imagine they are uncomfortable wearing. Sleep will be disrupted if the material is in direct contact with the skin. The patient experiences patience and stress when wearing these braces at bedtime. Short-time use and/or poor brace fixation appear to be ineffective.

The aim of our orthotic concept is to provide flexible but strong corrective power and comfort for long-term wear. Moreover, unlike traditional nocturnal orthotics, ours can correct the big toe metatarsal varus. We used a super-elastic alloy and ultrafine fiber cloth to develop the brace. Super-elastic alloys are metals with unique properties that allow them to return to their original shape after being subjected to deformation ten times greater than the elastic limit of ordinary metals such as mild steel (see Figure 7). Kainuma et al.[7] developed a copper, aluminum, and manganese alloy with flexible deformation behavior and excellent super-elastic shape recovery.

With an orthotics, the member that imparts corrective force is a Cu–Al–Mn super-elastic alloy. When worn, the super-elastic alloy will deform more by the HV angle due to the flexible nature originating from the stress plateau during deformation, as shown in Figure 8, providing a continuous restoring force. Furthermore, even when the amount of deformation changes, the force applied to the big toe by the super-elastic alloy is nearly constant. It is reasonable to expect that the patient with mild or moderate HV will experience no change in pain. Because nighttime HV orthotics must be worn for extended periods, fit and fixation are critical considerations. All patients in this study could sleep comfortably while wearing the device, with no steaminess or pain. This is due to the ability of the super-elastic alloy to maintain a constant restoring force

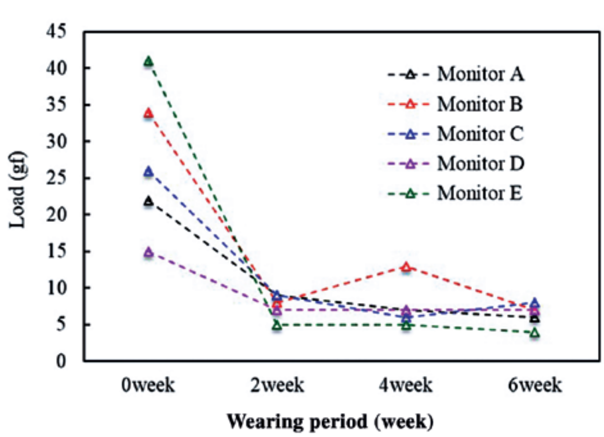

Figure 5. Weight of the moment the big toe begins to move. The traction value test is shown schematically.

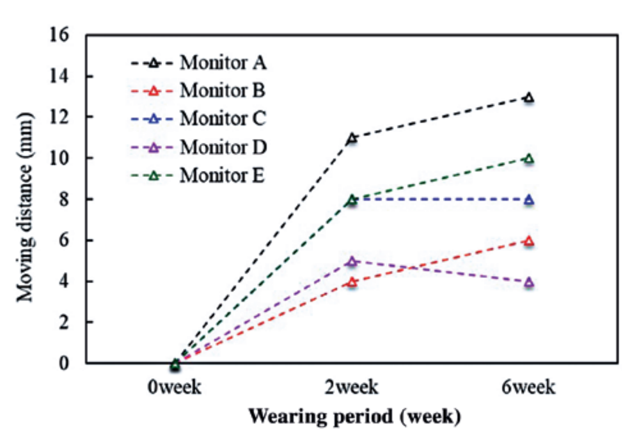

Figure 6. Moving distance of the tip of the big toe when pulled to 15 gf.

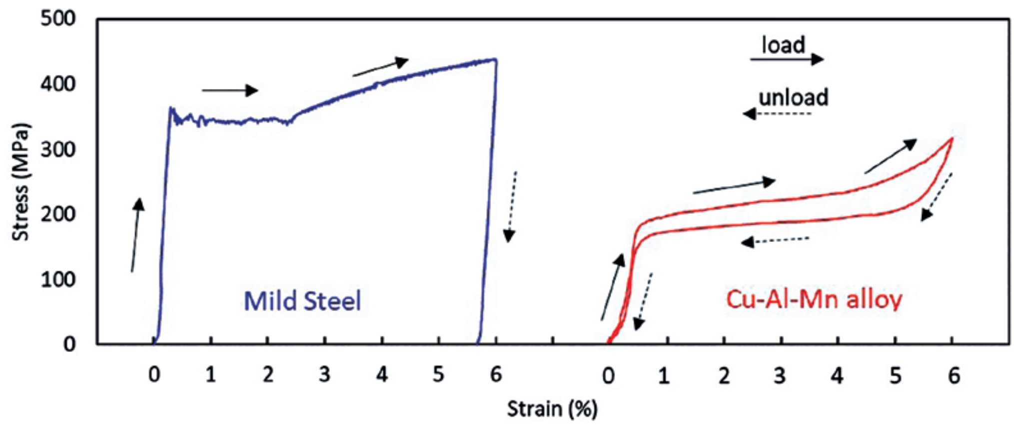

Figure 7. Stress-strain behavior of general mild steel and Cu-Al-Mn super-elastic alloy.

