FDA Executive Summary

Prepared for the October 26 & 27, 2022 Meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

Classification of Nail Prosthesis

Product Code: MQZ

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1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) is convening the General and Plastic Surgery Devices Advisory Panel (the Panel) for the purpose of obtaining recommendations regarding the classification of nail prosthesis, a pre-amendments device type which remains unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of nail prosthesis under product code "MQZ". The device names and associated product codes are developed by the Center for Devices and Radiological Health (CDRH) in order to identify the generic category of a device for FDA. While most of these product codes are associated with a device classification regulation, some product codes, including "MQZ" remain unclassified.

FDA is holding this panel meeting to obtain input on the risks to health and benefits of the nail prosthesis under product code "MQZ". The Panel will discuss whether the nail prosthesis under product code "MQZ" should be classified into Class I (subject only to General Controls).

1.1 Current Regulatory Pathways

Nail prostheses are a pre-amendments, unclassified device type. This means that this device type was marketed prior to the Medical Device Amendments of 1976 but was not classified by the original classification panels. Currently these devices are being regulated through the 510(k) pathway and are cleared for marketing if their intended use and technological characteristics are "substantially equivalent" to a legally marketed predicate device. Since these devices are unclassified, there is no regulation associated with the product code.

1.2 Device Description

Nail prostheses are devices intended to temporarily provide structure (e.g., splint, brace) to ingrown or damaged nails to correct or support nail growth. In general, nail prostheses are constructed out of polymeric and/or metallic materials.

On ingrown nails, which are predominantly toenails, a nail prosthesis device may be used to apply outward pressure on each side of the nail between the nail and the surrounding skin and correct nail over-curvature. For injured or deformed nails, such as after traumatic injury, which is predominantly on fingernails, a nail prosthesis device may be used as a temporary splint (cover) for nail bed reconstruction, and then the device is removed. A nail prosthesis intended for injured or deformed nails can be temporarily sutured in place and subsequently removed once the desired natural healing of the nail has taken place.

A nail prosthesis intended to correct ingrown nails may be suitable for home use, while a nail prosthesis intended for injured or deformed nail bed is intended to be used in surgical settings.

2. Regulatory History

Nail prostheses are pre-amendments devices that have been in commercial distribution prior to May 28, 1976.

To date, FDA has cleared three 510(k)s under the MQZ product code. Please refer to Table 1 for a listing of the manufacturers, device names, and associated 510(k) submission numbers for devices cleared under product code "MQZ":

Table 1: 510(k) clearances for nail prostheses under product code "MQZ"

510(k) Number	Trade Name	Sponsor
K850803	Nail Splint	INRO MEDICAL DESIGNS, INC.
K960843	STOP-N-GROW	EUROPEAN TOUCH CO. INC.
K162525	Oniko nail brace	BEGUM SAGLIK HIZMETLERI TIBBI MALZEMELER DANISMANLIK LSTI

3. Indications for Use

The Indications for Use (IFU) statement identifies the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.

The nail prostheses under the product code "MQZ" have been cleared for the following indications for use:

- To correct the shape of overcurved and/or painful nails without operation. To loosen and to give shape to thickened nails, overcurved nails and pincer nails without operation
- To restrain the ingrown portion of the nail to grow in a forward motion, thus eliminating the ingrown nail
- Splint for reconstruction in acute nail bed injuries or other deformities of the nail plate

4. Clinical Background

4.1 Disease Characteristics

Ingrown toenail (onychocryptosis) is a common foot condition in people of all ages. Around 18 percent of US adults have had an ingrown toenail at certain point in their lives.[1] The condition may develop in any toenails, but more often in the big toe. An ingrown toenail occurs when a nail grows into the skin along the side of the toe or when the skin on one or both sides of a nail grow over the edges of the nail. Common symptoms are pain, redness, swelling, and infection. Factors that may lead to ingrown nails include wearing tight shoes, improper grooming and trimming of the nail, trauma, infection or certain medical or congenital conditions. Infections related to ingrown toenails in patients with diabetes or

[1] Institute For Preventive Foot Health. National Foot Health Assessment 2012. Slide 15. https://www.ipfh.org/images/research_materials/2012_National_Foot_Health_Assessment_June_2012.pdf

significant vascular compromise may require aggressive soft tissue debridement, long term antibiotic treatment and potentially toe, foot or leg amputations.

