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Podiatric Treatment of Hyperkeratotic Plantar Lesions with Marigold *Tagetes erecta*

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To assess the effectiveness of marigold therapy, using *Tagetes erecta*, in the treatment of hyperkeratotic plantar lesions, a double-blind placebo controlled trial was designed to be carried out over a period of 8 weeks. Thirty adult patients were randomly selected and allocated to three groups, Group A treated with marigold preparations plus protective pad, Group B with placebo plus protective pad, Group C with marigold therapy without protective pad. Each group was treated at the clinic once a week for 4 weeks, followed by 4 weeks home treatment. The effect in reduction of corn and callus and in the level of pain was recorded. Marigold therapy was found to be effective for the reduction of corn and callus width, length and the level of pain.

Keywords: marigold therapy; podiatry; *Tagetes erecta*; antikeratotic.

INTRODUCTION

Corn and callus have been defined as hyperkeratotic lesions, a corn being an area of callus which has become moulded into a nucleus (Neale and Adams, 1985). These are the most common dermatological conditions treated in podiatric practice, treatment being chemical, biomechanical or surgical, depending upon the patient's systemic associated conditions. A model for the formation of corn and callus demonstrated that when thick and heavy callus builds up, it causes irritation and produces stress in the keratinocytes and possibly causes an inflammatory response in dermal structures (Springett, 1993).

The aim of treatment is to restore the skin and subcutaneous tissues to normal and eliminate the stresses responsible for the formation of corn and callus. This usually involves first paring away the thickened stratum corneum and then the use of some form of emollient on the skin. The majority of patients continue to require regular treatment which may in some cases be difficult due to pain or hypersensitivity experienced in and around the lesions. A need therefore existed to expand the availability of non-invasive treatments.

Marigold (*Tagetes erecta*) preparations have been used in chiropodial practice for the treatment of skin, bone and nail conditions (Khan and White, 1982). The chemical action of marigold therapy in relieving pain and reducing soft tissue thickness has been confirmed (Saify, 1986). It has also been used in the treatment of verrucae, hallux abducto valgus and fungal infection of nails (Rawal *et al.*, 1988; Khan, 1986; Khan, 1992).

It is widely accepted that when pressure causes continuous damage to the skin cells (keratinocytes), rapid formation of callus results. This can be minimized by removal of pressure from the lesions. Marigold preparations are therefore used in conjunction with chiropody felt pads for redistribution of pressure from the lesions.

MATERIALS AND METHODS

Plant material was identified as *Tagetes erecta*. Chemical analysis of this species has shown that the volatile oil from the flower and leaves contains tagetone, d-limonene, ocimene, linalyl-acetate, linalool 9.8%, together with other minor terpenes (Leung, 1980). The marigold paste, tincture and oil were prepared from fresh leaves and flowers of *T.erecta*.

A double-blind placebo controlled clinical trial was carried out over a period of 8 weeks, patients being treated once a week for 4 weeks and observed at the end of weeks 6 and 8. A 'pain diary' was completed by the patient throughout the trial period and brought to the clinic on each visit. The size of the lesions was measured by an independent assessor before treatment began and on each visit.

Thirty adult patients were selected; ten to receive treatment with marigold therapy active with protective pad, (Group A); ten to receive treatment with marigold therapy placebo with protective pad (Group B); and 10 marigold therapy (active) without pad, (Group C). The latter group was included to investigate the contribution of the protective pad to the treatment. The inclusion criteria were as follows: Male and female adults between 20 and 70 years, painful, hyperkeratotic plantar lesions of longstanding duration (in excess of 2 years), and not receiving concomitant treatment of any kind; with lesions requiring routine clinical treatment at least every 4 to 8 weeks (that could not normally be fully operated upon due to pain).

The exclusion criteria were as follows: patients currently taking analgesics and/or tranquillizers on a regular basis; suffering from diabetes, vascular impairment, psoriasis, active eczema, or with plaster allergy; pregnancy.

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Allocation of the 30 patients to the three groups was by simple random sampling (Armstrong *et al.*, 1990).

Marigold therapy *Tagetes erecta* preparations used in this study were paste, tincture and oil prepared by a pharmacist according to the British Patent Specification (1984), the Homoeopathic Pharmacopoeia of the United States (1979) and the Homoeopathic Pharmacopoeia for Podologists (1986). *Tagetes erecta* active samples were prepared as follows: a paste of the fresh plant was prepared and mixed with isopropyl alcohol; tincture was made up from paste and isopropyl alcohol; oil was made up from paste and arachis oil.

The placebo samples were prepared as follows: in order to ensure that no active chemical remained in the placebo samples, marigold paste with expired shelf-life was washed several times in alcohol and then in cold water before being brought to boiling point. It was allowed to cool and then filtered through fine muslin. The residue was used as a placebo paste. The placebo tincture was prepared from isopropyl alcohol and arachis oil was used as the placebo oil.

