

## **Treatment of pincer nails using devices made of NiTi shape-memory alloys**

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## Abstract

The authors treated pincer nails with stent-shaped orthotic devices using shape-memory alloy (NiTi) and had good results. Shape-memory alloy (NiTi) has been found to be safe as a medical material, but it is difficult to process and this is the first time it has been made into an orthotic device. The orthotic device is applied in a way that sandwiches the free edge of the nail plate from the top and bottom, making it easier and less invasive than conventional treatments for pincer nails. The authors believe this report may be very useful as a new option for future pincer nail treatment.

## Introduction

A variety of treatments have been devised and tried for pincer nails and ingrown nails, but in recent years the mainstream has shifted from surgery to conservative treatment. A variety of such methods are being used, including acrylic gutter splints,<sup>1)</sup> anchor taping,<sup>1)</sup> VHO orthotics,<sup>2)</sup> shape-memory alloy (NiTi) wires,<sup>2)</sup> and shape-memory alloy (Cu-Al-Mn) orthotic devices.<sup>3,4)</sup> The authors treated pincers nails of 12 consenting patients using NiTi shape-memory alloy orthotic devices as a new conservative treatment method.

## Subjects

The subjects were patients who, between April 2011 and March 2012, came to Shuwa General Hospital, either with their major complaint being a pincer nail on the big toe or who were found to have a pincer nail on the big toe as outpatients for foot care. The scope of subjects was limited to those who had no metal allergies, uncontrolled diabetes or circulatory disorders, and had no infection, granulation, etc. in the area where the device would be used. For this study, a pincer nail was defined as a nail plate with edges that curve inward, with at least one edge having a tangent angle of less than 90° between the nail plate and nail edge (Fig. 1-a, b). There were 12 patients who wore the orthotic device (three men and nine women; ages 28-77) on a total of 17 nails. All subjects consented to the use of the NiTi shape-memory alloy orthotic device.

## Method

The orthotic devices were made of NiTi shape-memory alloy and shaped like a C in cross-section (Fig. 2-a, b), and each was chosen to match the thickness and width of the free edge of the patient's nail plate, with opening slits of 1.0 or 1.2 mm and widths ranging from 15-18 mm. The orthotic device was put on in a way that sandwiched the free edge of the patient's big toenail from the top and bottom and was anchored with adhesive to soft tissue to prevent it from falling off (Fig. 2-c, d). Aside from that, there was no anchor taping, etc., so the device was not anchored with tape, plaster, etc. In cases where the nail plate's free edge was too wide for the orthotic device or it was difficult to apply the device to the entire free edge because of severe deformity, the device was applied only where the deformity was particularly severe, and if the device fell off, patients were asked to come back to the hospital as soon as possible to have it re-applied. Patients came in to the hospital when the device was applied, two and four weeks later, and then four weeks after they stopped wearing it, to determine its effectiveness.

## Evaluation method

- (1) Measure before applying the device
- (2) Measure after two weeks, with the patient wearing the device
- (3) At four weeks after applying the device, remove the device and measure
- (4) Measure four weeks after the device was removed

Measurements were taken four times as above, then a nail height index (nail height at the tip of the nail plate divided by nail width at the tip of the nail plate) was used as based on a report by Kosaka et al.<sup>5)</sup> to evaluate the curve of the nail plate. The patients were also checked for any subjective symptoms. Finally, cases where the nail plate had an inward coil shape were not evaluated because it was impossible to do so using this index.

## Results

The effectiveness of the device was evaluated for 11 patients, with 15 treated nail plates, who were able to come in to the hospital to apply the device, come in again two and four weeks later, and again four weeks after it was removed. The nail height index was objectively analyzed, with the results shown in Table 1. Figure 3 shows photos of Case 1 before and after applying the orthotic device, and two and four weeks later.

The analysis found improvement in the nail height index for all 15 cases after two weeks. The average nail height index for the 15 cases was 57.5% when first applying the device, 40.1% after two weeks and 36.1% after four weeks, demonstrating significant effectiveness two weeks after application. In 80% of the cases, the effectiveness remained four weeks after removing the device as compared to when the patient first began wearing it, but the pincer nails were found to have recurred in 20% of cases. In those cases where there was recurrence, the pincer nails were found to have become worse than at initiation.

At initiation, the patients reported moderate spontaneous pain or tenderness that interfered with their daily lives from time to time in seven cases, but in the fastest improvement cases these symptoms disappeared immediately after applying the device and in the slowest cases in the first two weeks of wearing it. There was similar effectiveness even in cases where the orthotic device was applied to only a part of the free edge of the nail plate. There were also good results in those cases where the nail plate had an inward coil shape, so the authors had those patients continue to wear the orthotic device for half a year and followed the progress as reference. The photos in Figs. 4 and 5 show the progress with the right big toe (Case 16) and left big toe (Case 17).

