

From Traditional Prep to Modern Standards: A Comprehensive Review of Ksharasutra.

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ABSTRACT

One of the most important pharmacosurgical advances in Ayurveda is Ksharasutra treatment. It has been used to treat Nadi Vrana (sinus), Bhagandara (fistula-in-ano), and Arsha (piles), combining the concepts of controlled tissue healing with chemical cauterization. The pharmacognosy of Ksharasutra's main ingredients, their pharmacological activities, and current developments in standardization and quality assurance are all critically examined in this paper, along with both traditional and modern ways of preparation.

Pharmacopeial manuals, peer-reviewed scientific studies published in indexed journals, and traditional Ayurvedic texts were all used in a comprehensive literature study. Results indicate that although the most widely used substances are still Apamarga (*Achyranthes aspera*), Snuhi latex (*Euphorbia neriifolia*), and Haridra (*Curcuma longa*), other modifications have been developed to improve efficacy, sterility, and shelf life. Tensile strength, pH, microbial load, and uniform coating thickness are examples of standardization parameters that are widely acknowledged as factors that determine therapeutic consistency. The bioactive components of these substances contribute to the medication's caustic, antibacterial, and wound-healing qualities, according to the integration of pharmacological data.

The review comes to the conclusion that phytochemical fingerprinting, verified sterilization procedures, and harmonized pharmacopeial standards can ensure that Ksharasutra is accepted worldwide as a natural, evidence-based treatment for surgery by bridging traditional knowledge with contemporary quality standards...

Keywords: Ksharasutra, Apamarga, *Euphorbia neriifolia*, *Curcuma longa*, standardization, pharmacognosy....

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INTRODUCTION

Ksharasutra holds a unique position among the many pharmaco-surgical contributions of *Ayurveda*. By blending herbal chemistry with mechanical action, it represents a synthesis of medicine and surgery. It is not merely a therapeutic tool but a sophisticated biomedical concept that integrates the principles of herbal pharmacology with precise and controlled surgical mechanics. The foremost and most authoritative description of use of *Ksharasutra* found in *Sushruta Samhita* under *Nadi Vrana*¹ (sinus) and *Bhagandara Chikitsa*² (fistula in ano), employs a medicated thread coated with alkaline and latex-based herbal substances to achieve both cutting, cleansing and healing of pathological tracts³. *Ksharasutra* exemplifies the holistic synthesis of medicine and surgery that is a hallmark of classical Ayurvedic practice. Unlike conventional surgical excision, which is often associated with bleeding, recurrence, wound complications and potential damage to the anal sphincters complex leading to incontinence⁴, *Ksharasutra* acts slowly, promoting controlled debridement of unhealthy tissues and fibrosis while the mechanical tension of the thread ensures progressive cutting of the tract, the process, eventually obliterates the tract in sinuses or anal fistulas and thereby preventing recurrence⁵.

Over the past few decades, the therapy has drawn global attention as a minimally invasive, cost-effective, and

efficacious alternative for managing fistula-in-ano and related anorectal disorders. Yet, despite its proven clinical potential, the pharmacological and manufacturing dimensions of *Ksharasutra* have not been standardized uniformly. Variations in the source plants, coating techniques, and sterilization methods continue to affect reproducibility of results. A scientific understanding of its preparation and the bioactivity of its constituents is therefore essential for integration into evidence-based surgical practice.

This review was undertaken utilizing a narrative critical review approach to synthesis classical *Ayurvedic* literature with contemporary scientific information relating to *Ksharasutra* preparation, ingredients, pharmacology, and standardization.

Materials and Methods

The *Sushruta Samhita*, *Charaka Samhita*, and their authoritative commentary served as the sources of classical references. Original research publications, clinical trials, experimental studies, review articles, and pharmacopeial documents published in English were included. Excluded were studies that just looked at surgical results and had no bearing on formulation. To determine preparation methods, pharmacological mechanisms, standardization factors, regulatory obstacles, and future research objectives, data were critically examined.

Ksharasutra, *Apamarga Kshara*, *Euphorbia neriifolia*, *Curcuma longa*, *Ayurvedic* surgery, fistula-in-ano, pharmacognosy, and standardization were among the keywords utilized.