The active and placebo samples were identical in colour and texture.

A numerical visual analogue scale was used in this study. On this scale, numbered from 0 to 10, 0 represents no pain and 10 represents the worst pain. Although the patient could see the previous day's record (which could be considered a disadvantage leading to bias), this method makes it possible to define more accurately the duration as well as the level of pain, e.g. whether the patient experiences improvement for one day or more or for the whole week. Any alteration to the previous day's record would be noticeable (Sternbach, 1978).

Week 1. Pre-operatively in all active groups, marigold tincture was applied over the lesion. The overlying callus was then removed and tincture re-applied (Fig. 1). For placebo groups, tincture was applied over the lesion, the overlying callus was then removed and tincture re-applied. For Groups A and B a 5mm semi-compressed felt cavity pad was placed over the lesion and marigold therapy paste placed in the cavity covering the lesion (Fig. 2). The cavity was covered with surgical tape (Fig. 3) and the cavity pad strapped on. For Group C no cavity pad was used, the marigold paste being placed over the lesions and covered with a piece of gauze before applying strapping. (This treatment was repeated at weeks 2, 3 and 4).

At the end of the four clinic treatments patients in all three groups were given marigold tincture and oil (active or placebo) for follow-up home treatment, with Tubifoam foam. The home treatment regime was as follows.

A few drops of tincture, followed by oil, were applied to the lesion by gentle massage twice a day for the first week then once a day for the second week. Tubifoam foam was used over the lesion every day for the first week and three times during the second week. Patients were asked to return for the first observation at the end of these two weeks.

Tincture and oil were to be applied three times a week during the third week but not at all during the fourth week, at the end of which the patient returned for the second observation. Patients were asked to complete pain diaries during these 4 weeks returning them to the clinic on each observation.

On the first attendance the following data were recorded: age, sex, ethnic origin, duration of corn and callus, level of pain, site, and previous treatment. On the subsequent three weekly visits, and follow-up home treatment for a further two visits, the length, width and level pain of the corn and callus were recorded. To enable statistical analysis to be performed, data were transferred into the Microsoft Excel program.

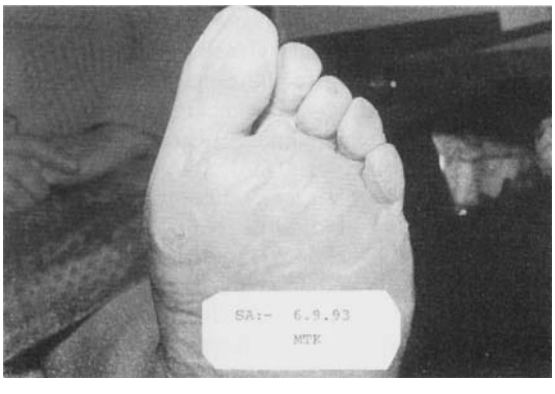

Figure 1. Hyperkeratotic plantar lesion, pre-treatment.

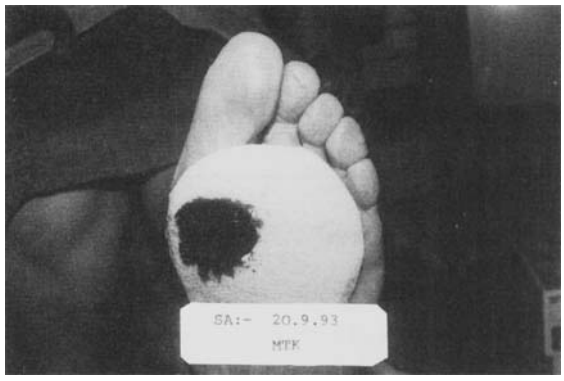

Figure 2. During treatment, overlying callus was removed, a cavity pad placed over lesion and filled with marigold paste.

RESULTS

The results for Group A (active) show a gradual reduction of corn and callus width, length and level of pain during the treatment from 0–8 weeks (Fig. 4).

The results using the placebo show some decrease in corn and callus width, length and level of pain during weeks 0–4 and then a gradual increase from weeks 4–8 (Fig. 5).