In patients who sustain trauma to the nail plate and nail bed, which may include partial toe or finger amputations, the treatment and healing may be more complicated and may affect both aesthetic appearance and functional performance of the nail. Failure to achieve a clean flat nailbed may result in a poorly attached nail, dystrophic nail, split nail, thickened and discolored nail and even a short nail with tissue overgrowth. In cases where the nail plate does not grow to the tip of the finger, significant loss of tactile sensation may occur, causing functional debility and compromised quality of life.

4.2 Patient Outcomes

Ingrown toenails may be noticed by the patient at early stage when pain starts. The healthcare provider may diagnose an ingrown toenail based on the visual checking on the affected toe, the patient's symptoms, and possible causes. No complex examinations are needed. Some lab tests such as blood test, may be requested if the doctor think an ingrown toenail has caused other complications.

Trauma to the nail plate and nail bed may require specialized care, including first treating the nail bed injury and any associated soft tissue loss, followed by ensuring the proper longitudinal growth of the nail plate across a well healed, vascularized flat nail bed. Preparing the nail bed may require dermabrasion, excision of scar tissue and tissue grafting and flaps. In both phases of treatment, the use of a nail prothesis or splint is critical to ensure the best cosmetic and functional outcome.

4.3 Currently Available Treatment

For ingrown nails, correction of over-curvature is commonly addressed with surgical techniques to remove the ingrown portion of the nail. Over-the counter products are also available to correct the over-curvature, which include bandage and gel combinations to soften the nail, and topical products that may soften the nailbed to prevent inward growth of the nail. Patients with over-curvature of nails may also decide not to seek treatment, or to try home remedies such as soaking feet in warm water or applying petroleum jelly to the overcurved nail.

For nails with traumatic injury where part or all of the nail has been damaged, patients may receive treatment including surgical repair of the finger and nailbed that has received trauma. Wound care and bandaging may be used to support the injured nailbed and surrounding tissue. A damaged or removed nail can also be left to heal on its own.

4.4 Risks

FDA has identified the following risks to health associated with nail prostheses:

Table 2: Risks to Health and Descriptions/Examples for Nail Prostheses

Identified Risk	Description/Examples
Adverse tissue reaction	This can result from the use of device materials that are not biocompatible.
Discomfort, pain or nail breakage	This can result from the device applying too much pressure on the nail.
Nail infection	This can result from inadequate cleansing of the nail before application of the prosthesis or from the introduction of microorganisms to the area once the prosthesis is in place.

The Panel will be asked whether this list is a complete and accurate list of the risks to health presented by nail prostheses under product code "MQZ" and whether any other risks should be included in the overall risk assessment of the device type.

5. Literature Review

5.1 Methods

A systematic literature review was conducted in an effort to gather any published information regarding the safety and effectiveness of nail prostheses under product code "MQZ."

Online literature searches were performed to identify all published articles between May 1, 1976, and April 1, 2022, in two databases (PubMed and EMBASE). The search was limited to human clinical studies with full text available in English language focusing on the following terms: nail, ingrown, deformed, malformed, pincer, onychocryptosis, prosthesis, brace, device, podiatry/ instrumentation or Ingrown/therapy. Because the initial search did not capture the Inro Splint device (K850803), a supplemental literature search was conducted to identify literature reporting outcomes related to the use of Inro Splint, using search terms "INRO splint" and "nail prosthesis", and date ranges of 1976 to July 2022.

Detailed methods, search terms and filters are provided in Appendix A. The number of articles meeting inclusion and exclusion criteria is summarized in the flow diagram in Appendix B.