2. Historical Background

References to the use of *Kshara* (alkaline preparations) occur as early as the *Charaka Samhita*⁶, but it was *Sushruta* who systematized their use in surgical practice. He described *Ksharakarma* (application of alkali) and *Ksharasutra* (alkali-coated thread) as specialized measures for conditions where both excision and healing were desired simultaneously⁶. He advised the use of alkaline substances derived from plants like *Apamarga*, *Arka*, and *Snuhi*, emphasizing their ability to dissolve necrotic tissue and promote purification (*Shodhana*) of the wound. With time, the therapy evolved beyond the classical description. Modern practitioners developed practical methods for thread coating, drying, and storage, leading to the standardized “*Apamarga Ksharasutra*” described by the Central Council for Research in *Ayurvedic* Sciences (CCRAS) in the 1970s. Since then, numerous modifications—such as *Guggulu Ksharasutra*, *Sphatika*

Ksharasutra, *Aloe vera Ksharasutra* etc.—have been introduced to suit various pathological conditions.

3. Method of Preparation

3.1. Selection of Thread

Traditionally, a sterile *Barbour's surgical linen* thread number 20 is used as the base⁷. The thread must be clean, uniformly twisted, and free from knots to ensure smooth coating. Linen possesses desirable tensile strength, moderate absorbency, and minimal elasticity, making it suitable for sustained drug retention and gradual cutting⁸.

3.2. Constituents

The classical *Apamarga Ksharasutra* employs three major ingredients:

***Snuhi* latex** (*Euphorbia neriifolia*) – acts as a binding agent⁹.

Apamarga Kshara (*Achyranthes aspera* alkali-stepwise method of preparation depicted in **Fig. 1**) – provides the principal cauterizing and debriding action¹⁰.

Haridra churna (*Curcuma longa* powder) – imparts antiseptic and healing properties while reducing irritation.^{11,12}



Fig. 1- Stepwise method of preparation of Kshara

3.3. Stepwise Procedure

The preparation follows a coating-drying sequence¹³:

First 11 coatings: *Snuhi* latex alone to build adhesive layers.

Next 7 coatings: *Snuhi* latex mixed with *Apamarga Kshara*.

Last 3 coatings: *Snuhi* latex with *Haridra* powder, ensuring smooth surface and antimicrobial finish.

Each layer is allowed to dry under aseptic conditions before applying the next, ensuring uniformity. The fully coated threads are finally dried in a cabinet drier at 40–45°C, stored in airtight glass tubes, and sterilized either by gamma irradiation or ethylene oxide before clinical use¹³.

4. Variations in Preparation

Over the years, several herbal and mineral substitutes like *Aloe-vera*, *Arka*¹⁴, *Guggulu*¹⁵ etc have been evaluated to improve efficacy or adapt to availability.

5. Pharmacognostic Overview of Constituents (Table 1)

5.1. *Achyranthes aspera* (*Apamarga*)

A common weed found throughout India, *Apamarga*'s whole plant is used for alkali preparation. Its major constituents include achyranthine, ecdysterone, oleanolic acid, and potassium carbonate¹⁶. The high alkalinity produced upon incineration contributes to its tissue-

digesting and hemostatic properties. Pharmacologically, it exhibits antimicrobial, anti-inflammatory, and astringent effects¹⁷.

5.2. *Euphorbia neriifolia* (*Snuhi*)

The latex of this plant contains diterpenes such as euphorbon, tiglane esters, and triterpenoids¹⁸. These compounds are known for their irritant yet potent proteolytic actions that facilitate sloughing of necrotic tissue¹⁸. The viscous nature of the latex also ensures firm adherence of coatings to the thread.

5.3. *Curcuma longa* (*Haridra*)

Curcumin, demethoxycurcumin, and bis-demethoxycurcumin are the principal curcuminoids responsible for *Haridra*'s antioxidant, antimicrobial, and wound-healing actions¹⁹. They modulate cytokine activity, promote fibroblast proliferation, and inhibit infection, making *Haridra* a soothing counterbalance to the caustic components²⁰.

6. Pharmacological Basis of Action

The mechanism of *Ksharasutra* can be interpreted as a sequence of biological and chemical events:

Chemical Cauterization: The alkaline component (*Kshara*) dissolves unhealthy tissue by saponifying fats and

denaturing proteins, resulting in controlled chemical cauterization⁸.