The results of Group A (active) and Group B (placebo) were compared for significant differences using an unre-

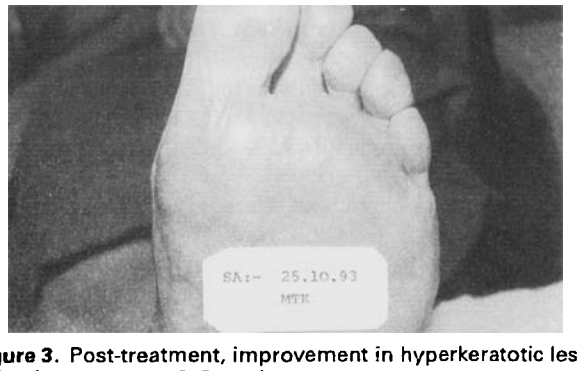

Figure 3. Post-treatment, improvement in hyperkeratotic lesion following treatment 0–8 weeks.

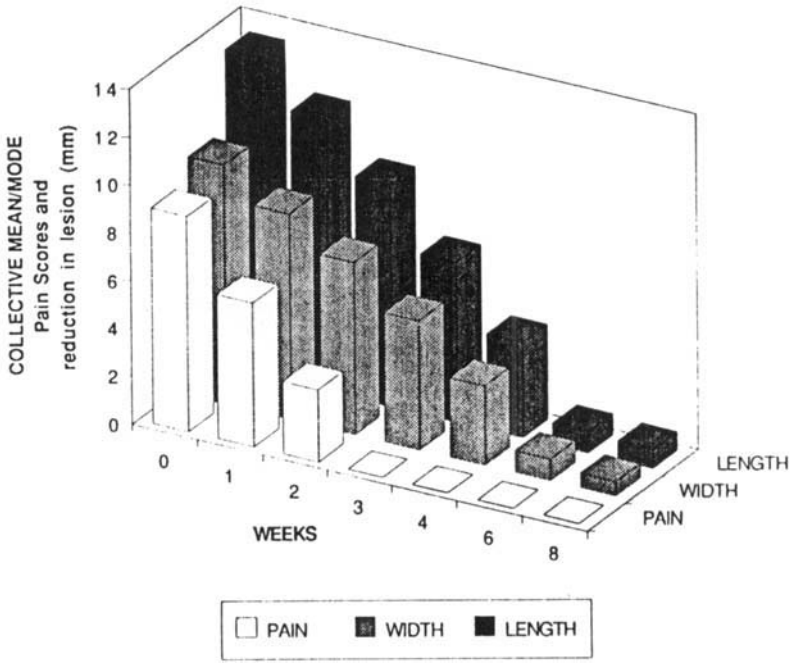

Figure 4. Group A. Marigold therapy (Active)+protective pad. Collective (mean value measured in mm) width and length of the lesion and (mode value) level pain scores from pre-treatment and during weeks 0–8.

lated *t*-test. Callus width ($t=11.7586$, $n=10$), the results show a significant difference at $p<0.001$. Callus length ($t=11.7758$, $n=10$), the results show a significant difference at $p<0.001$. Level of pain ($t=17.2653$, $n=10$), the results show a significant difference at $p<0.001$.

The results of Group C (active, without protective pad) show a gradual decrease of corn and callus width, length and level of pain during 0–4 weeks and then a gradual increase from 4–8 weeks (Fig. 6).

The results of Group A (active) plus protective pad were compared with Group C (active) without protective pad, using an unrelated *t*-test. Callus width ($t=3.7131$, $n=10$), the results show a significant difference at $p<0.001$. Callus length ($t=3.1483$, $n=10$), the results show a significant difference at $p<0.005$. Level of pain ($t=5.0853$, $n=10$), the results show a significant difference at $p<0.001$.

Analysis of the results suggest that the incidence of foot problems is greater in women than men, 76.6% in this trial being female, 23.4% male. In addition, 50% of the patients treated had the complaint in the right foot and 50% in the left.

DISCUSSION

Except for the absence of the protective pad from weeks 0–4 in group C, both A and C active groups received identical marigold therapy treatment. Both groups showed improvement in the width and length of the lesion and the level of pain. However, the improvement in Group A was at a much higher level and maintained throughout the 8 week trial

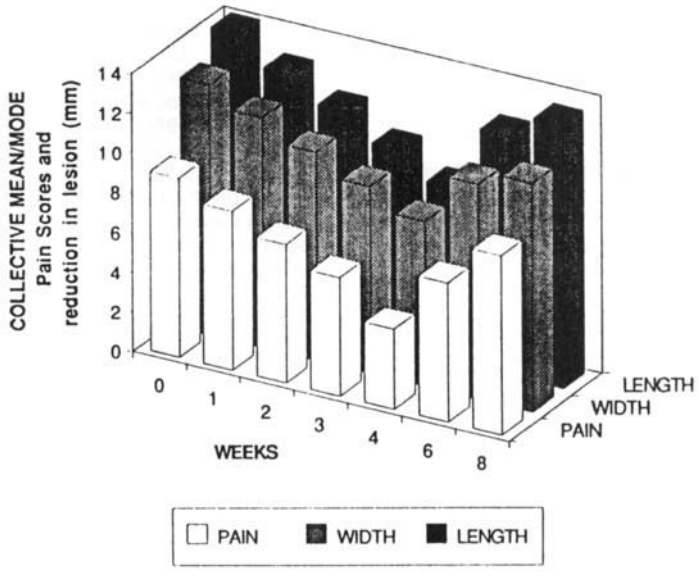

Figure 5. Group B. Marigold therapy (Placebo)+protective pad. Collective (mean value measured in mm) width and length of the lesions and (mode value) level of pain scores from pre-treatment and during weeks 0–8.