## Discussion

The authors objectively analyzed the degree of improvement made by treating pincer nails with stent-shaped orthotic devices using shape-memory alloy (NiTi). The analysis found improvement in the nail height index for all cases two weeks after applying the device, with an average 17.4% improvement. It also found improvement in subjective symptoms within two weeks.

The shape-memory alloy (NiTi) used here has also been used for vascular treatment, etc., and found to be safe as a medical material. It is, however, difficult to process and until now had never been made into an orthotic device for pincer nails. With this study, however, it has now been made into an orthotic device using the same method as stent-making, which involves starting with a tube and processing it with a laser.

The shape-memory alloy (NiTi) has a wide elastic region, and even if the amount of deformity increases, its stress has a uniform plateau region. For this reason, the shape of the orthotic device itself can be significantly modified and applied to even very deformed nails, and even when altered in shape the corrective force is not overly strong and can treat pincer nails at a constant stress, without putting too much burden on the nail. This characteristic is considered to be the reason why there were no cases of cracking at the nail edge in this study, even though such cracking frequently occurs during pincer nail treatment. Also, because the device was shaped like a C in cross-section and applied in a way that sandwiched the free edge of the patient's affected toenail from the top and bottom, there was no waste in the direction in which force was applied, and the force worked in the direction to correct the pincer nails. This shape makes it easy to apply even to nails that have been cut to be round, short nails, and nails with severe deformity. It can easily be applied to nails without causing them any burden; for example, having to make a hole in the tip to pass a wire through. When the orthotic device supports the free edge of the nail plate from the top and bottom, it makes contact with the skin below the nail plate and is constant; the orthotic device will never dig into the space between the nail plate and skin. For this reason, even if the patient were to hit the orthotic device against something while wearing it, it would put little burden on the nail or toe and the pain would be minimal, so patients will enjoy a better QOL since they can still lead an active lifestyle while undergoing treatment. This study found no harmful effects that would cause problems for the patient.

In addition, the fact that the treatment method discussed here proved to be effective against cases of severe nail deformity that would have been difficult to correct with earlier methods, such as pincer nails with an inward coil shape, suggests that the new method would be very

useful as a new option for future treatment of pincer nails. It is expected that altering the width of the orthotic device and the width of the slit will increase the number of cases in which this device can be worn.

One problem is that the pincer nails were found to recur after treatment in 20% of cases. As the method used here does not consider the thickness or hardness of the nail, no data is available on these parameters, however the study gave the impression that the effect of the treatment may be slower to occur in harder and thicker nails and recurrence of symptoms may be more likely.

When the corrective force of the orthotic device was measured, it was found to correspond to that of wire of the same material measuring  $\Phi 0.2 - \Phi 0.3$  mm, so the fact that there is less corrective force than with a wire of about  $\Phi 0.5$  mm, which is used in conventional wire treatment, would seem to be one cause of more frequent recurrence.

In Case 5, the patient wished to continue the treatment because the nail height index was worse four weeks after removing the orthotic device than after four weeks of wearing it. Therefore, the orthotic device was applied for another three months, and the nail height index achieved with the device on was still maintained two months after the end of treatment. This suggests that long-term wearing of the device may make recurrence less likely.

To treat pincer nails and ingrown nails, it is important to choose a treatment method suited to the patient's nail, but it appears that a NiTi shape-memory alloy orthotic device may be very useful as a new option for future pincer nail treatment.

(NiTi shape-memory alloy orthotic devices were supplied by Actment Co., Ltd. Although they are not currently available on the market, Actment reports that they will supply the devices to those wishing to use them.)

Explanation of figures

Fig. 1: a. Tangent angle of  $90^\circ$  between the nail plate and nail edge

b. Tangent angle of less than  $90^\circ$  between the nail plate and nail edge

Fig. 2: a, b. Orthotic device; c, d. How the orthotic device was applied.

Table Results: Trend in nail height index

Fig. 3: Clinical photos. Case 1 (female, age 62), right big toe.

a. Before applying orthotic device. b. Immediately after applying device. c. Two weeks after applying device. d. Four weeks after applying device.

Fig. 4: Clinical photos. Case 16 (female, age 41), right big toe.

a. Before applying orthotic device. b. One month after applying device. c. Two months after applying device. d. Six months after applying device.

Fig. 5: Clinical photos. Case 17 (female, age 41), left big toe.

a. Before applying orthotic device. b. One month after applying device. c. Two months after applying device. d. Six months after applying device.