5.2 Results

The literature search yielded three articles for nail prosthesis devices that correct ingrown nails.[2,3,4] The supplemental literature search for INRO Splint yielded one article.[5] Data from one prospective comparative study, two single arm studies and one retrospective chart review were used to assess nail prostheses, for a total of four articles. Three studies were conducted outside of the US (Taiwan[2], Turkey[3], and South Korea[4]), while one study was conducted in the US[5]. Devices were used to treat the ingrown nails[2,3,4] or used as a splint for nailbed injuries[5] across and within studies. The included studies reported on 18[5] - 159[3] patients whose mean ages ranged from 24[5] to 54.7[2] years. The length of follow-up ranged from 6 weeks[5] to 2 years[3].

A comparative, prospective study by Wang 2020[2] examined the efficacy of two types of nail braces (unspecified brace 2 only vs. brace 1 + 2; see Table 4 in Appendix C for details) for treatment of ingrown nails on 28 patients with acute inflamed (AI) and 25 patients with chronic dystrophic (CD) ingrown toenails. Most patients were pain free after one day and able to return to work regardless of their condition (AI or CD) or the type of bracing treatment received. Mean post brace removal follow up was 281.6 days or 9.3 months. The authors concluded that nail brace application was an effective, noninvasive treatment for CD nails with high patient satisfaction, low recurrence rates, and favorable outcomes.

A retrospective chart review by Guler 2015[3] compared the use of Oniko nail braces to the Winograd procedure for the treatment of ingrown toenails in 159 patients. Patient satisfaction favored the nail braces group (94.6% vs. 82.4%). There was no statistically significant difference for recurrence rates and the cumulative progression-free period between the two treatment groups.

A single-arm prospective study by Kim 2009[4] reported results on the treatment of ingrown toenails with a prosthetic device, K-D, which included a compound alloy and prefabricated toenail side-engaging hook (S&C Biotech, Seoul, South Korea). All nail deformities were corrected within 3 weeks, but the study did not include a control group.

A single-arm study by Ogunro 1989[5] reported results on the treatment of nail bed injuries with INRO surgical nail splint. The study followed up the patients for 4-18 months, and reported that 15 out of 17 patients, the injured nails are fully recovered, which represent the nail regain its size, shape, smoothness and growth as the normal nail. One patient's nail regrew, but did not regain the original size,

[2] Wang HH, Yang TH, Liu CW, Tsai TY, Huang YC. Efficacy of Nail Braces for Acute and Chronic Ingrown Toenails: A Prospective Study. Article. Dermatol Surg. 2020;46(2):258-266. doi:10.1097/DSS.0000000000001905

[3] Guler O, Tuna H, Mahirogullari M, Erdil M, Mutlu S, Isyar M. Nail Braces as an Alternative Treatment for Ingrown Toenails: Results From a Comparison With the Winograd Technique. J Foot Ankle Surg. Jul-Aug 2015;54(4):620-4. doi:10.1053/j.jfas.2015.04.013

[4] Kim JY, Park JS. Treatment of symptomatic incurved toenail with a new device. Foot Ankle Int. Nov 2009;30(11):1083-7. doi:10.3113/fai.2009.1083

[5] E.Olayinka Ogunro. External fixation of injured nail bed with the INRO surgical nail splint. J Hand Surg Am. 1989 Mar;14(2 Pt 1):236-41:236-41. doi: 10.1016/0363-5023(89)90012-9.

shape and smoothness. One patient's nail did not regenerate and was operated on 19 days after injury.

5.3 Adverse Events Associated with Nail Prosthesis

With regards to safety, few patients experienced temporary pain with the treatment of nail braces (2.5% patients)[2], nail brace dislocations (3/28 patients)[2] and minor nail infections (7/31 toes, 1/18 fingers)[4,5]. No other safety events were reported.

5.4 Effectiveness Associated with Nail Prosthesis

With regards to effectiveness, 4-8%[4] of patients experienced a recurrence in nail deformity and nearly all patients reported pain relief within one day[2]. In 16 nails out of 18 fingers treated with INRO surgical nail splint, nail regrowth was observed[5].

