Effect of Curettage After Segmental Phenolization in the Treatment of Onychocryptosis: A Randomized Double-Blind Clinical Trial

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BACKGROUND Segmental phenolization for the treatment of onychocryptosis has a number of disadvantages, resulting from the cauterization of the tissue, including delayed healing and prolonged drainage. Although one may expect excision or curettage of the cauterized tissue after phenolization to benefit the healing process, these simple procedures have not been suitably studied.

OBJECTIVE To examine the effect of curettage primarily on cicatrization or healing time and secondarily on postoperative bleeding.

MATERIALS AND METHODS Fifty-one patients (80 feet) with stage I or IIa onychocryptosis according to the classification of Mozena were enrolled in this randomized, double-blind, parallel-group, controlled clinical trial. A total of 137 phenolizations were performed on affected folds of ingrowing hallux nails. Each hallux was randomly assigned to one of two groups (experimental [phenolization with curettage]; control [phenolization alone]).

RESULTS Curettage reduced healing time (7.49 ± 1.76 days vs 12.38 ± 3.01 days; $p = .001$), increased postoperative bleeding ($p < .001$), led to lower rates of infection ($p = .01$), and increased postoperative pain ($p = .028$).

CONCLUSION Curettage of the cauterized tissue after segmental phenolization reduces healing time.

The authors have indicated no significant interest with commercial supporters.

There are numerous surgical procedures for the treatment of onychocryptosis, but segmental phenolization is one of the most-common procedures for the permanent removal of toenails. There is ample literature on the use of phenol, including descriptions of numerous variations with respect to materials, methods, and techniques. In particular, there have been many techniques presented designed to improve postoperative care so as to accelerate patient recovery,[1–3] but few have provided conclusive data regarding improvements attained. The many variants used regarding timing, procedures, phenol concentrations, and postoperative nursing make it impossible to establish firm evidence-based recommendations.[4] The only existing meta-analysis concluded that the technique is effective (lower rate of symptomatic recurrences), although it significantly increases the risk of postoperative infection.[5] The main disadvantages of the procedure appear to be linked to the cauterization of the tissue, which results in delayed cicatrization, prolonged serous drainage, acute reaction to the chemical agent, and greater risk of superinfection. Although symptomatic recurrence has been the variable most frequently studied, few clinical trials have examined mean cicatrization time after segmental phenolization, and those that have, report disparate results, ranging from 2 to

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8 weeks, with different criteria as to what should be understood by the term "healed" or cicatrized wound.[6–9]

Some authors state that the excision of cauterized tissue after phenolization reduces healing time by 7 to 10 days, although no research study has substantiated this assertion.[10] Some retrospective studies seem to confirm that cicatrization time associated with curettage of cauterized tissue after phenolization is similar to that with other nonincisional techniques (the Suppan I or Lelievre technique),[11] but clinical trials are needed to confirm this hypothesis. The present study was therefore designed to determine the effect of curettage after segmental phenolization on healing time.

Materials and Methods

Study Design

This was a randomized, double-blind, parallel-control-group, clinical trial. The sample consisted of patients treated at the Área Clínica de Podología of the University of Seville and at the San Lazaro Hospital (Seville, Spain). The study was performed in accordance with the Declaration of Helsinki and the Guidelines for Good Clinical Practice and was approved by the Ethics and Experimental Committee of the University of Seville and the Ethics Committee of the Virgen Macarena Hospital (Seville, Spain) before data collection began. Participating patients gave written consent. The first participant was enrolled on October 2008, and the last participant completed the study on January 2011. Participants were monitored for up to 1 year after treatment.

The treatment of the two groups was randomized intraoperatively by drawing a numbered ball from a bag (ball number 1 = the patient's nail fold or folds underwent segmental phenolization alone; ball number 2 = the patient's nail fold or folds underwent segmental phenolization plus curettage of the matrix and nail bed).

Patients

A selection was made of 51 patients who presented onychocryptosis in 152 hallux nail folds that had previously received conservative treatment (removal of the ingrown nail spicule and local antiseptic treatment) without definitive results. Patients were randomly assigned to two groups in which the affected ingrown hallux nails were subjected to one of the experimental conditions: the first, the control group, comprised 25 patients (79 nail folds) who underwent segmental phenolization alone; the second, the experimental group, comprised 26 patients (73 nail folds) who underwent segmental phenolization plus matrix and nail bed curettage (Figure 1).