Mechanical Pressure: The tension of the thread ensures gradual cutting of the tract as fibrosis sets in behind the advancing thread.

Antimicrobial Effect: *Haridra*¹⁹ and *Apamarga*²¹ possess documented antibacterial and antifungal properties that prevent infection in the wound bed.

Anti-inflammatory and Healing Promotion: Bioactive compounds of *Snuhi* and *Haridra* modulate inflammation, encourage granulation tissue, and reduce postoperative discomfort^{19,22}.

Sustained Drug Release: Layered coatings allow slow and continuous delivery of active substances, ensuring prolonged therapeutic effect at the site.

Table 1. Constituents, Phytochemicals and Pharmacological Actions.^{23,24,25,11,12}

Ingredient	Major Phytochemicals	Pharmacological Actions
<i>Achyranthes aspera</i>	Alkaloids, potassium salts, ecdysterone	Caustic, antimicrobial, debriding
<i>Euphorbia neriifolia</i>	Diterpenes, triterpenoids	Proteolytic, tissue sloughing
<i>Curcuma longa</i>	Curcuminoids	Antioxidant, antimicrobial, wound healing

Experimental studies have demonstrated inhibition of common pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *E. coli* from *Ksharasutra* extracts, supporting its antimicrobial claims²⁶.

7. Standardization Parameters

Uniform quality assurance remains the most challenging aspect of *Ksharasutra* production. The following parameters are considered critical:

7.1. Physical Characteristics²³

Thread Diameter: Ideally between 1.5–2 mm for *Apamarga Ksharasutra*.

Tensile Strength: Minimum of >5 kg/cm² to withstand surgical tension.

Coating Uniformity: Should exhibit smooth layers without cracks or flakes.

Length: Standardized at 30 cm for single use.

Shelf life: 6-12 months

7.2. Chemical Parameters

pH: Typically, alkaline (9–11), ensuring caustic efficacy.²⁷

Ash and Moisture Content: Controlled to prevent degradation.

Alkali Concentration: Determined by acid–base titration to maintain consistent potency.

7.3. Microbiological Tests

Bioburden and Sterility: No viable microorganisms should remain post-sterilization.

Antimicrobial Assay: Periodic testing against standard strains ensures activity retention during storage.

8. Sterilization Techniques

Traditional methods relied on sunlight drying, which offers only limited microbial reduction. Modern approaches use:

Gamma irradiation: Effective, non-thermal method maintaining chemical stability.

Ethylene oxide sterilization: Preferred for large-scale production, though aeration time must be optimized to eliminate toxic residues.

UV exposure and autoclaving: Often avoided as they alter the chemical structure of latex and curcuminoids.

Sterilization validation should include biological indicators to ensure compliance with pharmacopeial standards.

9. Quality Control and Regulatory Perspective²⁸

The *Ayurvedic Pharmacopeia of India* and *CCRAS* have recommended protocols for *Ksharasutra* preparation. However, implementation across teaching hospitals and private setups remains inconsistent. Standard operating procedures (SOPs) should include:

Botanical authentication of raw drugs.

Use of stainless-steel apparatus to prevent contamination.

Environmental monitoring during coating and drying.

Batch labelling with preparation date, sterilization method, and expiry.

Inclusion of *Ksharasutra* in national pharmacopeial monographs, along with validated analytical parameters such as HPTLC fingerprints and infrared spectra, will greatly enhance regulatory acceptance.

10. Recent Advances

Modern research has introduced several innovations:

Herbo-mineral Ksharasutras: Incorporating agents like *Tankana*²⁹, *Sphatika*³⁰ etc. for stronger antiseptic action.

Polymer-based Ksharasutra: Experiments with absorbable sutures like polyglactin 910 to reduce post-procedure pain.

Automation of coating: Mechanized coating units ensure uniform layer thickness and minimize human error²⁸.

These trends show a growing inclination toward harmonizing traditional preparation with pharmaceutical technology.

11. Challenges in Standardization

Despite recent progress, several challenges persist:

Variation in Raw Material Quality: Seasonal and geographical factors affect alkali strength and latex composition.