5.5 Overall Literature Review Conclusions

The literature search between years 1976 to 2022 yielded a total of four literature references that were applicable to evaluating the safety and effectiveness of nail prostheses. The quality of evidence in the reviewed studies was low with very limited generalizability.

6. Risks to Health Identified through Medical Device Reports (MDRs)

6.1 Overview of the MDR System

The MDR system provides FDA with information on medical device performance from patients, health care professionals, consumers and mandatory reporters (manufacturers, importers and device user facilities). The FDA receives MDRs of suspected device-associated deaths, serious injuries, and certain malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. MDRs can be used effectively to:

- Establish a qualitative snapshot of adverse events for a specific device or device type
- Detect actual or potential device problems used in a "real world" setting/environment

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the submission of incomplete, inaccurate, untimely, unverified, duplicated or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about the frequency of device use. Finally, the existence of an adverse event report does not definitely establish a causal link between the device and the reported event. Because of these limitations, MDRs comprise only one of the FDA's tools for assessing

device performance. As such, MDR numbers and data should be taken in the context of the other available scientific information.

6.2 MDR Data: Nail Prosthesis

On May 24, 2022, a search of MDRs was conducted for product code MQZ with no date limitation. This query resulted in two MDRs unrelated to nail prosthesis devices that were miscategorized under the MQZ product code. Further queries included searching the brand and manufacturer names: Brand Name-Oniko Nail Brace, Brand Name-Stop-N-Grow, Manufacturer-European Touch, Manufacturer-Begum Saglik, and Manufacturer-Oniko. The search did not identify any relevant MDRs for nail prosthesis devices.

7. Recall History

7.1 Overview of Recall Database

The Medical Device Recall database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") identified on the database indicates the date FDA classified the recall, it does not necessarily mean that the recall is new.

7.2 Recall Results: Nail Prosthesis

The FDA conducted queries of the Medical Device Recall database on August 18, 2022, to identify recalls related to nail prosthesis (product code MQZ). The search was not timeframe restricted and included all recalls reported under product code MQZ. The search did not identify any relevant recalls for nail prostheses.

8. Summary

In light of the information available, the Panel will be asked to comment on whether the nail prostheses under product code “MQZ”:

meet the statutory definition of a Class III device in accordance with section 513 of the Food, Drug, and Cosmetic Act (FD&C Act):

- insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, and

- the device is purported or represented to be for use in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, or

- if the device presents a potential unreasonable risk of illness or injury

or would be more appropriately regulated as Class II, in which:

- general and special controls, which may include performance standards, postmarket surveillance, patient registries and/or development of guidelines, are sufficient to provide reasonable assurance of safety and effectiveness;

or as Class I, in which:

- the device is subject only to general controls, which include registration and listing, good manufacturing practices (GMPs), prohibition against adulteration and misbranding, and labeling devices according to FDA regulations.

For the purposes of classification, FDA also considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;

2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

4. The reliability of the device.

The Panel will be asked whether they believe nail prostheses would be appropriately regulated as Class I. If the Panel does not agree with FDA's proposed classification, the Panel will be asked to provide their rationale for recommending a different classification.

8.1 Special Controls

For nail prostheses intended to correct or support nail growth in ingrown or damaged nails, FDA does not believe that special controls will be required and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness of nail prostheses.

8.2 Overview of Proposed Classification/FDA Recommendation

Based on the safety and effectiveness information gathered by the FDA, the identified risks to health and recommended mitigation measures, we recommend that nail prostheses indicated for use on ingrown or damaged nails to promote healthy nail growth be regulated as Class I exempt devices.

878.3560 Nail prosthesis.

(a) *Identification.* A nail prosthesis is intended to temporarily provide structure to ingrown or damaged nails to correct or support nail growth. A nail prosthesis device intended for ingrown nails helps to correct nail over-curvature. A nail prosthesis device intended for injured or deformed nails, such as after traumatic injury, may serve as a temporary splint to physically cover and protect the injured or damaged nailbed during the healing process. A nail prosthesis is not intended for used on infected nails.