The criteria for inclusion in the study were stage I or IIa onychocryptosis according to the classification of Mozena (fold depth < 3 mm)[12]; patients with clotting problems, wound cicatrization disorders, uncontrolled diabetes, underlying bone pathology, allergy to local anesthetics, or undertreatment with steroids or immunosuppressants were excluded. No exclusions were made on the basis of age.

The primary outcome parameter was wound healing time after segmental phenolization, analyzing the effect of curettage of the cauterized tissue. Secondary outcome parameters were postoperative bleeding, infection rate, postoperative pain, and recurrence rate.

Surgical Procedure

The surgical procedure consisted of partial ablation associated with segmental phenolization of the affected nail folds as follows. A digital block of the hallux was performed using 2% mepivacaine (Scandinibsa, Inibsa SA, Barcelona, Spain); after surgical lavage of the operative field, a digital tourniquet was applied for local hemostasis. Using a Freer elevator, the affected nail plate was separated from the nail bed and eponychium. Partial ablation

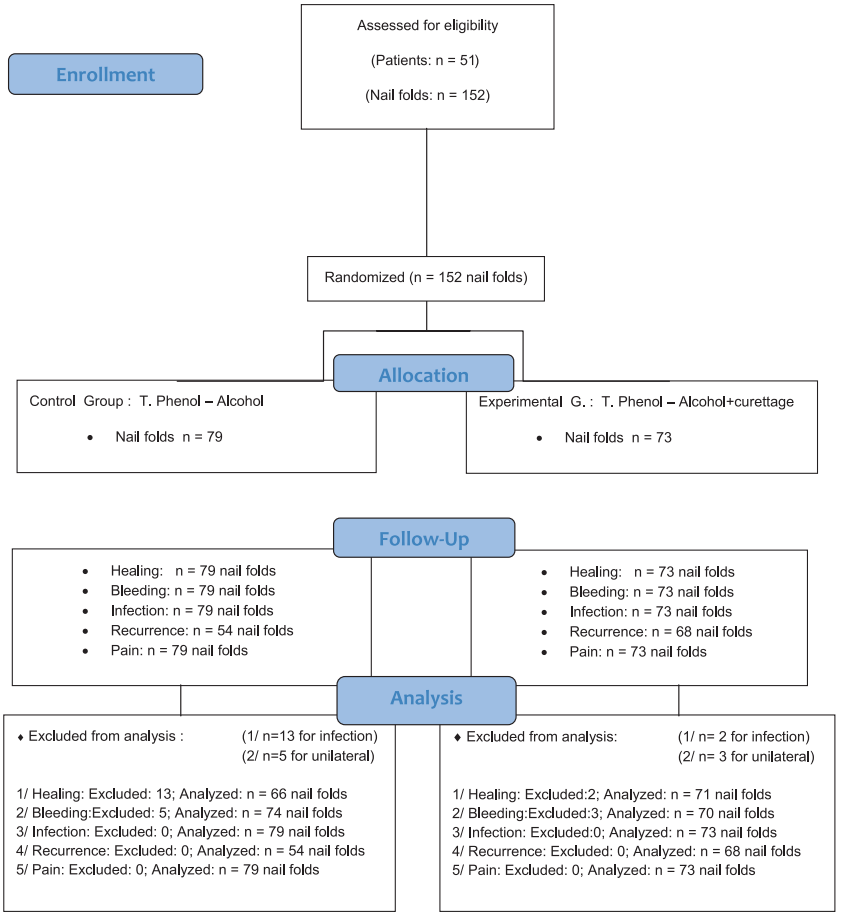

Figure 1. Flow chart of participants detailing their follow-up or exclusion through each phase of the study.

of the nail plate was performed using a nail splitter and a hemostat. After removing the portion of the nail, a cotton ball soaked in 100% phenol was applied with a swab for 1 minute to the matrix and the nail bed. The zone was then irrigated with 76% ethanol for 1 minute and then with physiological saline solution. In the experimental group, a Martini bone curette was used to carefully remove all of the cauterized tissue with a whitish appearance. This procedure was performed on both nail folds of the hallux when the treatment was bilateral (72 cases) or on one when it was unilateral (8 cases). All patients received oral antibiotic prophylaxis 60 minutes before the procedure as a single dose of cephalexin 2 g (Kefloridina Forte, Lilly, Madrid, Spain) or 500 mg levofloxacin (Tavanic, Sanofi Aventis, Barcelona, Spain) if the patient was penicillin-allergic. All surgical wounds were dressed using a thin layer of sulfadiazine silver cream and covered using a sterile, nonadherent polypropylene dressing. Gauze was placed around the hallux and covered using a sterile compressive bandage.

