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Anti-edematous effect of escin lysinate in patients treated with corrective foot osteotomy

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Abstract

Introduction Surgical treatment of the forefoot deformities using corrective osteotomies can be associated with local reactions, manifested by postoperative swelling and pain. The factors can impact the timing and quality of early patient rehabilitation. The search for safe and effective means to relieve postoperative swelling and pain is essential in modern traumatology and orthopedics. The escin lysinate solution with angioprotective, anti-edematous, and analgesic effects, is considered as a pathogenetically substantiated approach.

The **objective** was to compare the efficacy and safety of escin lysinate used to reduce postoperative swelling and pain in patients after corrective osteotomies of the foot and the standard therapy and therapy supplemented with a short course of systemic glucocorticosteroids.

Material and methods A prospective randomized study included 30 patients (18–70 years) who underwent SCARF osteotomy of the first metatarsal bone, AKIN osteotomy, and/or Weil osteotomy. Patients were divided into three groups (10 individuals each) who underwent standard therapy (control); standard therapy + escin lysinate; standard therapy + dexamethasone. The severity of swelling of the limb, pain assessed with the visual analog scale (VAS), the need for nonsteroidal anti-inflammatory drugs (NSAIDs), the level of C-reactive protein, and the safety of therapy were dynamically evaluated.

Results The pain significantly reduced in the first three postoperative days in the escin lysinate group as compared to the control group with a reduced need for NSAIDs. A greater edema regression was observed at the metatarsal level at six weeks. Dynamics in pain was noted in the dexamethasone group at a short term with a less need for NSAIDs. No adverse reactions or clinically significant changes in laboratory parameters were recorded.

Discussion Postoperative edema was more evident in the foot as compared to other anatomical sites due to limited soft tissue volume and slow venous and lymphatic outflow from the distal extremities. In this context, medications that reduce vascular and tissue permeability play a role. Aescin lysinate was shown to demonstrate efficacy in neurosurgery and otolaryngology with the use being associated with reduceed edema and inflammation. In orthopedics and traumatology, the drug demonstrated angioprotective and analgesic potential in lower extremity injuries. Unlike systemic glucocorticosteroids such as dexamethasone having a pronounced but short-term anti-inflammatory effect and being associated with the risk of hyperglycemia, infections and bone loss, escin lysinate has a safety profile and can be considered as a pathogenetically justified agent for the control of postoperative inflammation and edema.

Conclusion A comparative evaluation of the adjuvant use of escin lysinate, standard therapy, and therapy supplemented with a short course of systemic glucocorticosteroids after corrective foot osteotomies demonstrated earlier pain relief and accelerated edema resolution with no risk of adverse reactions with escin lysinate. The drug can be considered an effective and safe addition to standard therapy, providing a more favorable early postoperative effect.

Keywords: corrective osteotomy, foot, foot surgery, escin lysinate, postoperative edema, pain, visual analog scale, dexamethasone, orthopedics, anti-edema therapy

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INTRODUCTION

Corrective osteotomies of the metatarsal bones and phalanges are a common method for surgical correction of forefoot deformities [1–3]. A local inflammatory reaction including edema, pain and impaired function is an integral component of the postoperative treatment and can predetermine the duration and quality of early rehabilitation of patients [4, 5].

The relief of the symptoms early post-op remains an area of active research [6]. Despite the widespread use of nonsteroidal anti-inflammatory drugs (NSAIDs) and multilevel analgesia as part of standard protocols, the effectiveness might be insufficient [7–9]. In this context, the use of drugs aimed at the pathogenetic links in the formation of inflammation and edema appears to be promising [10]. Potential candidates for modulating postoperative inflammation include glucocorticosteroids (e.g., dexamethasone), which have a potent systemic anti-inflammatory effect [11], as well as venoactive drugs with proven angioprotective and anti-exudative effects.

Aescin lysinate reduces the activity of lysosomal hydrolases preventing the breakdown of mucopolysaccharides in the capillary walls and surrounding connective tissue. This normalizes increased vascular and tissue permeability and provides anti-exudative (anti-edematous) and analgesic effects. The mechanism allows the drug to be used for post-traumatic and post-operative soft tissue edema in various locations; swollen cerebral or spinal cord of traumatic or post-operative origin; and peripheral venous circulation disorders accompanied by edema.

The **objective** was to compare the efficacy and safety of escin lysinate used to reduce postoperative swelling and pain in patients after corrective osteotomies of the foot and the standard therapy and therapy supplemented with a short course of systemic glucocorticosteroids.

