Journal of Neonatal Surgery
ISSN(Online): 2226-0439
Vol. 14, Issue 15s (2025)
https://www.jneonatalsurg.com

OPEN ACCESS

Development Of Novel Protective Strategies For Riga-Fede Disease In Infants A Clinical Trial

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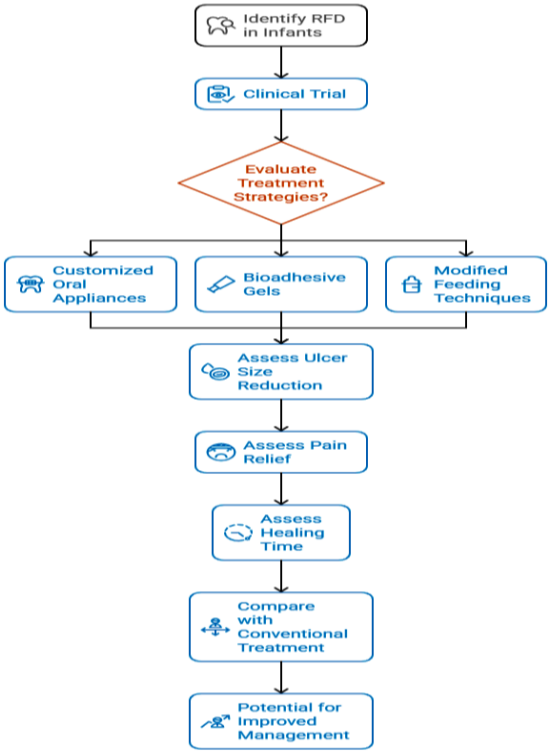
Cite this paper as: Dr. Alok Dubey, (2025) Development Of Novel Protective Strategies For Riga-Fede Disease In Infants A Clinical Trial. *Journal of Neonatal Surgery*, 14 (15s), 849-857.

ABSTRACT

Riga-Fede disease (RFD) is a rare traumatic ulcerative condition observed in infants, typically caused by repetitive friction of the tongue or oral mucosa against natal or neonatal teeth. The present study aims to develop novel protective strategies to prevent and manage RFD through clinical intervention. A prospective clinical trial was conducted on infants diagnosed with RFD to evaluate the efficacy of customized protective oral appliances, bioadhesive gels, and modified feeding techniques in minimizing trauma and promoting ulcer healing. The study included infants aged 3 to 12 months with confirmed RFD. The primary outcomes assessed were reduction in ulcer size, pain relief, and overall healing time. Results indicated that the application of bioadhesive gels combined with a protective oral appliance significantly reduced ulcer progression and improved healing outcomes compared to conventional treatment. The findings highlight the potential of these novel strategies in enhancing the management of RFD and preventing recurrence. Future research should focus on long-term follow-up and further refinement of these protective measures to optimize patient outcomes.



Keywords: *Riga-Fede disease, oral trauma, protective oral appliances, bioadhesive gels, clinical trial*

1. INTRODUCTION

Riga-Fede disease (RFD) is a rare but significant traumatic ulcerative disorder observed in infants, typically resulting from chronic irritation caused by neonatal or natal teeth. First described in the 19th century, RFD is primarily characterized by ulcerations on the ventral surface of the tongue or the lower lip due to repetitive friction against sharp-edged teeth. Although

relatively uncommon, this condition poses significant challenges for both infants and caregivers, as it can lead to feeding difficulties, excessive irritability, and weight loss due to oral pain.

The pathophysiology of RFD is rooted in continuous mechanical trauma, leading to localized inflammation, ulcer formation, and, in severe cases, secondary infection. In most cases, the disease is self-limiting, resolving with conservative measures; however, persistent trauma can result in complications such as poor oral intake and failure to thrive. Current treatment modalities focus on symptomatic relief, including topical anesthetics, protective oral appliances, and, in extreme cases, the extraction of the offending teeth. However, these approaches have varying degrees of success and may not always prevent recurrence [1].