(b) *Classification.*

Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of the nail prosthesis under product code "MQZ."

Appendix A: Literature Search Terms and Filters for Nail Prosthesis

The search strategies were generated using the intervention, condition of interest, Boolean operators, medical subject heading [MeSH] terms or the Emtree thesaurus. The search was limited to human clinical studies with full text available in English language focusing on the following indications: nail, ingrown, deformed, malformed, pincer, onychocryptosis, prosthesis, brace, device, podiatry/instrumentation or Ingrown/therapy. Multiple searches were conducted using product names combined with brand names and related terminologies without the limitation of indication of use. All published studies, including case reports, were considered.

The table below summarizes the patients, interventions, comparisons, outcomes, timing, and settings (PICOTS) elements that informed the inclusion/exclusion criteria.

Table 3: Literature Eligibility Criteria

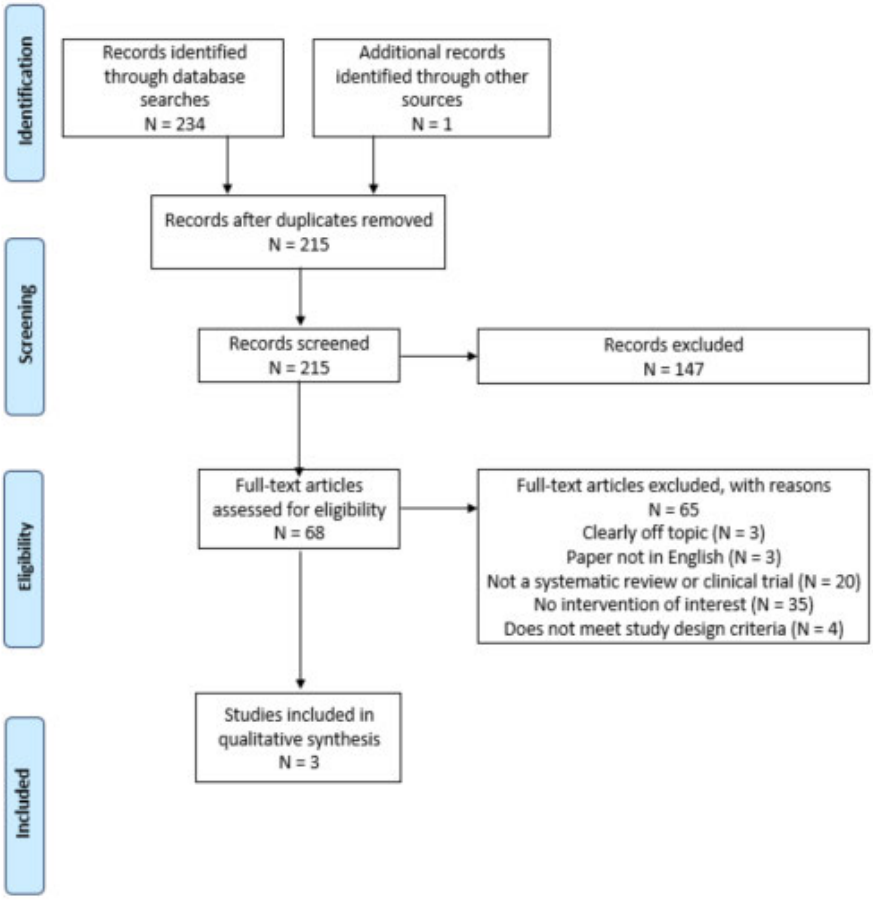
PICOTS	Inclusion Criteria	Exclusion Criteria
Population	Patients with deformities of the fingernail or toenail, including ingrown toenail	Patients without deformities
Intervention	Nail prosthesis Nail brace	No device
Comparison	• No use of a nail prosthesis/brace • STOP-N-GROW vs. Oniko Nail Brace	No exclusion
Outcomes	Time until correction of nail deformity Adverse tissue reactions Irritation Itching Pain Infection Device malfunction Device breaks Device becomes dislodged	Studies will be excluded if they do not report on any of the specified outcomes
Timing	All	None
Setting	US and OUS	No exclusion
Study Design	• Randomized controlled trials • Cohort studies (prospective/retrospective) • Case-control studies • Cross-sectional studies • Systematic literature reviews (SLRs) • Meta-analyses The following will be included if there are no comparative studies available • Case series/single-arm studies (≥10 patients) Case reports (≤9 patients)	Laboratory studies Animal studies Economic and cost-effectiveness analyses Non-clinical trials (narrative reviews, conference abstracts, editorials, etc.)
Language	Articles published in English	Non-English Language
Publication dates	May 1, 1976, to April 1, 2022	Published outside of date range

