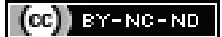


Comparative Evaluation of the Efficacy of Shallakyadi Plaster and Standard POP in the Management of Simple Fractures of Long Bones of the Upper Limb: A Research Protocol

GV PAVITHRA JAIVARSHAA¹, DEVYANI DASAR²

ABSTRACT

Introduction: Fracture management is one of the well-established concepts in Ayurveda with numerous fracture healing drugs mentioned for topical application. The present study is an attempt to form a compound of few of those drugs which can be used as a plaster cast. The effect of this Herbomineral ayurvedic plaster cast on fractures would be studied both in aspects of immobilisation and fracture healing. Shallakyadi plaster which is a novel compound composed of resin of *Boswellia serrata Roxb*, resin of *Acacia nilotica* (Linn.) Willd.ex Del, root of *Glycirrhiza glabra Linn*, whole plant of *Cissus quadrangularis Linn*, Stem of *Rubia cordifolia Linn*, bark of *Terminalia arjuna Wight & Arn (W&A)*, resin of *Commiphorawightii Arn*, *Kaolinite* (phyllosilicate of aluminium) and *hydrated magnesium silicate* can be used as a herbomineral ayurvedic compound for the healing of fractures.

Need of the study: Standard Plaster of Paris (POP) cast has no therapeutic role on healing of fracture other than the purpose of immobilisation, whereas the drugs in Shallakyadi Plaster have known effects on bone healing and also provide the adequate immobilisation provided by Standard POP cast. Hence, the

present study will compare the efficacy of Shallakyadi Plaster and Standard POP in the management of simple fractures of long bones of upper limb.

Aim: To study and compare the efficacy of Shallakyadi plaster and standard POP in the management of simple fractures of long bones of upper limb.

Materials and Methods: The present study is designed as a randomised control trial which would be conducted in Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACHRC), Salod Hirapur (H), Maharashtra, India for three months, in which 60 patients will be enrolled. Standard POP Plaster or Shallakyadi plaster will be applied for local application over the fractured area. Parameters like pain, swelling, loss of function, tenderness would be studied subjectively and callus formation would be taken as the objective parameter. Statistical analysis would be done using GraphPad Prism 7.0 V software and statistical tests- Chi-square test, Wilcoxon's rank sum test and Wilcoxon's signed rank test will be applied with level of significance as 0.05.

Keywords: Fracture, Herbomineral plaster, Orthopaedic cast, Plaster of paris, Shallakyadi cast, Sushruta

INTRODUCTION

Management of traumatic fractures has seen endless advancements in this modern world, with the invention of imaging techniques like X-ray, techniques such as open reduction, fixation of dynamic screws and inert wires, replacement, grafting with modern surgical tools, and the usage of plasters, fibreglass casts, and lighter splints for non surgical management [1]. The total incidence of fractures per 100,000 people per year was 406. The overall incidence of lower limb fractures is 247, whereas the overall incidence of upper limb fractures is 159 [2].

In spite of the recent advances, the basics of fracture management such as reduction, immobilisation, and rehabilitation can be traced back to the management protocols of Sushruta. Acharyas have mentioned various drugs that help in the healing of fractures and also provide symptomatic relief from pain and swelling [3]. Charaka has mentioned Sandhaneeya Dashemani [4]. Susrutha has mentioned Priyangu-Ambastadhigana, Nyagrodhadhi Gana [5], and various Nighantu quotes and many Asthi Sandhanakara Dravyas. For fracture management, reduction and immobilisation are universally required and should be done according to prescribed standard protocols.

In the treatment of fractures, anatomical union is not only the ultimate aim, but attention must also be paid to avoid or minimise the

forthcoming complications such as scaling, ulceration, maceration, itching, and burns due to exothermic reactions. The underlying skin is prone to Staphylococcus-induced dermatitis. However, the toughest complication is compartment syndrome and the resulting sequelae of Volkmann's ischaemic contracture [6].

