Microwave Energy for the Treatment of Painful Intractable Plantar Keratosis

A Retrospective Medical Record Review of Nine Patients

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Background: Plantar keratoma are common hyperkeratinized, deep-seated lesions, often located on weightbearing areas of the foot. Such lesions are frequently associated with pain and disability. Intractable plantar keratomata (IPK) are highly recurrent and, in most patients, require regular, palliative treatment visits with a significant impact on patient time, cost, and quality of life.

Methods: We undertook a retrospective chart review of 9 patients (with a total of 21 lesions) who underwent a minimum of two treatments using microwave therapy to their IPK. Pain levels were assessed at each of their treatments using a 10-point scale and patients were invited for review for follow-up in the following year. A total of seven patients undertook four treatments and were included in the final analysis.

Results: Mean baseline pain scores significantly dropped with each subsequent treatment, equating to a 90.4% mean reduction in pain between the first and fourth visits, with 71.4% of patients reporting a zero-pain rating at their final treatment visit.

Conclusions: The use of microwave therapy has been shown to be effective in producing significant and prolonged pain reduction in a cohort of patients with painful IPK. (J Am Podiatr Med Assoc 114(3), 2024; doi:10.7547/23-019)

Because humans are a bipedal species, the soles of the feet are under the regular intermittent forces of pressure and friction from standing or walking. The body's defense mechanism against these excessive forces is to increase the thickness of the outer layers of the epidermis with a reduction in desquamation[1] in areas experiencing high degrees of stress, resulting in hyperkeratosis, clinically observed as callus (or keratoma) formation. For a proportion of patients, a callus can develop into a nucleated area of hyperkeratinized skin, also known as a corn (or clavus). Lesions that have become chronic, painful, and refractory to treatment have been termed *intractable plantar keratoses (IPKs)*. Surveys have demonstrated that corns and callus affect 22% to 78% of the adult population. Their development is often caused and/or exacerbated by ill-fitting footwear and foot deformities. Corns have been shown to be a significant cause of embarrassment, pain, and disability,[2,3] increasing with age,[2] and in smokers.[4] In podiatric medical practice, corns and calluses continue to be the most commonly presented and treated foot problem.[5,6]

The difficulties in treating and resolving chronic corns are due to their highly recurrent nature, and current treatments are mostly palliative and need to be repeated routinely. Removal of the keratin using scalpel debridement has been shown to have an immediate effect in reducing the pain of plantar corns[7]; however, further work has shown this effect to be short lived (approximately 7 days) and palliative.[8] Common strategies include decompression of the affected area (insoles, padding, orthopedic shoes, or partial off-loading with orthotic devices), the use of moisturizing creams, application of chemical agents (salicylic acid, bleomycin sulfate) to soften hardened keratin, or cryosurgery. However, the most common treatment of choice remains regular palliative debridement with a scalpel.[9] New energy-based approaches such as laser surgery have been used in recent years and have been suggested to be effective and safe.[10] However, patients were

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Table 1. Patient Demographics and Microwave Treatment Details

Factor	Total/Range	Mean ± SD	Median
Sex (No.)	6	NA	NA
Male	3		
Female			
Age (years)	23–65	35.4 ± 13.4	29
IPKs (No.)	21/1–7	2.1 ± 1.85	1.5
Treatments (No.)	2–6	3.8 ± 1.1	4
Treatment dosage (W)	5–10	8.2 ± 1.4	8
Treatment time (sec)	2	NA	NA
Treatment interval (wk)	3.9–5.0	4.4 ± 0.36	4.3

Abbreviations: IPK, intractable plantar keratosis; NA, not applicable.

left with a deep, open wound for approximately 3 to 5 weeks, which could evoke adverse events such as bleeding, pain, or infection. Microwaves constitute another form of energy-based treatment. The manufacturer of the Swift microwave device (Emblation Ltd, Stirling, England) claims highly localized heating of lesions to a subablative temperature (hyperthermia; <50°C). The modality is a novel approach for skin lesions and is widely used in Europe and North America with great success in the treatment of common and plantar warts, with a clearance rate of 75.9% over the course of 6 months,[11] significant reductions in reported pain, and high patient satisfaction.[12] A common feature between plantar warts and IPK lesions is the presence of a hyperkeratinized layer of epidermis, which can be painful to the patient and affect mobility and quality of life.