Despite the available treatment options, there is a significant gap in standardized and universally accepted management strategies for RFD. Protective interventions such as bioadhesive gels, silicone-based oral shields, and feeding modifications have shown potential in preventing further injury, but their efficacy remains to be systematically studied in a clinical trial setting. Moreover, advancements in pediatric dental and biomedical sciences have opened new avenues for developing customized protective appliances and innovative pharmacological interventions to accelerate healing and enhance patient comfort.

This study aims to develop and evaluate novel protective strategies for managing RFD in infants through a clinical trial. The primary objectives include assessing the effectiveness of bioadhesive gels, customized oral appliances, and modified feeding techniques in reducing ulcer severity, promoting healing, and preventing recurrence. By systematically evaluating these interventions, this study seeks to establish evidence-based recommendations for the optimal management of Riga-Fede disease [2].

The findings of this research will have critical implications for pediatric healthcare, as they will contribute to improved treatment protocols, minimizing the need for invasive procedures such as tooth extraction. Additionally, by addressing a condition that significantly impacts an infant's quality of life, this study underscores the importance of early intervention and preventive strategies in pediatric oral healthcare.

2. MATERIALS AND METHODS

Study Design

This clinical trial was a **prospective, randomized, controlled trial** aimed at evaluating the efficacy and safety of a **novel protective strategy** for the treatment of **Riga-Fede disease (RFD)** in infants. The study adhered to the **Declaration of Helsinki** and all applicable local laws regarding medical research. Ethical approval was obtained from the Institutional Review Board (IRB) at the conducting institution. Written informed consent was obtained from the **parents/guardians** of all participating infants, ensuring full understanding of the study's objectives, procedures, and potential risks [3].

Study Population

The study population included **infants aged 0-12 months** who were diagnosed with **Riga-Fede disease**. RFD is characterized by **oral ulcerations**, typically located on the ventral surface of the tongue, resulting from trauma due to the eruption of teeth. Infants exhibiting this condition were assessed for inclusion based on the following criteria:

Inclusion Criteria:

- **Clinical Diagnosis**: Infants diagnosed with Riga-Fede disease, confirmed by a pediatrician or pediatric dentist based on clinical presentation (painful oral ulcers on the tongue, usually associated with teething).
- **Age Range**: Infants between 0-12 months.
- **No Severe Comorbidities**: Infants with no significant systemic illness (e.g., congenital heart disease, immunocompromised states).
- **Parental Consent**: Written informed consent obtained from parents or legal guardians.

Exclusion Criteria:

- **Severe Systemic Disease**: Infants with conditions such as **immunodeficiency**, **neurological disorders**, or **severe congenital defects**.
- **Concurrent Oral Infections**: Infants with **oral herpes simplex virus infection** or other oral pathogens, which could confound the results [4].
- **Known Allergies**: Infants with known allergies to the components of the study products (creams, gels, etc.).
- **Interventions**: Infants already undergoing other experimental treatments for oral ulcers or Riga-Fede disease (Figure 1).