For this purpose, the role of indigenous drugs in fracture healing is continuously under scrutiny by scientists for their mechanism of action. According to reviews, the interest and curiosity of many research scholars have been focused on the oral use of various indigenous drugs and local applications for fracture healing agents. After a thorough review of previous work done by different scholars, it was observed that little emphasis is given to the combined use of local and systemic drugs. Most of the time, surgeons face problems with simple fractures of the hand, wrist, ankle, foot, etc., not due to the fracture itself, but due to immobilisation with standard POP [7].

Considering the high incidence of this type of fractures occurring in day-to-day life and the resulting complications with POP, it was decided to undertake the present study. The existing plaster casts do not have any local therapeutic effects and only work for immobilisation [8]. Existing Ayurvedic medicines work as local application agents and do not serve the purpose of immobilisation for which splints are used externally. Lakshadi Plaster is an existing Ayurvedic plaster that acts as a cast and helps in fracture healing,

but no further studies have been conducted on the properties of this plaster [9]. This herbomineral plaster comprises natural resins such as *Boswellia Serrata Roxb*, *Acacia arabica Wild.var. indica Benth*, *Commiphora wightii Arn*, along with the roots of *Glycyrrhiza glabra Linn*, the whole plant of *Cissus quadrangularis Linn*, the roots of *Rubia cordifolia Linn*, the bark of *Terminalia arjuna W&A*, as well as Kaolinite clay and hydrated magnesium silicate. All these drugs are already known as fracture healing agents in Ayurvedic literature, and the natural resins help achieve the desired plaster cast form [10,11]. Hence, the present study aims to find the efficacy of Shallakyadi Plaster when compared with Standard POP plastering in the management of simple fractures of long bones of the upper limb.

The objectives include:

1. To study the efficacy of Shallakyadi Plaster on pain, swelling, loss of function, and tenderness, which are taken as subjective parameters, and callus formation, which is taken as an objective parameter in simple fractures of long bones of the upper limb.
2. To study the efficacy of standard POP on pain, swelling, loss of function, and tenderness, which are taken as subjective parameters, and callus formation, which is taken as an objective parameter in simple fractures of long bones of the upper limb.
3. To compare the efficacy of Shallakyadi plaster and standard POP in the management of simple fractures of long bones of the upper limb.

Null hypothesis (H0): Shallakyadi Plaster is not efficacious as standard POP in the management of simple fractures of long bones of the upper limb.

Alternate hypothesis (H1): Shallakyadi Plaster is more efficacious than standard POP in the management of simple fractures of long bones of the upper limb.

Alternate hypothesis (H2): Shallakyadi Plaster is equally efficacious as standard POP in the management of simple fractures of long bones of the upper limb.

REVIEW OF LITERATURE

Despite recent advances, the contemporary management of simple fractures remains similar to Sushruta's technique, which involves Anchana, Peedana, Samkshepana, and Bandhana. Along with various procedures, many drugs have been mentioned to possess bone-healing properties. In the present study, Sushruta's technique and these drugs have been used in the management of fractures to assess their efficacy in bone healing and providing symptomatic relief. The management of simple closed fractures with closed reduction is followed by the application of a cast or splint, POP plastering, and physiotherapy after the period of immobilisation and removal of plasters or casts. This approach focuses on the main principles of reduction, immobilisation, and rehabilitation. POP plastering aligns with the basic principle of immobilisation.

The gum resin of Shallaki has potent anti-inflammatory action due to its active ingredients α and β boswellic acid and other pentacyclic triterpenic acids, which affect 5-lipoxygenase, cyclooxygenase, and the complement system. Acetyl-11-keto- β -boswellic acid proves to be a potent inhibitor of 5-lipoxygenase [7,12]. Both Guggulu and the methanol extract of *C. mukul* are found to have Shothahara (anti-inflammatory) and Bhagna Sandhankara (fracture healing) properties. The inhibition of bone loss occurs by suppressing osteoclastic activity, either by suppression of NF- κ B activation or by other antioxidant mechanisms promoting bone mineralisation [9,13]. Yastimadhu, mentioned as Sandhaneeya by both Susrutha and Charaka, has anti-inflammatory and analgesic properties. Glycyrrhetic acid, liquiritoside, and Licochalcone exhibit significant anti-inflammatory properties, while flavonoids such as Isoliquiritigenin exhibit analgesic activity [14]. Asthishrinkala, known as Hadjod, has anti-inflammatory, analgesic, and antipyretic activities, and contains