We, therefore, hypothesized that localized microwave energy therapy may be a suitable treatment for corns in adults. The feasibility of microwave treatments for corns has already been assessed in two patients,[13] with a successful, lasting reduction in pain levels after the intervention. To gain further evidence of the effectiveness of microwave treatment for hyperkeratotic lesions, we undertook a retrospective medical record review of clinical data from a cohort of nine patients who received treatment for painful corns in a single podiatric medical clinic based in New York.

Methods

We performed a retrospective medical record review of nine patients who had undergone a course of microwave treatments using Swift for their IPKs at one podiatric medical practice location. The institutional review board (Advarra, Columbia, Maryland) designated this study as

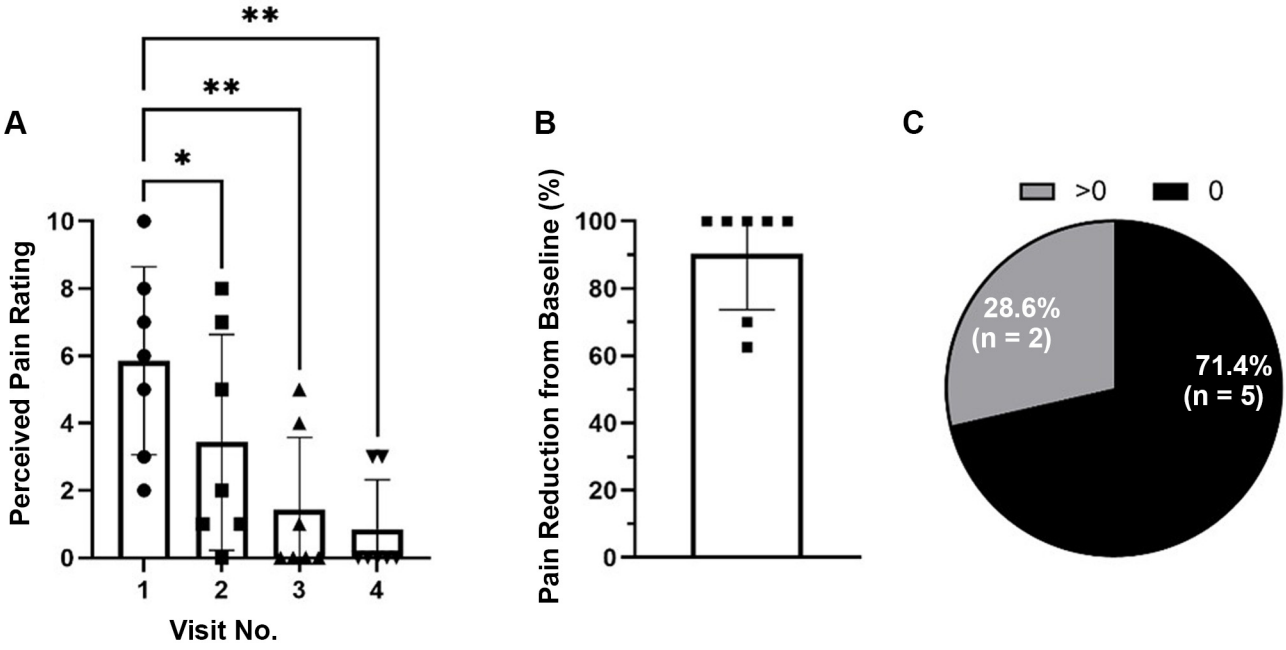

Figure 1. Patient-reported pain levels. A, Mean ± SD values for patient-perceived pain ratings at baseline (visit 1) and at each subsequent treatment visit. *$P < .05$, **$P < .01$ determined by one-way analysis of variance with the Dunnett post hoc test. B, Percentage reduction in pain scoring from baseline to visit 4. C, Percentage and total number of patients reporting a pain level of zero at visit 4.