		For any included SLRs, ≥80% of the included studies in the SLR must have been published within this date range.

More details on the search strategy for each database and yield is given included in Figure 1 in Appendix B.

Appendix B: Flow Diagram of Systematic Literature Review Search Results

Figure 1: Nail Prosthesis, Nail Brace PRISMA



A supplemental literature search was conducted to identify literature reporting outcomes related to the use of nail prosthesis device, the Inro Splint (K850803). This search returned 1 article[5] describing a clinical study for the INRO splint device.

The details of the four relevant articles are included in Table 4 in Appendix C.

Appendix C: Literature Evidence Table

Table 4: Studies Included in the Literature Review for Nail Prostheses

Study Characteristics	Patient Characteristics	Device Brand/ Manufacturer	Safety Outcomes
Reference: Wang et al. 2020[2] **Country:** Taiwan **Study Design:** Prospective open label study, patient choice determined treatment assignment **Purpose:** To prospectively examine and compare the efficacy of nail braces for treatment of acute inflamed (AI)-type and chronic dystrophic–type ingrown toenails. **Length of follow-up:** Mean post brace removal follow up was 281.6 days or 9.3 months **Funding Source:** Ministry of Science and Technology, Taiwan, grant no. (b) (4) **Note:** There were reporting errors by the authors in Table 2 of percentages for one month and personal final PGA data that we were able to correct. ***Follow-up duration (d), p<0.001*** CD 240.8 (115.7) AI 350.8 (96.7)	**Patients (N):** 53 patients (96 affected sides) - Acute inflamed (AI) 28 patients (35 sides) - Chronic dystrophic (CD) 25 patients (61 sides) Brace 2 was used in 83 affected sides, whereas brace 1 combined with brace 2 were used in 13 sides. **Age mean (SD):** 50.8 (SD 20.9) years AI: 47.3 (SD 23.7) years CD: 54.7 (SD 16.9) years **Sex (% male):** 21 (39.6%) AI: 16 (57.1%) CD: 5 (20%) **Diagnosis:** Ingrown toenails, mean disease duration was 3.9 (SD 4.6) years **Inclusion criteria:** Patients (age ≥12 years) with ingrown toenails who visited the authors' clinic between January 1, 2017, and July 31, 2017, were offered nail brace treatment. Patients who were treated for >1 month were included for outcome analysis. **Exclusion criteria:** Patients with psoriasis, severe onychomycosis, or those receiving target therapy **Note:** There were 2 different braces used, however the study	**Intervention:** Brace 2 was made of a spring wired hook attached to the rim of the nail plate and a square adhesive pad glued onto its dorsum. The brace 2 group was composed of participants with noninfected or mildly infected ingrown toenails and brace 2 was applied instantly. 100% of CD; 62.9% of AI **Comparator:** Brace 1 was composed of an adhesive pad with an embedded activating wire. The combined brace 2 and brace 1 group was composed of participants with severe paronychia, with or without pyogenic granuloma. 37.1% of AI **All:** All patients were prescribed oral analgesics and antibiotics for 1 week, after which the nail brace was applied.	**Pain of treatment visual analogue scale (VAS), mean (SD)** CD 3.1 (2.5) AI 3.4 (2.5), p=.717 ***Pain-related questionnaire data (Likert scored 0 [least] to 5 [most]), mean (range), for all patients combined*** Does the nail brace make painful sensation? 1-month 0.4 (0–3); 3-month 0.2 (0–3); 6-month 0 (0–1) Is the pain improved after treatment? 1-month 4.6 (2–5); 3-month 4.8 (3–5); 6-month 4.8 (3–5) **Physician Global Assessment (PGA), n (%)** ***1st month, p <0.001*** Excellent: CD=16 (28.1%), AI=23 (71.9%) Fair: CD=26 (45.6%), AI= 7 (22.9%) Mild improvement: CD=15 (22.3%), AI= 2 (5.2%) Worse: CD= 0, AI= 0 ***3rd month, p= .018*** Excellent: CD=29 (53.7%), AI= 20 (83.3%) Fair: CD=22 (40.7%), AI= 3 (12.5%) Mild improvement: CD=3 (5.6%), AI= 0 Worse: CD=0, AI= 1 (4.2%) ***6th month, p= .019*** Excellent: CD=29 (85.3%), AI= 6 (66.7%) Fair: CD=5 (14.7%), AI= 1 (11.1%) Mild improvement: CD= 0, AI= 0 Worse: CD= 0, AI= 2 (22.2%) ***Personal final PGA, p= 0.394*** Excellent: CD=49 (96.1%), AI= 30 (100%) Fair: CD=2 (3.9%), AI= 0 Mild improvement: CD=0, AI=0 Worse: CD=0, AI=0 ***Treatment duration (d), p<.001*** CD 213.6 (SD 96.5) AI 120.7 (SD 64.3) ***Pain relief from ingrown nail***