natural steroids and vitamins that are useful for early bone healing [15]. External application facilitates rapid healing [16]. Manjista is known to have anti-inflammatory, haemostatic, antipyretic, and analgesic properties [17]. It is Rakta Prasadaka and Ushna Veerya, due to which it will increase peripheral arterial blood flow. The Kaphapitta Shamaka property will reduce the local oedematous residue, and its Ushna Veerya property helps penetrate into local tissue. The calcium salts, gum, resinous matter, and its properties initiate early callus formation [18]. Arjuna bark contains calcium carbonate (34%), other calcium salts (9%), and tannin (16%). Besides, it also contains aluminium, magnesium, organic acid, colouring matter, and sugar, and is highly potent in promoting the healing of broken bones [19,20]. Dughdhapashana and Shuddha Khatika aid in the development of plaster and play an important function in reducing pain and swelling [21,22]. Baboola is used for enhancing fracture healing and is bhagnasandhanakara. Babool resin has almost 52% calcium with magnesium, galactose, and other active principles. It causes an increase in osteoblast differentiation and a reduction in osteoclast activity, promoting more cell proliferation and significantly increased mineralisation of bone-like matrix [23,24].

Methodology

The randomised controlled trial will be conducted at Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod (H). The total study period will be three months, including the follow-up period. The study has obtained ethical clearance from the Institutional Ethical Committee of DMIMS, Wardha, Maharashtra, India, numbered as MGACHRC/IEC/July-2021/343. The Clinical Trials Registry-India (CTRI) registration number is CTRI/2021/12/038784. The study will commence after obtaining informed written consent from the patients.

Sample size calculation: The Cochran formula was used for sample size estimation, with a confidence level of 1.96 and a margin of error of 0.10, resulting in a fixed sample size of 30 in each group. Patients were equally allocated to two groups using a computer-generated randomised table method. Blinding/masking was not performed in the present study, as the application of plaster cannot be blinded.

Inclusion criteria: Patients aged 10 to 50 years will be enrolled after obtaining written informed consent. Patients with clinical features of traumatic simple fractures of long bones of the upper limb will be included after screening. Patients of any gender, occupation, or economic status will be included.

Exclusion criteria: Patients with systemic disorders such as diabetes mellitus, tuberculosis, Human Immunodeficiency Virus (HIV), hepatitis, and renal diseases will be excluded. Open fractures, multiple, compound, or comminuted fractures, as well as fractures other than those in the upper limbs, will be excluded. Patients with nerve and vessel injuries and those with bone infective diseases such as osteomyelitis and TB will be excluded. Additionally, patients below 10 years of age and above 50 years of age will be excluded.

Preparation of Shallakyadi Plaster

Purification (Shodanam) of drugs: *Glycyrrhiza glabra Linn*, *Rubia cordifolia Linn*, *Cissus quadrangularis Linn*, and *Terminalia arjuna W&A* will be washed and cleaned thoroughly. These herbal drugs do not require any specific purification before formulating for external application.

Preparation of (kashaya) decoction: Coarse powders of *Glycyrrhiza glabra Linn*, *Rubia cordifolia Linn*, and *Terminalia arjuna W&A* will be taken in equal quantity (1 kg each) and soaked in sufficient water overnight (for 12-16 hours). One kg of crushed whole plant of *Cissus quadrangularis Linn* will be soaked in sufficient water for 4-8 hours. Then these will be added together and boiled with 64 L of water. Once the mixture starts boiling, maintain the temperature around 60-120 degrees Celsius and reduce it to 1/4th (around 15 L to 17 L). The obtained kashayam will be filtered with white muslin cotton cloth.