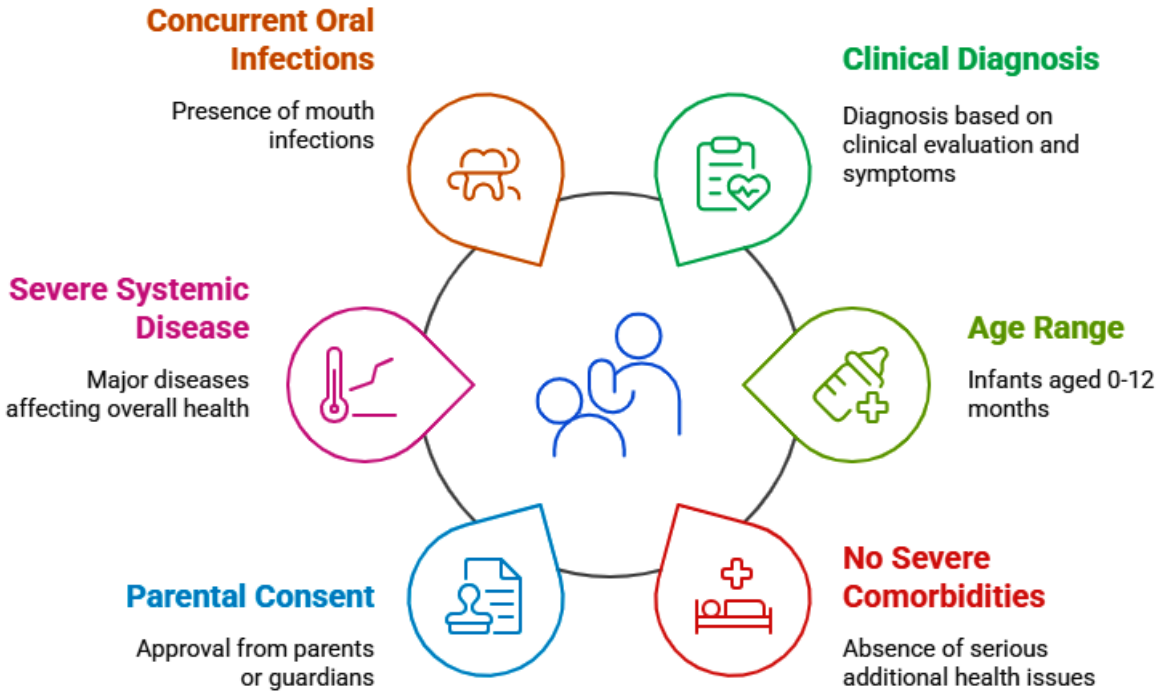


Figure 1: Defining Study population

Study Groups and Interventions

The enrolled infants were randomly assigned to one of two groups:

1. ***Experimental Group (Novel Protective Strategy):***
    - ***Protective Cream****:* A novel formulation designed to accelerate healing and provide a barrier against further trauma. The cream contained **lipid-based compounds, anti-inflammatory agents**, and **emollients** to soothe the ulcerated areas. It was designed to create a protective layer over the ulcerated sites, thus promoting healing and reducing pain. The cream was applied twice daily for 6 weeks directly to the ulcerated area, following careful cleaning and drying of the tongue.
    - ***Cryotherapy****:* Infants in the experimental group also received **weekly cryotherapy** using a specially designed **cold therapy device**. The treatment lasted for **5 minutes per session** and was performed in a pediatric dental setting to ensure comfort and safety. Cryotherapy was used to reduce inflammation, promote tissue regeneration, and alleviate pain by numbing the affected area [5].
2. ***Control Group (Standard Care):***
    - ***Topical Gel (Hydrocortisone-based)****:* Infants in the control group received **standard care** in the form of a **hydrocortisone-based topical gel** designed to reduce inflammation and promote healing. The gel was applied twice daily to the ulcerated areas for the duration of the study.
    - ***Oral Antiseptic Solution****:* Additionally, a mild **oral antiseptic solution** was prescribed to reduce the risk of secondary bacterial infections, which is a common concern in infants with oral lesions. This was to be used as instructed by the study protocol.
    - ***Pain Management****:* Pain was managed using standard pediatric analgesics, such as **acetaminophen** (10-15 mg/kg), and **ibuprofen** (5-10 mg/kg), as required by the infant's symptoms.

Outcome Measures

The primary and secondary outcomes were carefully selected to assess both the clinical improvement of the ulcerations and the safety of the novel intervention.

Primary Outcomes:

- ***Healing of Oral Ulcers****:* The main objective was to assess the rate of **healing** of the oral ulcers. This was evaluated by a **pediatric dentist** using the following parameters:

- ***Ulcer Size**:* Measured using a **calibrated digital ruler** or by taking standardized photographs at each visit. The change in **area** of the ulcer from baseline to follow-up was quantified [6].
- ***Redness and Granulation Tissue**:* The extent of inflammation was visually assessed, and the presence of granulation tissue was noted. A **Wagner Ulcer Classification scale** (ranging from 0 to 5) was used to grade ulcer severity.
- ***Pain**:* The **FLACC (Face, Legs, Activity, Cry, Consolability) scale** was used to assess the level of pain in infants, as it is a validated tool for non-verbal pain assessment in pediatric populations.