Figure 2. Patient photographs show an example of a plantar corn on a patient's foot over the course of treatment, along with patient-reported pain levels (0 is no pain at all; 10 is the worst pain imaginable).

"exempt human subjects research" and waived further institutional review board oversight.

A treatment course was defined as a minimum of two separate sessions of microwave treatment with a final review appointment to assess the clinical appearance of the IPK and the experienced pain levels. All of the IPKs were treated and assessed by the same clinician (R.L.). Pain levels were assessed at each appointment using a 10-point pain scale ranging from 0 (no pain) to 10 (worst pain imaginable).

After their last Swift treatment, patients were invited for follow-up in the following year. Data were tabulated and analyzed using a software package (GraphPad Prism 9; GraphPad Software, La Jolla, California). Statistical outcomes were analyzed by one-way analysis of variance with the Dunnett post hoc test, and data are presented as mean ± SD unless otherwise stated. Statistical significance was determined as $P < .05$.

Results

Nine patients were included in the review, representing a complete, consecutive cohort of cases from March 9, 2021, to November 9, 2021. The cohort consisted of six male and three female patients aged 23 to 65 years (mean ± SD, 35.4 ± 13.4 years; median, 29 years). There were 21 IPKs across ten feet (per foot: mean ± SD, 2.1 ± 1.85; median, 1.5; range, 1–7) that received at least two treatments (mean ± SD, 3.8 ± 1.1; median, 4; range, 2–6) of microwave energy nominally set between 7 and 9 W (mean ± SD, 8.2 ± 1.4 W; median, 8 W; range, 5–10 W) for 2 sec, repeated five times per lesion, with a 5-sec pause between repeats. Patients were seen at intervals of 4 to 5 weeks (mean ± SD, 4.4 ± 0.36 weeks; median, 4.3 weeks; range, 3.9–5.0 weeks), and IPKs on seven of ten feet received four treatments. A patient summary is given in Table 1.

An early case study based on two patients with IPKs treated three to four times with the microwave system reported that lesions did not visibly resolve; however, patient pain levels were reduced to zero, and both patients remained entirely pain free up to 6 months after their last microwave treatment.[7] We, therefore, sought to assess patient-reported pain levels as the main determination of efficacy for Swift and, based on the outcomes previously herein, included only the data from feet that received four treatments (n = 7). At visit 1, patients reported a baseline mean ± SD pain level of 5.9 ± 2.8 (median, 6; range, 2–10), which was significantly reduced with each subsequent treatment (Figs. 1A, 2, and 3), consistent with the findings reported by Bristow and Webb.[13] Accordingly, mean ± SD patient pain levels were rated as 3.4 ± 3.2 (median, 2; range, 0–8; $P = .0233$ compared with baseline) at the second treatment visit, 1.4 ± 2.1 (median, 0; range, 0–5; $P = .0021$ compared with baseline) at the third treatment visit, and 0.9 ± 1.5 (median, 0; range, 0–3; $P =$

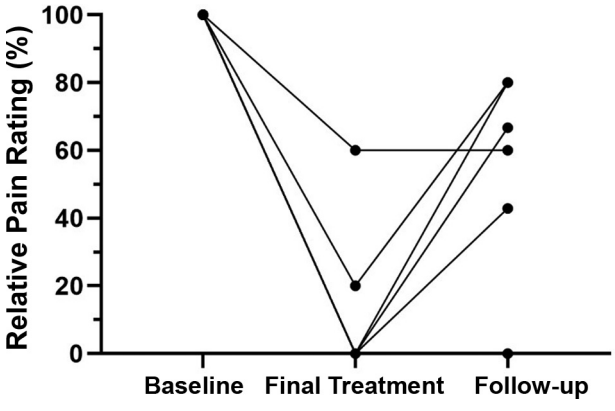

Figure 3. Posttreatment pain levels. Individual dot plots show the percentage of each patient-rated pain level before microwave therapy (baseline), at the point of their final treatment relative to baseline, and at the point of follow-up (relative to baseline).