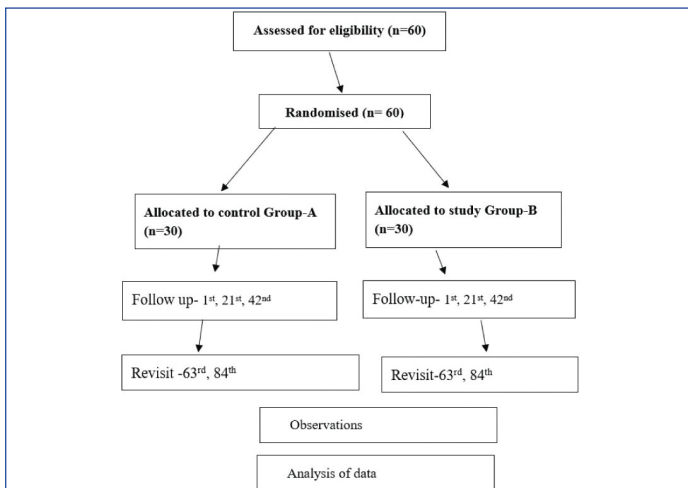
Preparation of fine churna (powder): Fine powder of all the resins will be made and sieved through sieve number No. 85/100/120 (IS 460-1978) individually.

Preparation of Shallakyadi gauze roller bandages: Fine powder of shodita (purified) resin of Commiphora wightii Arn and resin of Boswellia serrata Roxb, resin of Acacia nilotica (Linn.) Willd. ex Del followed by fine powders of Kaolinite (phylosilicate of aluminum) and hydrated magnesium silicate will be added in equal ratios to a quantity sufficient amount of decoction made in step 1. It will be mixed and dissolved completely. Gauze roller bandages of 4 inches (2.7 m long), 6 inches (2.7 m long), and 2 inches (2.7 cm long) will be soaked in this paste for 5-30 minutes, impregnated with the paste and dried. (An air blower can be used)

Application of Shallakyadi cast/slab:

- i. Soft cotton padding is applied circumferentially over the fractured limb, extended as the nature and site of the fracture require.
- ii. Applied as either Shallakyadi cast/slab after the reduction of the fracture.

Diagnosed patients of simple fractures of long bones of the upper limb will be enrolled in the present study after fulfilling the inclusion criteria. A total of 30 patients will be divided into two groups, where Group A patients will be treated with Shallakyadi Plaster cast, and Group B will be treated with the standard POP plaster cast for a period of 56 days according to the type of fracture. Follow-up will be done on the 63rd and 84th days [Table/Fig-1]. The following table shows the intervention [Table/Fig-2].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

Group	Sample size	Intervention	Frequency	Duration	Follow-up
Group-A	30	Shallakyadi plastering	Lakshadiguggulu 500 mg after food, twice a day with luke warm water	56 days assessment on day 0,7,21,28, 35,42,56	63 rd , 84 th day
Group-B	30	POP plastering	Calcium 500 gm with Vit D3 1000 IU Once a day Analgesics and anti-inflammatory with water	56 days assessment on day 0,7,21,28, 35,42,56	63 rd , 84 th day

[Table/Fig-2]: Intervention table.

Assessment Criteria

The following subjective and objective parameters will be assessed.

Subjective Parameters

Acute Pain-Weekly assessment will be conducted.
 G0- No pain, G1- Mild pain without difficulty in working, G2- Moderate pain with severe difficulty in working, and G3- Severe pain making working impossible.

Acute Swelling (assessed by measuring the circumference of the fractured limb compared to the normal limb)-will be assessed before applying the slab/cast and after the removal of the slab/cast.

G0- No swelling, G1- Mild: Girth increased up to 2 cm, G2- Moderate: Girth increased 2-6 cm, G3- Severe: Girth increased by more than 6 cm.

Acute Tenderness (initial assessment elicited by palpating the fractured site, subsequent assessments by springing test)-will be assessed before applying the slab/cast and after the removal of the slab/cast.

G0- Tenderness absent, G1- Patient winces with pain, G2- Patient winces and withdraws the affected part, G3- Patient does not allow touching the affected part.

Acute Loss of function-will be assessed before applying the slab/cast and after the removal of the slab/cast.

G0- Proper function of bones and joints, G1- Mild pain during movement, G2- Severe pain and restricted movement, G3- Total loss of function.

Objective parameters: Callus formation (visible on X-ray) on the day of the fracture, 21 days after the fracture and cast application, and 42 days after the fracture and cast application (or other days as needed according to the case).

G0-No callus, G1-Soft callus, G2-Hard callus.