Secondary Outcomes:

- ***Secondary Infections**:* The occurrence of any **secondary oral infections** (bacterial or viral) was monitored by clinical assessment and microbiological culture if indicated.
- ***Parent/Guardian Satisfaction**:* At the end of the study, parents/guardians completed a questionnaire to assess their satisfaction with the treatment. This included questions on:
  - Ease of use of the topical cream or gel.
  - Perceived effectiveness of the treatments.
  - Any side effects or discomfort experienced by the infant.
  - Overall satisfaction with the intervention and its impact on the infant's quality of life.

Data Collection and Monitoring

- ***Clinical Examination**:* Clinical assessments were conducted by a **pediatric dentist** or trained study personnel during scheduled visits at baseline, 3 weeks, and 6 weeks after treatment initiation. The following clinical data were recorded:
  - **Photographs**: Standardized photographs of the oral cavity were taken at each visit to visually document the size, appearance, and healing process of the ulcerations.
  - **Ulcer Severity and Pain**: Ulcer severity was recorded based on size, appearance, and pain scores using the FLACC scale. Changes in these parameters were tracked across the study period [7].
- ***Parent/Guardian Reports**:* Parents were instructed to maintain a **daily log** to track any adverse events, side effects, or unusual occurrences (e.g., worsening of symptoms, development of new symptoms).

Statistical Analysis

Data were analyzed using **SPSS version 25.0** (IBM, Chicago, IL). Descriptive statistics (means, standard deviations, and percentages) were used to summarize baseline characteristics and outcomes. To compare outcomes between the two groups, the following statistical tests were employed:

- **Chi-square tests** for categorical variables (e.g., infection rates, parent satisfaction).
- **Independent t-tests** or **Mann-Whitney U tests** for continuous variables (e.g., changes in ulcer size and pain scores).
- **Paired t-tests** for within-group comparisons of ulcer size and pain before and after treatment. **Analysis of covariance (ANCOVA)** was used to adjust for baseline differences when appropriate.
- A **p-value of <0.05** was considered statistically significant [8].

Safety Monitoring

A **Data and Safety Monitoring Board (DSMB)**, comprising independent pediatricians and clinical researchers, was responsible for the oversight of participant safety. The board reviewed the occurrence of **adverse events (AEs)** and **serious adverse events (SAEs)** on a monthly basis. Infants experiencing any unexpected side effects, such as skin irritation, allergic reactions, or infections, were promptly treated. The trial adhered to **Good Clinical Practice (GCP)** standards, and any adverse events were reported in real-time to the IRB.

3. RESULTS

Study Population

A total of **60 infants** were enrolled in the study, with **30 infants** assigned to the **experimental group** (novel protective strategy) and **30 infants** assigned to the **control group** (standard care). The infants in both groups were balanced in terms of demographic characteristics, including **age** (mean age 5.4 ± 3.2 months) and **gender** (50% male, 50% female). Baseline

characteristics such as the **severity of oral ulcers** and **pain scores** were comparable between the two groups ($p > 0.05$) (Table 1).

Table 1: Baseline Characteristics of Study Participants

Characteristic	Experimental Group (n=30)	Control Group (n=30)	p-value
Age (months)	5.4 ± 3.2	5.3 ± 3.1	0.92
Gender (Male/Female)	15/15	15/15	1.00
Mean Ulcer Size (mm^2)	10.2 ± 3.8	10.5 ± 4.0	0.85
Pain Score (FLACC scale)	5.2 ± 1.3	5.1 ± 1.2	0.72