Treatment Measures

The same clinician (JAJ) performed all procedures. Observers blinded to which procedure had been used evaluated clinical efficacy and adverse effects. Healing was monitored for spontaneous wound closure using clinical assessments and digital photographs over 1 month. Patients were seen every 48 hours. From the fourth day onward, the treatment administered to both groups consisted of applying povidone iodide antiseptic solution. Daily checks were made until the healing time criteria were completely satisfied. The clinical criteria of

early healing time were considered to be absence of drainage (no exudate evident), granulation tissue covered by a scab (no evidence of hypergranulation tissue), and no signs of infection (i.e. pain and clinical evidence of discharge in association with redness extending proximally).[13] The patient was then allowed to bathe. All criteria had to be met before the wound was considered cicatrized (healed).

After 48 hours, a qualitative and comparative evaluation was made of bleeding, establishing three categories: light (the dressing showed no external staining; only the nonstick polypropylene dressing in contact with the wound, and the gauze in contact with that were partly stained); moderate (the dressing showed slight staining on the back or sides; the nonstick dressing was completely stained, and the gauze in contact with that was partly stained); and abundant (the external dressing was completely or almost completely stained).

Pain was measured in the 2 days after the surgical procedure using a 10-cm visual analogue scale (0 = no pain; 10 = maximum pain).

Patients underwent a 9 ± 3.4 months of follow-up to assess the results of the surgical procedure. Recurrence rate was evaluated as growth of the released nail (or of a piece of the released nail) even though that recurrent nail might be asymptomatic.

Statistical Analysis

The sample size required for the study was calculated using CTM-1.1 (Glaxo Wellcome SA, Madrid, Spain). The result of the computation was that, to detect a clinically relevant difference of 5 days in mean healing time between the experimental and control groups for a significance level of $\alpha = 0.05$ and an error $\beta = 0.15$, a minimum of 19 patients would be necessary in each group.

Statistical analyses were performed using SPSS 15.0 (SPSS, Inc., Chicago, IL). A first exploratory analysis was made of the data to detect outliers and to characterize differences between subgroups of individuals. Quantitative variables were summarized in terms of their means and standard deviations; qualitative variables were expressed as percentages. The Kolmogorov–Smirnov test was applied to test for normality, and the Mann–Whitney *U*-test for skewed distributions was used for comparison of quantitative data. The categories light and moderate of each group were merged for the statistical analysis. For the inferential analysis of the variable bleeding, only the toes on which the procedure had been performed on both nail folds were taken into account. For between-group comparisons, the chi-square test with the Yates correction for continuity was applied to the two-by-two contingency tables of the qualitative variables bleeding, recurrence, and infection and the Mann–Whitney *U*-test for the nonnormally distributed variables healing time (measured in days) and pain (measured on a visual analogue scale). Between-group differences were considered statistically significant when $p < .05$.

Results

Between October 2008 and January 2011, 51 patients (152 nail folds) were enrolled in the study. Of the 152 nail folds, 13 (16.5%) of the control group and two (2.7%) of the experimental group were excluded from completion of the study because they presented a clinical pattern of postoperative infection. The final study sample consisted of 137 nail folds (50 patients): 66 in the control group (24 patients) and 71 in the experimental group (26 patients). The characteristics and distribution of the study population are listed in Table 1.

Primary Outcome Parameter

The primary outcome parameter was the influence of curettage after segmental phenolization on healing time as described in Materials and Methods. The result was 7.49 ± 1.76 days in the experimental group and 12.38 ± 3.01 days in the control group. The difference was statistically significant (Mann–Whitney *U*-test: $p = .001$).

TABLE 1. General Features of Patients

	Control Group	*Experimental Group*	*Total Analyzed*
Patients	25 (49.02%)	26 (50.98%)	51
Males	9	9	18 (35.29%)
Females	16	17	33 (64.71%)
Withdrawn	1	0	50
Feet	42	38	80
Withdrawn	5	0	75
Nail folds	79 (51.97%)	73 (48.03%)	152
Males	25	24	49 (32.24%)
Females	54	49	103 (67.76%)
Withdrawn	13	2	137
Average age	36.71	31.59	34.05
Standard deviation	21.55	16.57	19.23

Secondary Outcome Parameters

The differences between the control and experimental groups in post-operative bleeding, pain, and infection rate were also significant. In the first case, 30 patients (42.9%) in the experimental group had abundant postoperative bleeding, versus 4 (5.4%) in the control group (Yates chi-square test: $p < .001$). With regard to postoperative pain, the experimental group's score on the visual analogue scale was 3.95 ± 2.25 points and 3.06 ± 2.21 points for the control group (Mann–Whitney *U*-test: $p = .028$). In the last case, the difference in infection rate between the two groups was also statistically significant (Yates chi-square test: $p = .01$).