Criteria for discontinuing or modifying allocated interventions: Patients will be withdrawn from the intervention if any harmful incidents, signs of drug allergy, or any problems occur. Patients will be offered treatment free of cost until the fracture heals and local symptoms subside.

STATISTICAL ANALYSIS

The statistical analysis will be conducted using GraphPad Prism 7.0 software. The Chi-square test will be used for subjective parameters, while the Wilcoxon's rank sum test will be used for the other parameters. Additionally, the Wilcoxon's signed rank test will be used for comparisons, with a significance level set at 0.05. [Table/Fig-3] displays the Gantt chart.

Scholar/Investigator	Dr. Pavithra Jaivarshaa GV					
Title	"Comparative evaluation of efficacy of Shallakyadi Plaster and Standard POP in the management of simple fractures of long bones of upper limb"					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
IEC clearance and CTRI approval	█					
Enrollment of patients		█	█	█		
Drug collection and preparation		█	█	█		
Data collection		█	█	█		
Writing thesis parts up to methods			█	█	█	
Data analysis				█	█	
Writing rest of thesis					█	█
Submission						█

[Table/Fig-3]: Gantt Chart (Quarterly).

REFERENCES

- [1] Sudesh G, Bhawana G, Anuradha T, Hardip S, Shivani B. Sushruta's general principles of fracture care treatment & management. Ayushdhara. 2015;(6):385-89.
- [2] Meling T, Harboe K, Søreide K. Incidence of traumatic long-bone fractures requiring in-hospital management: A prospective age- and gender-specific analysis of 4890 fractures. Injury. 2009;40(11):1212-19. Doi: 10.1016/j.injury.2009.06.003. Epub 2009 Jul 5. PMID: 19580968.
- [3] Kaviraj Ambika Dutta Shastri, Sushruta Samhita, Ayurveda Tatwa Sandeepika Hindi Commentary, Nidanasthana Bhagnaadhyaya 15, Varanasi: Chaukhamba Sanskrit Sansthan; 2002: Pp. 291-94.