	results are stratified by indication for use, not type of brace. The authors' previous study on brace 1 and brace 2 indicated that both braces were effective with low recurrence rates. Authors did not state whether these were significantly different.		Pain relief was achieved in almost all patients within1 day, and they were able to return to work immediately. ***More than one treatment cycle required, n (%), p<0.001*** CD 48 (84.2%) AI 14 (43.8%) ***Recurrence, n (%), p=.132*** CD 2 (3.9%) AI 4 (13.3%) 3 recurrences occurred less than 6 months after nail brace dislocation, and the other 3 occurred between 6 months and 1 year after nail brace removal. ***Complication (any), n*** CD 0 AI 0
Reference: Guler et al. 2015[3] **Country:** Turkey **Study Design:** Retrospective chart review **Purpose:** To compare nail braces versus the Winograd technique for treating ingrown toenails. **Length of follow-up:** 2 years Mean follow-up duration for the patients in the nail brace group was 12.7 (SD 3.9) months and for the Winograd technique group was as 13.4 (SD 4.8) months. **Funding Source:** None	**Patients (N):** 159 74 Nail brace group 85 Winograd technique group **Age mean (SD):** Nail brace group: 29.51 (8.48) years Winograd technique: 26.9 (8.00) years **Sex (% male):** Nail brace group: 33 (45%) Winograd technique: 37 (44%) **Diagnosis:** stage I, II, or III, 1-sided, ingrown toenail at the big toe according to the Heifetz classification **Inclusion criteria:** Patients admitted with pain, granulation, and difficulty walking. **Exclusion criteria:** Clinical fungal infection, neurologic or vascular disease, recurrence.	**Intervention:** Oniko nail braces consisting of 0.4 mm of steel wire with 2 hook-like projections on both sides and a dental string in the middle that was only fixed to 1 side **Comparator:** Winograd technique of partial matrix excision under a digital anesthesia block and a toe tourniquet All: Tissues were treated with first generation cephalosporin group systemic antibiotics. Additionally, the patients were instructed regarding comfortable shoe wear and treated with foot care. The patients whose infection had been cured but who had not completely healed with antibiotic treatment underwent surgery using either nail braces or the Winograd technique.	**Interval to recurrence (months), mean (SD), p= 0.031** Nail braces: 12.46 ± 1.60 Winograd: 13.24 ± 2.48 **Recurrence, n (%), p=0.772** Nail braces: 6 (8.1%) Winograd: 8 (9.4%) **Cumulative Progression free period, mean (SD), p= 0.857** 1 year Nail braces: 10.0 ± 0.95 Winograd: 11.0 ± 0.94 2 years Nail braces: 14.0 ± 0.88 Winograd: 12.0 ± 0.90 **Patient satisfaction*, n (%), p= 0.018** Nail braces: 70 (94.6%) Winograd technique: 70 (82.4%)
Reference: Kim et al. 2009[4] **Country:** South Korea	**Patients (N):** 19 patients (31 incurved toenails) **Age mean (SD):** 38.8 (12.4) years **Sex (% male):** NR	**Intervention:** K-D device (S&C Biotech, Seoul, South Korea) which is composed of a central member made of a shape-memory alloy, and a prefabricated toenail side engaging	**Adverse tissue reactions** Minor paronychia managed with local wound care and oral antibiotics: 7/31 cases; No other complications were noted.