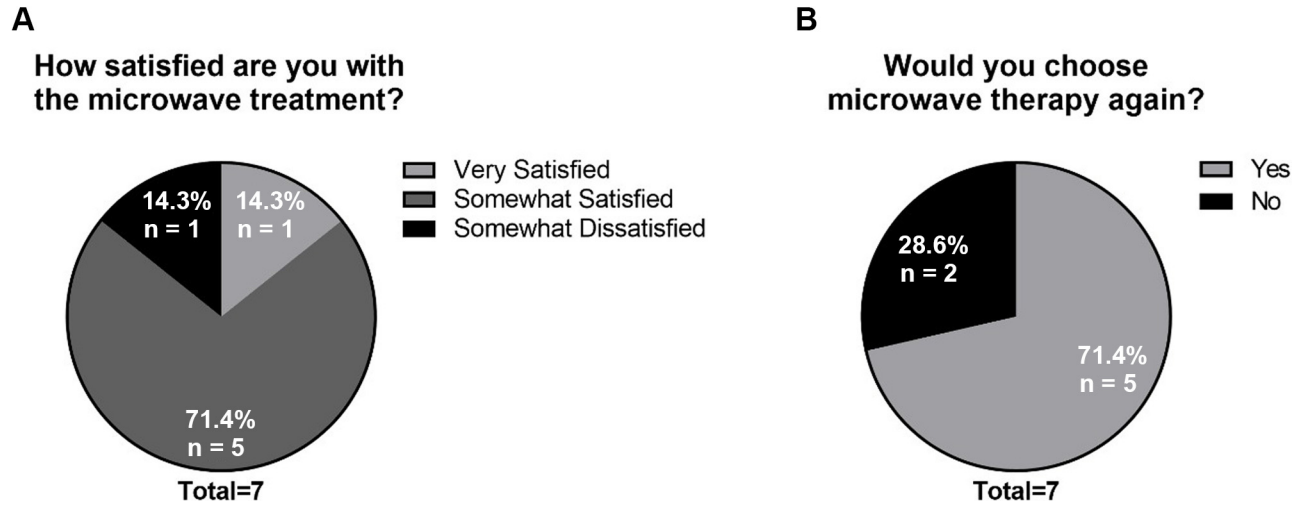

Figure 4. Patient satisfaction survey responses. Pie charts show the total numbers and percentages of patient-rated satisfaction of receiving microwave treatment on a 5-point scale (very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, very dissatisfied) (A) and whether patients would choose microwave therapy again (B).

.0011 compared with baseline) at the fourth treatment visit. Overall, this equated to a mean ± SD reduction in pain of 90.4% ± 16.6% (median, 100%; range, 60%–100%) (Fig. 1B) between the first and fourth visits and resulted in a treatment efficacy of Swift for IPKs, determined as a pain rating of zero at the fourth visit, of 71.4% (five of seven patients) (Fig 1C).