- [4] Kaviraj Ambika Dutta Shastri, Sushruta Samhita, Ayurveda Tatwa Sandeepika Hindi Commentary. Chikitsasthanambhagnachikitsa 3. Varanasi: Chaukhamba Sanskrit Sansthan; 2002: p. 20-25.
- [5] Yadavji Trikamji. Charaka samhita with Ayurveda deepika commentary Choukambha Krishnadas academy. Varanasi: Sutra Sthanam; 2005: p.32, 4/5.
- [6] Priya Vrta Sharma, Sushruta Samhita english commentary. Sutra Sthanam. 45-49/38. Varanasi: Chaukambha Visvabharathi; 2013: p.361-362.
- [7] Sharma H, Prabu D. Plaster of Paris: Past, present and future. J Clin Orthop Trauma. 2013;4(3):107-09.
- [8] Connolly J. Non-operative fracture treatment. In: Bucholz RW, Heckman JD, Court-Brown C, Tornetta P, Koval KJ, Wirth MA, eds. Rockwood and Green's Fractures in Adults. 6th ed. vol. 1. Philadelphia: Lippincott Williams and Wilkins; 2006:145e208.
- [9] Dudhamal TS, Mahanta VD, Gupta SK. Efficacy of Lakshadi Plaster and Laksha Guggulu in the Management of Bhagna (Stable Colle's Fracture) Case Report. International Journal of Ayurvedic Medicine. 2012;3(2):124-29.
- [10] Tichkule SV, Khandare KB, Shrivastav PP. Role of Khanduchakka (Ehretia laevis) Lepan (local application) in the management of delayed union of metatarsal fracture: A case report. J Indian Syst Med. 2019;7(2):127-30.
- [11] Ramesh PB. Ambashtadi Gana Kashaya Pana in Bhagna Sandhana-A case study. J Ayurveda Integr Med Sci. 2020;5(05):577-84.
- [12] Prabhavathi K, Chandra US, Soanker R, Rani PU. A randomised, double blind, placebo controlled, cross over study to evaluate the analgesic activity of Boswellia serrata in healthy volunteers using mechanical pain model. Indian J Pharmacol. 2014;46(5):475-79. Doi: 10.4103/0253-7613.140570.
- [13] Khan S, Dwivedi C, Parmar V, Srinivasan KK, Shirwaikar A. Methanol extract of dried exudate of Commiphoramukul prevents bone resorption in ovariectomized rats. Pharmaceutical Biology. 2012;50(10):1330-36. Doi: 10.3109/13880209.2012.675339.
- [14] Kaur R, Kaur H, Dhindsa AS. Glycyrrhiza glabra: A phytopharmacological review. Int J Pharm Sci Res. 2013;4(7):2470-77. Doi: 10.13040/IJPSR.0975-8232.
- [15] Ghouse MS, Baig MS. Bone healing activity of *Cissus quadrangularis* Linn. Int J Pharmacognosy. 2015;2(11):527-31. Available at: [http://dx.doi.org/10.13040/IJPSR.0975-8232.IJP.2\(11\).527-31](http://dx.doi.org/10.13040/IJPSR.0975-8232.IJP.2(11).527-31).
- [16] Rasale PL. Phytochemical and pharmacological review of fracture healing drug asthisamharak used in ancient Indian medicine. Int J Pharm Med Bio Sci 2014;3(3):28.
- [17] Meena AK, Pal B, Panda P, Sannd R, Rao MM. A review on Rubia cordifolia: Its phyto constituents and therapeutic uses. Drug Invention Today. 2010;2(5):244-46.
- [18] Mogal KM, Shah HS. Pain management by herbo-mineral paste application (ManjishthadiLepa) in post traumatic joint disorder. JMSCR. 2017;05(02):17568-72]. Doi: <https://dx.doi.org/10.18535/jmscr/v5i2.59>.
- [19] Reena G, Kiran G, Kamlesh P. Effect of anabolic steroid in accelerating healing process of experimentally fractured tibia of rats and compare its fracture healing property with terminalia arjuna. Int J Curr Microbiol App Sci. 2016;5(5):788-95. Doi: <http://dx.doi.org/10.20546/ijcmas.2016.505.079>.
- [20] Krithiga G, Hemalatha T, Deepachitra R, Ghosh K, Sastry TP. Study on osteopotential activity of Terminalia arjuna bark extract incorporated bone substitute. Bulletin of Materials Science. 2014;37(6):1331-38.
- [21] Angadi R. Rasa tarangini - Ayurveda pharmaceutics and transdense Indian alchemy, Talakadhivignyaniya Taranga sloka. 232-233/11. Choukambha Surbharati Prakashan; 2015: p.188.
- [22] Angadi R. Rasa tarangini - Ayurveda pharmaceutics and transdense Indian alchemy, descriptive commentary, Talakadhivignyaniya Taranga sloka. 211-212/11. Choukambha Surbharati Prakashan; 2015 p.185.
- [23] Singh V. Medicinal plants and bone healing. Natl J Maxillofac Surg. 2017;8(1):04-11. Doi: 10.4103/0975-5950.208972. PMID: 28761270; PMCID: PMC5512407.
- [24] Kakadia N, Vegad K, Kanaki N. Acacia arabica (Lam.) Willd. On osteoblastogenesis, osteoblast proliferation, osteoclastic activity, and bone calcium mineralisation. J Complement Integr Med. 2022;19(3):711-17.

PARTICULARS OF CONTRIBUTORS:

1. Postgraduate Scholar, Department of Shalyatantra, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (H), Datta Meghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha, Maharashtra, India.
2. Associate Professor, Department of Shalyatantra, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (H), Datta Meghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. GV Pavithra Jaivarshaa,
Postgraduate Scholar, Department of Shalyatantra, Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (H), Datta Meghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha-442001, Maharashtra, India.
E-mail: pavithra.jv.gv@gmail.com

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Jul 20, 2023
- Manual Googling: Sep 23, 2023
- iThenticate Software: Dec 09, 2023 (7%)

ETYMOLOGY: Author Origin**EMENDATIONS:** 7

Date of Submission: **Jul 19, 2023**
Date of Peer Review: **Sep 20, 2023**
Date of Acceptance: **Dec 12, 2023**
Date of Publishing: **Feb 01, 2024**