MATERIAL AND METHODS

Characteristics of the patient sample

The prospective and randomized study included all patients admitted to the hospital November 7, 2024, and July 4, 2025 for a forefoot reconstruction surgery and met the inclusion criteria.

Inclusion criteria:

— patient consent to participate in the study and signed informed consent;

— age from 18 to 70 years.

Non-Inclusion criteria:

— History of intolerance to the prescribed drug escin lysinate and/or its components;

— Ethanol intolerance;

— Myocardial infarction, stroke/TIA, pulmonary embolism less than 6 months before the start of the study;

— Diabetes mellitus type I/II in the stage of decompensation;

— Body mass index (BMI) ⩾35;

— Severe renal impairment (creatinine clearance 30 ml/min);

— Severe liver impairment (scored more than 9 on the Child-Pugh scale);

— Chronic use of anticoagulants;

— Severe congenital defects or serious chronic diseases, including any clinically significant chronic, psychiatric diseases confirmed by medical history or objective examination;

— Pregnancy and breastfeeding;

— Rheumatoid arthritis, SLE and other systemic diseases;

— History of chronic alcohol abuse and/or drug use.

Exclusion criteria for study population:

— intolerance to the prescribed drug and/or its components;

— the need to prescribe a combination of cephalosporin antibiotics and heparin anticoagulants or direct oral anticoagulants;

— the need to prescribe an aminoglycoside antibiotic (gentamicin, amikacin);

— erroneous inclusion in the study;

— development of serious adverse events;

— development of diseases in the patient described in the exclusion criteria;

— other reasons noted during the study that would prevent the study from being conducted according to the protocol.

The intervention included a SCARF osteotomy of the first metatarsal bone and an AKIN osteotomy, if indicated. The surgical intervention could be supplemented with a distal Weil osteotomy of the second to fourth rays of the foot, if necessary,

Study design

All patients (n = 30) were randomized into three groups on admission; recruitment to each group was completed after the inclusion of the 10th participant:

— control group (n = 10, control): standard therapy (cefazolin 2 g 30 minutes before surgery, 1 g 3 times a day No. 1 intravenously post-op; ketorolac up to 30 mg/day intramuscularly, omeprazole 20 mg 1 time per day during the period of ketorolac administration);

— escin lysinate group (n = 10, LYS): standard therapy + escin lysinate (Art-Pharm LLC, Russia), 10 ml of 0.1 % escin lysinate solution was pre-diluted in 100 ml of 0.9 % sodium chloride solution and administered intravenously slowly, drip, once a day the day before surgery and on the first, second, third days after;

— dexamethasone group (n = 10, DEX): standard therapy + 0.4 % dexamethasone solution 2 ml intramuscularly, once a day on the first, second, third days post-op.

Surgical interventions were performed under combined anesthesia (spinal anesthesia + intravenous sedation) according to the standard protocol of the institution. Prolonged epidural analgesia with a catheter placed into the epidural space was not used. Intra- and postoperative analgesia, except for the study drugs, was standardized and did not differ between the groups. All patients included in the study underwent pain assessment using a visual analog scale (VAS) from 0 (no pain) to 10 (unbearable pain), and the circumference of the operated lower limb was measured using a measuring tape at the level of the ankles (Fig. 1a) and at the level of the navicular bone of the tarsus (Fig. 1b) 24 hours before surgery, then daily for three days and after six weeks post-op. The anti-edema effect was assessed by the dynamics of changes in soft tissue volume, expressed in mm, compared with the preoperative level.

Additionally, during the first three days postoperatively, the number of NSAIDs taken by patients was recorded as an additional criterion for pain severity.

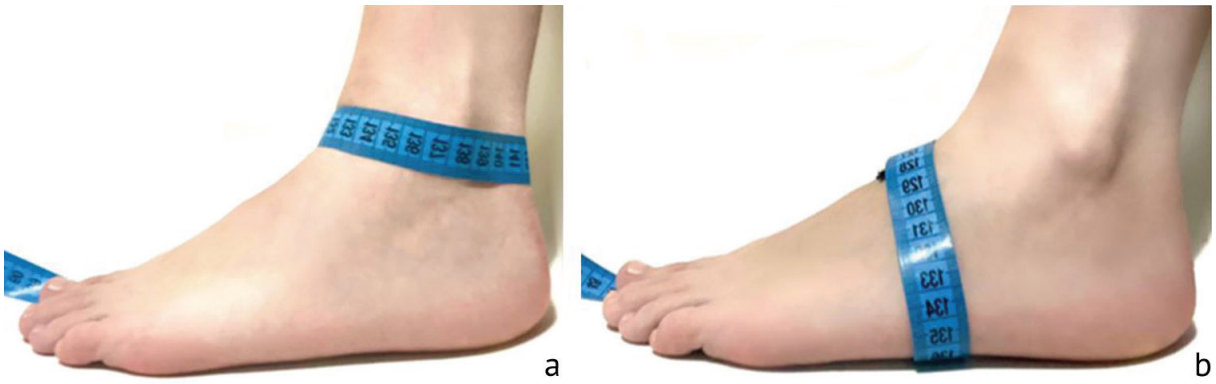

Fig. 1 Representative photographs of the limb level for measuring the circumference: (a) ankle; (b) metatarsus