After completion of their treatment course, patients were invited to fill in a patient satisfaction survey. Seven of nine patients (77.8%) responded to the survey, which was completed 10 to 18 months (mean ± SD, 14.7 ± 2.6 months; median, 15 months) after their last treatment. When asked about their experience with the treatment, six patients (85.7%) were very or somewhat satisfied and only one patient (14.3%) reported being somewhat dissatisfied (Fig. 4A). This positive outcome was also reflected in the fact that 71.4% of respondents (five of seven) (Fig. 4B) would choose Swift again in the future. Moreover, most respondents (five of seven, 71.4%) reported having undergone alternative treatments before Swift (Fig. 5A), which included wart medication, imiquimod, acids, and other topical therapies, injections, debridement, and duct tape. Of those patients, 80% (four of five) (Fig. 5B) rated Swift as either the same as or better than their previous treatments. Another likely contributing factor to patient

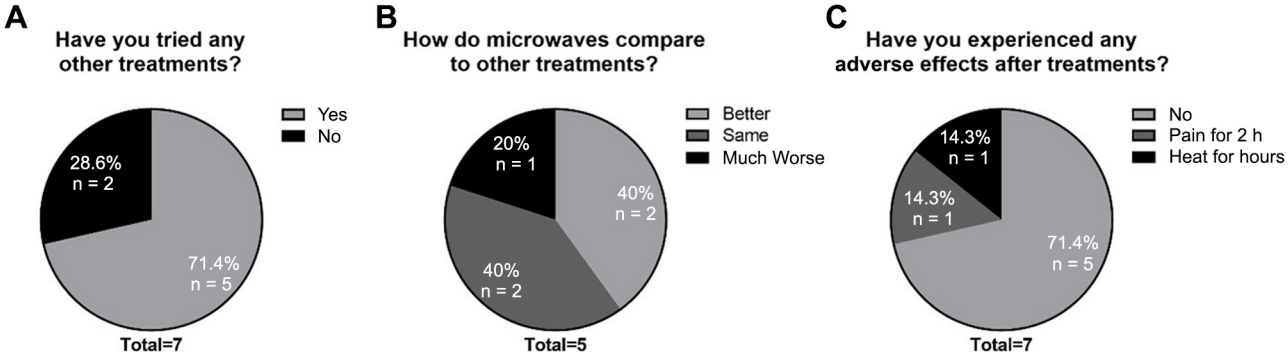

Figure 5. Patient treatment survey responses. Pie charts show the total numbers and percentages of patient survey responses regarding whether alternative treatments had been sought before receiving microwave therapy (A), how microwave treatment compared with alternative treatments on a 5-point scale (much better, better, same, worse, much worse) (B), and whether patients experienced any adverse effects as a consquence of microwave therapy (C).

satisfaction was the absence of any adverse effects in five patients (71.4%) (Fig. 5C); one patient (14.3%) reported pain lasting approximately 2 hours and another patient (14.3%) noted a sensation of heat lasting several hours after treatment. Finally, comparing pain scores of patients at their last treatment visit with their pain at the time of follow-up, it is encouraging to see that for 42.9% (three of seven patients) the pain score remained the same 13 to 18 months after their last treatment, whereas 57.1% (four of seven patients) reported a pain increase of 3 to 6 points on a 10-point scale 10 to 16 months after their last treatment. Overall, 100% of respondents still rated the pain as less than it was rated before any Swift treatment (Figs. 3 and 6). The perceived pain levels of patients over the course of their treatment are summarized in Fig. 7.

Discussion

The results of this case series highlight that Swift microwave therapy is a valuable and effective modality for podiatric physicians and dermatologists in the treatment of painful corns, resulting in a significant and prolonged reduction in patient pain levels for up to 18 months after only four treatments, with minimal to no adverse effects or downtime after the treatment. Because the device procedure does not require debridement or excision of the lesion, time spent in the clinic and patient adverse effects may be significantly reduced. In the longer term, pain levels were seen to increase in patients but not returning to previous, pretreatment levels. Further work exploring how pain may be further reduced or maintained with additional treatments is required to optimize treatment protocols. This would be beneficial not only for patients who are paying privately for their care but also for clinicians, who may gain valuable appointment time.