Manual Preparation Errors: Differences in layer thickness and drying conditions can alter therapeutic potency.

Lack of Central Quality Testing: Few laboratories perform routine batch validation or microbial testing.

Inadequate Documentation: Absence of digital batch records and traceability complicates post-market quality surveillance.

Regulatory Ambiguity: *Ksharasutra* lies between a “device” and a “drug,” complicating its categorization under existing laws.

12. Clinical Relevance and Outcomes

Several clinical trials have confirmed the superiority of *Ksharasutra* therapy over conventional surgery in treating fistula-in-ano³¹. Reported healing rates exceed 90%, with low recurrence and minimal incontinence³². The controlled fibrosis³³ produced by the thread facilitates tract obliteration without extensive tissue damage. In chronic

pilonidal sinus, *Ksharasutra* has demonstrated remarkable wound-healing potential¹.

The therapy's affordability, simplicity, and minimal hospitalization make it particularly suitable for resource-limited settings. However, practitioner skill and strict asepsis remain essential for successful outcomes.

13. Integrating Pharmacological and Clinical Evidence

The therapeutic efficacy of *Ksharasutra* is supported by its pharmacological profile. The synergistic combination of caustic, antimicrobial, and healing agents mirrors a multi-targeted drug design approach:

Apamarga alkali ensures chemical excision and debridement.

Snuhi latex provides enzymatic proteolysis and adhesiveness.

Haridra reduces oxidative stress and supports tissue regeneration.

Together, they sustain an ideal local microenvironment for healing. Modern pharmacology corroborates many of these actions through in vitro and animal studies, validating classical claims of *Shodhana* (cleansing) and *Ropana* (healing).

14. Future Directions

For global acceptance of *Ksharasutra* as a natural surgical remedy, the following steps are proposed:

Development of Pharmacopeial Monograph: Including detailed manufacturing, quality, and analytical specifications.

Standardized Sterilization and Packaging Protocols: Adoption of validated gamma irradiation facilities at regional levels.

Phytochemical Fingerprinting: Use of chromatographic and spectroscopic markers to verify consistency of herbal constituents.

Clinical Data Registry: Establishing multicentric digital records for efficacy and adverse events.

Good Manufacturing Practice (GMP) Implementation: Certification of institutional and commercial production units.

Interdisciplinary Research: Collaboration between Ayurvedic, pharmaceutical, and biomedical scientists for formulation optimization.

15. Discussion

Ksharasutra represents a unique pharmaco-surgical system wherein mechanical intervention is synergistically supported by sustained local drug delivery²⁰. Unlike conventional fistulotomy, which relies primarily on excision, *Ksharasutra* induces controlled chemical cauterization, gradual tract excision, and simultaneous wound healing⁵. This multifactorial mechanism parallels modern drug-eluting sutures used in contemporary surgery. However, the transition of *Ksharasutra* from a traditionally handcrafted therapy to a globally acceptable intervention is constrained by inconsistent preparation protocols and lack of harmonized regulatory standards. Variability in raw material quality, latex composition, and alkali concentration significantly affects therapeutic outcomes. While CCRAS and the Ayurvedic Pharmacopeia of India have proposed guidelines, their implementation remains inconsistent across clinical settings.

Emerging innovations such as phytochemical fingerprinting, polymer-based threads, and automated coatings demonstrate promising avenues to improve reproducibility and antimicrobial efficacy. Integrating Good Manufacturing Practices (GMP) with classical wisdom is essential to ensure patient safety, global acceptance, and regulatory clarity. Strengthening interdisciplinary collaboration between Ayurvedic surgeons, pharmacologists, and biomedical scientists will be pivotal in realizing the full therapeutic potential of *Ksharasutra*.

16. Conclusion

Ksharasutra is a scientifically plausible and clinically effective pharmaco-surgical intervention rooted in *Ayurvedic* principles. Its therapeutic success arises from the synergistic actions of controlled chemical cauterization, antimicrobial activity, and wound healing promotion. While classical knowledge provides a strong foundation, the uniform standardization, validated sterilization protocols, and pharmacopeial harmonization are critical for global acceptance. Future research focusing on analytical validation and multicentric clinical data will further establish *Ksharasutra* as a credible evidence-based surgical modality...

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