Postoperative care

Verticalization of the patients was initiated on the first postoperative day. All patients were advised to keep the operated limb elevated for the first three weeks and maintain gradual weight-bearing without additional support. Weight-bearing on the operated limb was permitted with heel support using Barouk shoes (shoes designed to relieve the forefoot) from the first day. The shoe wear period was six weeks to be followed by the use of regular shoewear and custom orthopedic insoles. Elastic compression of the lower extremities was not used postoperatively; all patients received a standard soft bandage.

Safety and Adverse Effect

A combination of clinical observations and laboratory data was used to assess drug safety and record possible adverse reactions. Patients were monitored daily for adverse events including allergic, gastrointestinal, and vascular reactions. Laboratory testing to be performed after three postoperative days included a complete blood count, ALT and CRP serum levels and a coagulogram to detect a hypocoagulation.

Statistical Data Processing

Data were analyzed using the Statistica 13.0 statistical package (StatSoft Inc., USA), and differences in data in the study groups were analyzed using the nonparametric Kruskal – Wallis test. Dunn's test with correction for multiple comparisons was used for pairwise comparison of groups (post-hoc analysis) in case of statistically significant differences ($p < 0.05$). Multiple comparisons were performed between the control group, the LYS and DEX groups. Data are presented as "median[Q1;Q3]".

RESULTS

Characterization of the sample

None of the patients dropped out of the study during the entire observation period. The mean age in the control group, LYS and DEX groups was 51.00 [37.25; 63.00], 52.50 [43.50; 61.75] and 51.50 [46.75; 61.00], respectively. The sample structure was asymmetric by gender with the majority being females (93 %), which corresponds to the real epidemiological picture of the diseases in question and does not affect the statistical interpretation of the results, given the nature of the pathology. Surgical intervention was limited to correction of the first ray (Scarf + Akin) in seven patients (7/30; 23.3 %). The remaining 23 patients (23/30; 76.7 %) underwent additional intervention on the metatarsal bones of the 2nd–4th rays with Weil osteotomy:

— Weil osteotomy of the 2nd metatarsal bone (n = 8; 26.67 %);

— Weil osteotomy of the 2nd–3rd metatarsal bones (n = 2; 6.67 %);

— Weil osteotomy of the 2nd, 3rd, and 4th metatarsal bones (n = 8; 26.67 %). Intervention on two or more metatarsal bones (2–4) was performed in 18 patients (60.0 %). Distribution of patients by the volume of surgical intervention in the groups is presented in Table 1.

Table 1

Distribution of patients by volume of surgical intervention

Type of surgery	Number of patients					
	Control (n = 10)		LYS (n = 10)		DEX (n = 10)	
	abs.	%	abs.	%	abs.	%
Scarf (+Akin)	6	60	2	20	4	40
Scarf + 2 Weil	3	30	3	30	2	20
Scarf + 2,3 Weil	0		2	20	0	
Scarf + 2,3,4 Weil	1	10	3	30	4	40
> 1 osteotomy	4	40	8	8	6	60

To assess the comparability of the groups in terms of the trauma of the intervention, the volume of the surgery was additionally analyzed as an ordinal variable, by the number of Weil osteotomies performed (0–3). No intergroup differences in this indicator were found (p = 0.155), which allows us to consider the groups as comparable in terms of the volume of surgical intervention.

Edema dynamics

Edema at the level of the metatarsus and malleoli was more severe after three postoperative days and measured 11 [4; 16] mm and 6.5 [0.75; 16.75] mm, respectively (Fig. 2). The severity of edema at the level of the metatarsus was present in all three groups early post-op. A difference in this indicator was observed between the groups after six weeks (p = 0.091). Less residual edema was observed in the LYS group as compared to the control group with – 2.0 [–10.0; 5.0] mm and 10 [2.5; 15] mm, respectively (p = 0.057), and no significant differences were found between the control group and the DEX group (p = 0.691). The severity of ankle edema was comparable between groups throughout the study.