After 9.7 ± 3.4 months of follow-up, only one released nail grew again in one participant's nail fold in the experimental group, representing a recurrence rate in this group of 1.5%. There was no significant difference between the groups (Yates chi-square test: $p > .99$).

The results for the four variables analyzed and their distribution in each group are given in Tables 2 and 3.

Discussion

When phenol is used in partial matricectomy, its effect is to denature proteins of the matrix, which is followed by cell death. The principal disadvantages of such chemical matricectomy include prolonged healing time, extended period of postoperative drainage, and greater risk of infection.[3–5]

Several studies have examined mean healing time after segmental phenolization, but the results they report are disparate, and they use different criteria as to what is meant by healed or cicatrized wound.[3–9]

TABLE 2. Distribution of Healing Time and Bleeding During Follow-Up

	Control Group	*Experimental Group*	p-*Values Between Groups*
Healing			
Nail folds (*n*)	66	71	Mann–Whitney *U*-test $p = .001$
Average healing time (days; mean±SD)	12.38 ± 3.01	7.49 ± 1.76	
Range of healing time (days)	6 –18	4–12	
Bleeding			
Nail folds (*n*)	74	70	Yates chi-squared test $p < .001$
Light/moderate	70 (94.6%)	40 (57.1%)	
Abundant	4 (5.4%)	30 (42.9%)	

TABLE 3. Distribution of Infection, Recurrence, and Post-operative Pain During Follow-Up

Infection	*Control Group*	*Experimental Group*	p-*Values Between Groups*
Nail folds (*n*)	79	73	Yates chi-squared test $p = .010$
Infection rate	13 (16.5%)	2 (2.7%)	
Recurrence (9.7 ± 3.4 months)			
Nail folds (*n*)	54	68	Yates chi-squared test $p = 1.000$
Recurrence rate	0 %	1 (1.5%)	
Pain			
Nail folds (*n*)	79	73	Mann–Whitney *U*-test $p = .028$
Mean±SD	3.06 ± 2.21	3.95 ± 2.25	

The data that can be extracted from published clinical trials are too limited to enable definitive conclusions to be drawn about the difference in healing time after phenolization and other techniques. In the present study, significant differences were found in healing time between the groups in favor of the experimental group, with healing times being determined by applying early cicatrization criteria similar to those used in other clinical trials.[11] The healing times observed in the experimental group are similar to those reported in other studies using nonincisional techniques without phenolization (Suppan I or Lelievre).[11,14] The only retrospective study of a series of cases that analyzed the technique used in our experimental group (modified phenol technique) compared it with other nonincisional techniques such as Suppan I and found no significant differences in healing time after surgery (13.65 ± 8.67 vs 12.40 ± 6.42 days) or the number of dressings required.[11] Guerritsma-Bleeker and colleagues describe a clinical trial with a parallel-group design comparing segmental phenolization performed in one group with a nonincisional technique similar to that used in the present study (partial nail extraction with partial matrix excision). Although they considered various parameters such as the exudate, it is impossible to make comparisons with respect to healing time or postoperative infection rate because the data reported in that study concern time to complete recovery, understood as the time it took to wear shoes and perform daily activities such as work but without objective criteria being used to define wound healing.[15] Van der Ham, in a clinical trial with a parallel-group design, report a mean healing time somewhat longer than that obtained in the present work (15.4 ± 4 days) using a 3-minute application of 80% phenol and again without specifying the healing criteria used.[7] Other authors have reported healing times of 14 to 18 days using 90% phenol but with much longer application times (8–10 minutes).[16]

Aksakal and colleagues performed a surgical procedure similar to that used in the present study on 67 patients.[17] They used 90% (instead of 100%) phenol followed by a 20- to 30-second application of ferric chloride to one group. Drainage from the surgical wound was significantly less ($p < .001$) in patients who received the ferric chloride application (6.13 ± 6.53 days), but because healing time was not determined, and the cicatrization criteria were not specified, it is not possible to compare the results of that study with the present findings.