Study Design: Prospective single arm study **Purpose:** Report the results of the treatment for symptomatic incurved toenails with the K-D device. **Length of follow-up:** 13.3 ± 4.9 months **Funding Source:** Authors report that "One or more of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article."	**Diagnosis:** Ingrown toenail 7/31 cases of onycomycosis 8/31 cases of trauma (toenail extraction for management of ingrown nail) **Inclusion criteria:** NR **Exclusion criteria:** NR	hook part, each being attached to both ends of the central member **Comparator:** no comparator	**Time to correction** 31/31 nails healed and the nail deformity was corrected within 3 weeks after the procedure. **Recurrence** 2/31 (6%) experienced a recurrence. Reapplication of K-D device was needed in one case because original placement was not located close enough to the proximal portion where the toenail deformity started. In the other case of recurrence, the patient had a thickened toenail due to onychomycosis after management. The patient took antifungal medication, and 6 months later, as the diseased toenail thinned, the recurrence occurred. For the treatment of this case, the K-D was reapplied. **Other** Improvement of shape of nail measured as mean center to edge angle of toenail: Improved from 51.1 ± 9.5 degrees to 18.4 ± 5.2 ($p < 0.001$) American Orthopedic Foot and Ankle Society (AOFAS) forefoot hallux score mean pretreatment score was 71.1 ± 13.9 and improved to 100 by the last follow-up ($p < 0.001$).
Reference: E. Olayinka Ogunro. 1989[5] **Country:** United States **Study Design:** Patient Case Studies **Purpose:** To present clinical data of patients treated from the period of October,1983 to March,1985	**Patients (N):** 18 patients with 20 injured nails. One patient was lost to follow-up. Data from 17 patients out of 19 fingers are reported. INRO surgical nail splint was used to all nails. **Age mean:** 24 years **Sex :** 15 male patients with 17 Fingers and 3 female patients with 3 fingers.l.	**Intervention:** InRo Surgical Nail Splint is an artificial nail serving as the splint for nail injury requiring to be sutured on top of the nail bed.	There was 1 case of infection throughout the whole study of 20 nails. The infection was treated one time by inserting a small 22 gauge needle between the splint and the nail bed, and irrigating it with peroxide followed by normal saline.

Length of follow-up: 4-18 months , mean follow up was 8 months .	**Diagnosis:** Severe degree injuries with involvement of the nail bed or the eponychial fold and the germinal matrix. **Inclusion criteria:** Patients with severe degree injuries with involvement of the nail bed or the eponychial fold and the germinal matrix. Patient were from local areas with a permanent residence in the same geographical area. They had to be aware of the severity of the injury and the need for follow-up, in order to generate the statistics which was necessary.		

Abbreviations: N: number; p: p-value; PGA: Physician global assessment; SD: standard deviation; VAS: Visual analogue scale

*Patient satisfaction included unspecified complications, cosmetic problems such as surgical scar tissue and a narrowed nail structure, and patients' answers to hypothetical questions about undergoing the same treatment protocol for the same situation if it were to occur again.

Note: all rates were reported as reported by study authors; no additional calculations were performed.