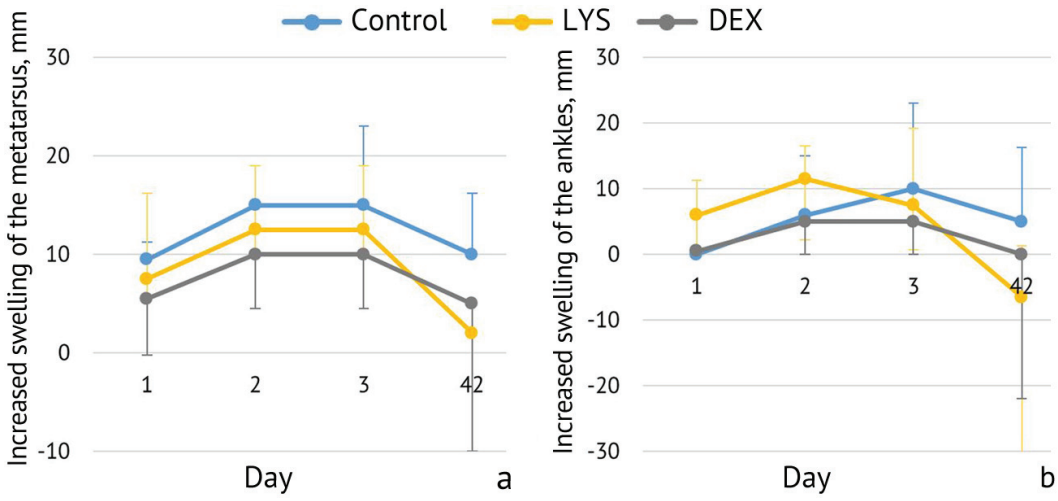

Fig. 2 Postoperative dynamics in the circumference of the lower limb: (a) at the level of the metatarsus; (b) at the level of the ankles

Pain assessment

The day before surgery, the pain was comparable in patients in all groups ($p = 0.17$). The differences between the groups were statistically significant ($p = 0.007$) on the first day after surgery, a similar picture persisted after two ($p = 0.004$) and three ($p = 0.023$) days. The pain level was significantly lower in the LYS group on the first postoperative day as compared to the controls and scored 3 [2.75; 5.25] and 7 [6; 8.25] ($p = 0.004$), respectively. Similar differences persisted after two ($p = 0.002$) and three days ($p = 0.012$) post-op. The use of dexamethasone on the first day only showed a lower ($p = 0.055$) level of pain compared to the controls (Fig. 3).

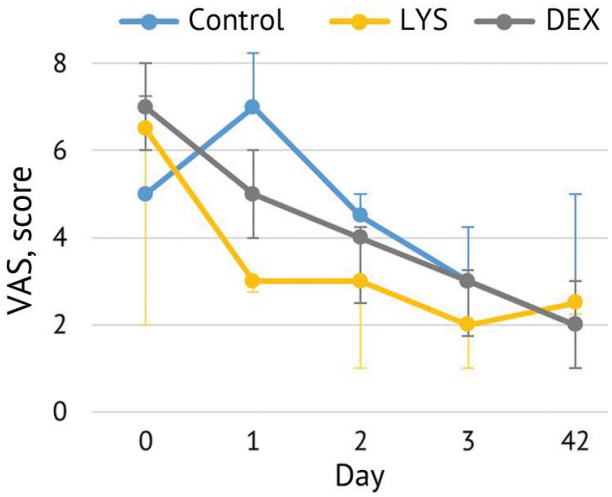

Fig. 3 VAS pain chart

Significant differences in the number of NSAID doses were found ($p < 0.001$) in the early postoperative period. Dexamethasone administration significantly reduced the frequency of NSAID intake compared to the control group on the first ($p < 0.001$) and second postoperative days ($p < 0.001$). In the LIZ group, a statistically significant reduction in NSAID consumption was noted on the second postoperative day ($p = 0.013$) (Table 2).

Table 2

Number of doses of NSAIDs taken by groups

Day	Control ($n = 10$)	LYS ($n = 10$)	DEX ($n = 10$)	p-value
0	0 [0; 0]	0 [0; 0.25]	0 [0; 0.25]	0.328
1	2 [2; 2]	2 [2; 2]	1 [0; 1.25]	< 0.001
2	2 [2; 2]	1 [1; 2]	0 [0; 0.25]	< 0.001
3	1 [1; 1]	1 [1; 1]	1 [1; 1]	> 0.9999
42	0 [0; 0]	0 [0; 0]	0 [0; 0]	0.427

Safety assessment

No adverse drug reactions were registered in any of the clinical groups. Laboratory parameters of ALT level and coagulation profile were within the reference ranges. However, CRP level in the control group and LIZ group was higher than the reference ranges and amounted to 27.8 [19.2; 32.26] mg/L and 11.2 [4.29; 33.91] mg/L, respectively, which can be explained by the surgery performed the day before. CRP concentration was significantly lower in the DEX group than in the control group measuring 2.7 [2.14; 3.71] mg/L ($p < 0.001$).