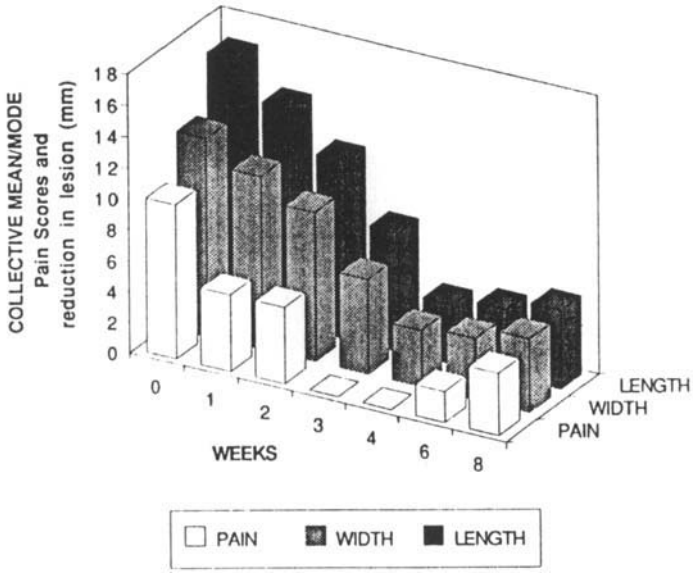

Figure 6. Group C. Marigold therapy (active) without pad. Collective (mean value measured in mm) width and length and (mode value) level pain scores from pre-treatment and during weeks 0–8.

period, the average decrease in width being 89%, length 90% and a reduction of 100% in the level of pain.

All other factors in the treatment being identical, the lower level of improvement in Group C would seem to be due to the absence of the protective pad during weeks 0–4, and furthermore during weeks 4–8 when the rate of improvement diminished still further.

The cavity pad serves not only as a container for the marigold therapy preparation but also redistributes pressure from the lesions. When there is friction or pressure over the skin surface, the keratinocytes are traumatized and enter an inflammatory state causing the release of cytokinese which activates production of keratinocytes (Springett, 1993).

Marigold therapy with protective pad proved to be more effective than marigold therapy without protective pad. However, even without the pad an improvement was obtained compared with the placebo, although at a lower level. This indicates that the therapy without the pad would be suitable for patients with plaster allergies. Marigold therapy would also be of benefit to those who do not respond to other treatments and patients who are at risk. It is good chiropody practice that advantage should be taken of a therapy which combines a lack of pain with effectiveness and is non-invasive.

REFERENCES

Armstrong, D., Calnan, M., and Grace, J. (1990). *Research Methods for General Practitioners.* Oxford Medical Publications, Oxford.

Khan, M. T. (1986). Report on clinical trials of *Tagetes erecta* species in the treatment of hallux valgus. *J. Br. Ass. Hom. Chiropodists,* **2**(2), 1–23.

Khan, M. T. (1992). Treatment of onychomycosis with marigold therapy. *J. Br. Ass. Hom. Chiropodists,* **8**, 12–16.

Khan, M. T., and White, A. (1982). *Comparative Clinical Studies of Calendula Officinalis, and Tagetes spp.* XXXV Inter. Congress. Proc. 488–92.

Leung, A. Y. (1980). *Encyclopedia of Common Natural Ingredients, Used in Food, Drugs and Cosmetics.* Academic Press, New York.

Neale, D., and Adams, I. (1985). *Common Foot Disorders,* 2nd edn. pp. 50–69. Churchill Livingstone, Edinburgh.

Rawal, R. S., Devitt, R., and Khan, M. T. (1988). Treatment of Verrucae Pedis using marigold therapy. *J. Br. Ass. Hom. Chiropodists,* **4**(2), 9–12.

Saify, Z. S. (1986). Tagetes, the herb that cures corns and callosities. *J. Br. Ass. Hom. Chiropodists* **2**(2), 24–25.

Springett, K. (1993). *The Influence of Forces Generated During Gait on the Clinical Appearance and Physical Properties of Skin Callus.* PhD Thesis, University of Brighton.

Sternbach, R. A. (1978). *Clinical Aspects of Pain.* Raven Press, New York.