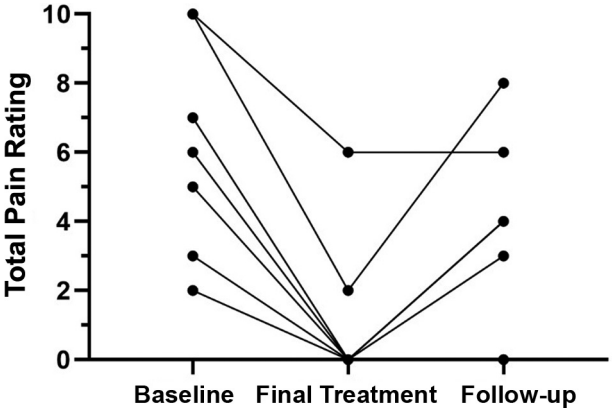

Figure 6. Total posttreatment pain levels. Individual dot plots show each patient-rated pain level before microwave therapy (baseline), at the point of their final treatment, and at the point of follow-up.

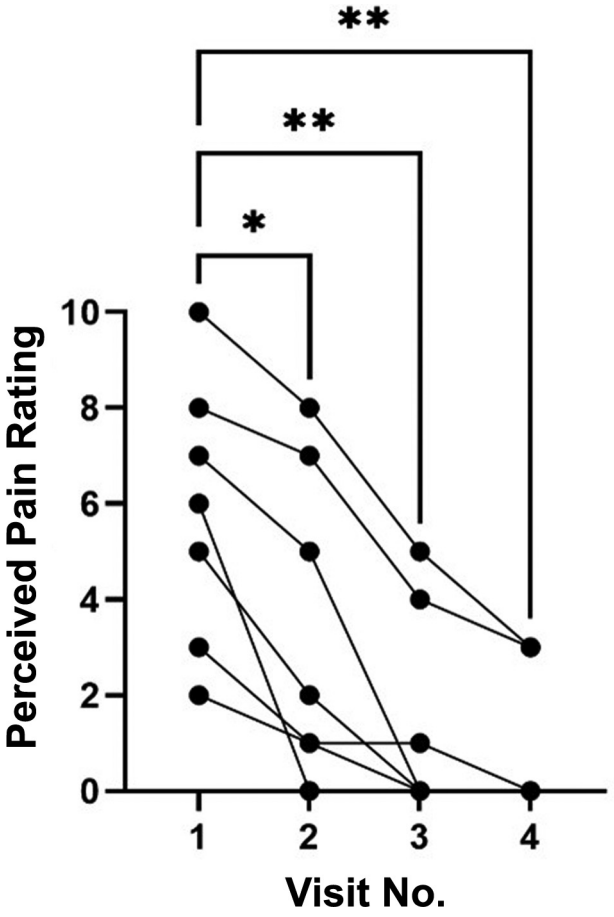

Figure 7. Patient-reported pain level progression. Individual dot plots show each patient-rated pain level at baseline (visit 1) and at each subsequent treatment visit. *$P < .05$, **$P < .01$ determined by one-way analysis of variance with the Dunnett post hoc test.

The complete mechanism of action remains unclear, but microwave energy (300 MHz–300 GHz) applied to human tissue has shown several effects, including pain relief. It has been postulated that heating peripheral nerve fibers increases nerve conduction velocity, potentially leading to denervation or an increase in the pain threshold,[14] which may account for the reported reduction in pain.

Conclusions

Plantar corns can be painful lesions that can have a significant effect on a person's quality of life. The

use of microwave energy presented herein introduces a novel, effective way to treat IPKs in a noninvasive and subablative manner, which significantly reduced pain levels for prolonged periods after treatment. As such, it allows patients to visit clinics less frequently, making it a cost-effective treatment option for patients and freeing up valuable clinician time.

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Conflict of Interest: Dr. Bristow is a consultant for Emblation Ltd. Dr. Lilker received consumables from Emblation Ltd and was compensated for the time required to collate the data presented herein.

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