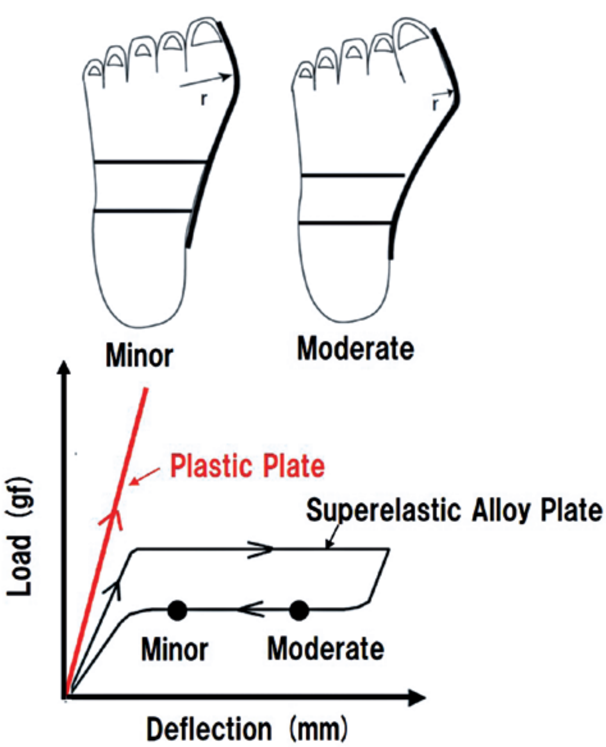

Figure 8. The force applied to each big toe angle by the metatarsal orthotic using super-elastic alloy is shown schematically.

even under large deformations. The high wearability can be attributed to a synergistic effect caused by using microfiber fabrics[9], which allow for comfortable sleeping due to their softness and nonsteaminess[10]. The microfiber fabrics also prevent the brace from slipping off the foot.

The loads for the initial movement and the distance of toe movement at 15 fg load were measured to see if the orthotics could improve the big toe MTP joint lateral contracture. The extensive literature search yielded no such experimental report. Within two weeks of application, the big toe MTP joint lateral contracture had improved. The reason might be that during the long hours of wearing the device at bedtime, a force was constantly applied to the big toe with minimal pain, achieving the same effect as stretching for an extended period. However, there was no discernible improvement in the HV angle during the experimental period. This could be due to the short measurement period and the fact that, even if the contracture improved, it did not sufficiently cause a change in angle. We want to investigate how satisfied patients are with this orthotic and whether there is any improvement in big toe complaints.

Conclusions

We created an orthotic device for HV correction using a Cu–Al–Mn super-elastic alloy brace that can be easily processed into a brace material, which has been difficult with traditional NT alloys. In addition to the super-elastic effect, a hinge mechanism that moves with the big toe and the use of ultrafine polyester fibers to prevent slippage against the skin without causing steam or discomfort to the skin were used to create a brace with both physical and ergonomic functions.

The developed orthotic was monitored by five patients who wore it daily for six weeks, and all patients could sleep comfortably while wearing it.

In the follow-up, all patients experienced relief of the big toe MTP joint lateral contracture within two weeks of wearing the device. This is thought to be due to the effect of long-term stretching while sleeping with a constant force applied to the big toe. We will continue to investigate the possibility of allowing the toes to move more easily, allowing the formation of arches during walking and contributing to reducing calluses, which are common in MTP patients.

Authors' contributions: Each author contributed individually and significantly to the development of this article: MH * (https://orcid.org/0000-0002-8402-5373) Conceived and planned the activity that led to the study, wrote the article, participated in the review process; SK *(https://orcid.org/0000-0002-7455-6349) data collection, bibliographic review; TK *(https://orcid.org/0009-0009-7469-2429) formatting of the article, bibliographic review; TO *(https://orcid.org/0000-0002-9877-5298) Interpreted the results of the study, participated in the review process; RK *(https://orcid.org/0000-0003-0713-6106) Performed the surgeries; data collection, statistical analysis. All authors read and approved the final manuscript. *ORCID (Open Researcher and Contributor ID) iD.

References

1. Tang SFT, Chen JTN, Chen CK, Tang ACW. Effective conservative treatment for managing painful hallux valgus. Med Res Arch. 2016;4(6):1-9.
2. Ying J, Xu Y, István B, Ren F. Adjusted Indirect and Mixed Comparisons of Conservative Treatments for Hallux Valgus: A Systematic Review and Network Meta-Analysis. Int J Environ Res Public Health. 2021;18(7):3841.
3. Miyazaki S, Otsuka K. Development of Shape Memory Alloys. ISIJ International. 1989;29(5):353-77.
4. Morgan NB. Medical shape memory alloy applications-the market and its products. Materials Science and Engineering A. 2004;378(1-2):16-23.
5. Kainuma R, Takahashi S, Ishida K. Ductile shape memory alloy system of the Cu-Al-Mn system. J Phys IV. 1995;5(C8):961-66.
6. Kainuma R. Recent Progress in Shape Memory Alloys. Mater Trans. 2018;59(3):327-31.
7. Kainuma R, Takahashi S, Ishida K. Thermoelastic martensite and shape memory effect in ductile Cu-Al-Mn alloys. Metall Mater Trans A. 1996;27:2187-95.
8. Ishibashi M, Tabata N, Suetake T, Omori T, Kainuma R, Yamauchi K, et al. A simple method to treat an ingrowing toenail with a shape-memory alloy device. J Dermatolog Treat. 2008;19(5):291-2.
9. Kamiyama M, Soeda T, Nagajima S, Tanaka K. Development and application of high-strength polyester nanofibers. Polym J. 2012;44:987-94.
10. Horikawa N, NumataM, Soeda T, Kamiyama M. NANOFRONTTR–New Technology Material to Change each day. SEN'I GAKKAISHI (Japanese). 2009;5:341-44.