There have been few studies conducted to determine the optimal concentration of phenol to reduce the inflammatory response, drainage, and risk of infection. Boberg and colleagues[18] describe an in vitro study of specimens of nail matrix in which they find the application of 89% phenol for 1 minute to be the minimum time and concentration required for complete destruction of the germinal nail matrix. Similarly, a recent study[9] performed to determine the efficacy and safety of the technique compared different lengths of phenol application. Three groups were compared, to which 89% phenol was applied for 1, 2, or 3 min-

utes. The best results with regard to postoperative complications (pain, drainage, and tissue damage) and complete cure times were obtained in the group to which phenol was applied for 1 minute, with mean complete cure times similar to the healing times obtained in our control group (13.5 ± 3.9 days).

Although it was not an objective of our study to compare postoperative infection rates, significant differences were observed between the two groups, with postoperative clinical infection causing a higher rate of experimental attrition in the control group. Some authors argue that clinical or subclinical infection of the wound as a consequence of bacterial superinfection may cause the delay in healing after segmental phenolization and advocate for he systematic use of preoperative antibiotic prophylaxis,[19] but current evidence does not support such use of preoperative antibiotic prophylaxis in onychocryptosis surgery except in special patients with infective onychocryptosis.[20] In their study, Guerritsma-Bleeker and colleagues found no significant differences between groups regarding what they defined as postoperative infection, understood as the presence of purulent exudate.[15] Nonetheless, there was a greater frequency of purulent discharge between the second and eighth days in the phenol group than in the matrix procedure group (48% vs 30%). Furthermore, the discharge was prolonged in 10% of the phenol group patients (up to 1 month after surgery) and none of the patients in the matrix procedure group. The present authors believe that the lower infection rate obtained in our study than in Guerritsma-Bleeker and colleagues' study may have been due more to the conservative treatment before surgery (removal of the ingrown nail spicule and local treatment with antiseptic) than to having used preoperative antibiotic prophylaxis. In spite of the fact that antibiotic prophylaxis is not commonplace for surgical treatment of onychocryptosis, it was decided to use it in the present study to reduce experimental losses.

Only a few studies have considered bleeding after segmental phenolization. Some of them have shown phenolization to reduce bleeding because of the hemostatic effect attributed to phenol.[21,22] The present study also analyzed bleeding using three predefined categories, as in previous clinical trials,[14] and found significant differences between the groups, with there being more-abundant bleeding in the experimental group. This is in agreement with the literature on this issue, reflecting the hemostatic effects of phenol. Greater bleeding after curettage of the cauterized tissue is to be expected given that a new wound is being made where the phenol's hemostatic effects are not yet present. The reactive hyperemia produced in the toe after removal of the ischemia in a zone as vascularized as is the nail bed exacerbates this condition. The greater bleeding has no effect on the final outcome of the procedure. Although it has been demonstrated that blood neutralizes the effects of phenol, the surgical procedures were performed under ischemic conditions, so a bloodless zone was obtained, and once the procedure had been completed and the alcohol had neutralized the effects of the phenol, the tourniquet was released, and bleeding occurred.

Although some authors have suggested that phenol may reduce postoperative pain as a result of neurolytic effect, only a few studies have analyzed this variable using pain scales.[23–25] In our study, the pain observed during the first 2 postoperative days was significantly less in the control group. This may have been due to the curettage having enhanced the acute inflammatory phase of the dermal wound-healing process.

From the results of our study, it can be said that cauterized tissue curettage after segmental phenolization results in significantly shorter healing time than the classic segmental phenolization technique. Although there exist no studies with a design similar to ours that would allow us to establish complete comparisons, it is nonetheless the case that, on comparing the results obtained in our

experimental group with those reported in the literature after phenolization, one observes major differences in mean healing time.

Conclusion

This randomized controlled clinical trial has shown that curettage of cauterized tissue after segmental phenolization significantly reduces mean healing time of the wound and appears to reduce the infection rate, although it leads to greater postsurgical bleeding and pain. The authors believe that these latter circumstances should not be taken into account in deciding on which technique to use because they do not adversely affect the patient's recovery time and can be controlled with other measures in the immediate postoperative period. Therefore, the authors believe that curettage after phenolization should be systematically considered to reduce the technique's complications and to speed the recovery of patients who undergo the procedure.

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