DISCUSSION

Dexamethasone solution is often used as an adjuvant in multimodal analgesia for trauma and orthopedic patients. A pronounced anti-inflammatory effect of the drug allows for a significant reduction in the severity of the inflammatory response, which explains the significantly lower level of CRP in patients in the DEX group. A positive effect of dexamethasone on edema and pain was reported after total joint arthroplasty of major joints [12, 13]. A significant reduction in pain intensity was reported with the perioperative administration of dexamethasone in addition to adequate basic analgesia, and the authors noted an increase in blood glucose concentration in patients with diabetes mellitus [14]. In addition to the possible development of hyperglycemia, systemic glucocorticoids increase the risk of psychosis, infections and loss of bone mineral density, which limits their routine use in the postoperative period [15, 16]. Thus, the search for drugs that can relieve local swelling and pain after surgery remains relevant.

Postoperative edema is a natural tissue response to surgical trauma and involves a complex of vascular, cellular, and humoral changes [17]. In the foot, edema is more severe due to anatomical and physiological characteristics including a limited volume for transudate distribution and relatively slow venous and lymphatic outflow from the distal parts of the limb [18]. Foot positioning during verticalization of the patient is an additional factor that increases edema contributing to venous congestion and prolongation of the exudative phase of inflammation.

The data obtained during the study suggest that the inclusion of escin lysinate in the postoperative care of patients following reconstruction foot surgery is essential. The drug's most significant and statistically confirmed effect was observed in pain relief. Significantly lower VAS scores in the LYS group compared to the control group in the first three days after surgery indicate an additional analgesic effect, which is evident in the acute period. This effect has important practical role, as intense pain is one of the key factors delaying patient mobilization and the onset of rehabilitation. The analgesic effect is further confirmed by a reduced need for additional NSAIDs on the second postoperative day.

Notably, dexamethasone demonstrated a more pronounced, albeit short-lived, effect in reducing the need for NSAIDs, but showed no long-term benefit. Regarding the anti-edema effect, the dynamics of the measurements reveal an interesting trend: although no significant differences were found between the groups in the first 72 hours, the escin lysinate group showed a more significant regression of edema at the metatarsal level compared to the control group after six weeks. This suggests that the drug influences the pathogenic mechanisms of edema formation, promoting stabilization and a more rapid long-term resolution.

Successful use of escin lysinate in neurosurgery was reported in the literature. A decrease in postoperative mortality was reported after removal of brain tumors [19]. The use of escin lysinate has a beneficial effect on the recovery of patients after focal brain contusions and other traumatic brain injuries [20, 21]. The anti-edematous, analgesic and anti-inflammatory effects of the drug in patients with ENT injuries were reported [22]. In trauma and orthopedics, escin lysinate demonstrated an anti-edematous and analgesic effect in severe lower limb injuries due to the normalization of vascular-tissue and membrane permeability [23]. Escin lysinate has no the above-mentioned disadvantages, having a favorable safety profile. The absence of registered adverse drug reactions and significant changes in laboratory parameters, including the coagulogram, indicates good tolerability of the drug in combination with standard therapy.

There is a paucity of literature reporting the use of escin lysinate in trauma and orthopedics. Our encouraging results regarding the long-term anti-edema effect, require further verification in larger studies involving a larger sample of patients. This will increase the statistical power of the findings and allow for a more detailed subgroup analysis. Thus, our results support the use of escin lysinate as an adjuvant to reduce pain and optimize long-term edema outcomes, contributing to a more comfortable and rapid functional recovery for patients.

CONCLUSION

The findings suggested that the escin lysinate included in the complex therapy of patients undergoing forefoot reconstruction surgery facilitates regression of postoperative edema and provides significant and earlier pain relief in the acute postoperative period compared to standard therapy alone. This reduces the time to functional recovery, reduces the use of NSAIDs, and promotes a more comfortable early rehabilitation without increasing the risk of adverse drug reactions.

Conflict of interests *The authors declare no conflict of interest / The investigational product was provided by Pharm-Active Capital LLC. The authors are not affiliated with the manufacturer; the manufacturer did not participate in the study design, data collection, statistical analysis, interpretation of the results, or preparation of the manuscript.*

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