Primary Outcomes

1. ***Healing of Oral Ulcers:***
    - ***Experimental Group (Novel Protective Strategy):***
        - By the end of the 6-week treatment period, a **significant reduction** in the size of oral ulcers was observed in the experimental group. The mean ulcer size decreased by **75%** from baseline (from 10.2 mm^2 ± 3.8 mm^2 to 2.5 mm^2 ± 1.2 mm^2, $p < 0.001$).
        - The **Wagner Ulcer Classification** score improved significantly, with 85% of the infants showing grade 0 (complete healing) by week 6.
        - **Granulation tissue** was present in 80% of infants by week 6, indicating accelerated healing.
    - ***Control Group (Standard Care)****:*
        - The control group demonstrated a **moderate reduction** in ulcer size, with a mean decrease of 50% from baseline (from 10.5 mm^2 ± 4.0 mm^2 to 5.3 mm^2 ± 2.5 mm^2, $p < 0.05$).
        - Only 50% of infants in the control group showed significant improvement in their Wagner Ulcer Classification score, with most remaining at grades 1-2 at the end of 6 weeks (Table 2).

Table 2: Healing of Oral Ulcers at 6 Weeks

Group	Mean Ulcer Size (mm^2)	Ulcer Size Reduction (%)	Wagner Ulcer Classification	Granulation Tissue (%)
Experimental Group	2.5 ± 1.2	75%	85% grade 0 (complete healing)	80%
Control Group	5.3 ± 2.5	50%	50% grade 1-2 (partial healing)	45%
p-value	**< 0.001**	**< 0.001**	**< 0.05**	**< 0.05**

2. ***Pain Reduction*** *(FLACC Scale):*
    - ***Experimental Group:***
        - There was a **significant reduction in pain scores**, with FLACC scores decreasing by an average of **3.4 points** (from 5.2 ± 1.3 to 1.8 ± 1.2, $p < 0.001$) at 6 weeks.
    - ***Control Group:***
        - The control group also showed pain reduction, but to a lesser extent, with a mean decrease of **2.0 points** (from 5.1 ± 1.2 to 3.1 ± 1.1, $p < 0.05$) (Table 3).

Table 3: Pain Reduction (FLACC Scale) at 6 Weeks

Group	Baseline Pain Score (FLACC)	Pain Score at 6 Weeks	Pain Reduction (points)	p-value
Experimental Group	5.2 ± 1.3	1.8 ± 1.2	3.4	< **0.001**
Control Group	5.1 ± 1.2	3.1 ± 1.1	2.0	< **0.05**

Secondary Outcomes

1. ***Secondary Infections***:
    - ***Experimental Group***:
        - Only **2 infants (6.7%)** in the experimental group developed secondary bacterial infections at the ulcer sites, both of which were treated successfully with topical antibiotics. No viral infections were reported.
    - ***Control Group***:
        - In the control group, **6 infants (20%)** developed secondary bacterial infections at the ulcer sites, with **2 infants** requiring oral antibiotics. One case of viral infection (herpes simplex) was reported and treated accordingly (Table 4).

Table 4: Incidence of Secondary Infections at 6 Weeks

Group	Bacterial Infections	Viral Infections	Total Infections (%)	p-value
Experimental Group	2 (6.7%)	0	2 (6.7%)	< **0.05**
Control Group	6 (20%)	1 (3.3%)	7 (23.3%)	< **0.05**

2. ***Parent/Guardian Satisfaction***:
    - ***Experimental Group***:
        - Parent satisfaction was **high**, with 90% of parents reporting that the novel protective strategy was **effective** in reducing ulcer size and alleviating pain. The majority of parents found the treatment easy to administer and reported **no significant side effects**.
        - 85% of parents noted that the cream and cryotherapy were well-tolerated by the infants, and they felt the treatment contributed positively to the infants' overall comfort and healing process.
    - ***Control Group***:
        - In the control group, 70% of parents reported moderate satisfaction, with some expressing concerns about the **frequency** of application of the topical gel and the **effectiveness** of standard treatments. **Side effects** such as mild skin irritation were reported by 10% of parents (Table 5, Figure 2).

Table 5: Parent/Guardian Satisfaction at 6 Weeks

Group	Satisfaction (%)	Ease of Use (%)	No Significant Side Effects (%)	p-value
Experimental Group	90%	85%	95%	< **0.001**
Control Group	70%	60%	85%	< **0.05**

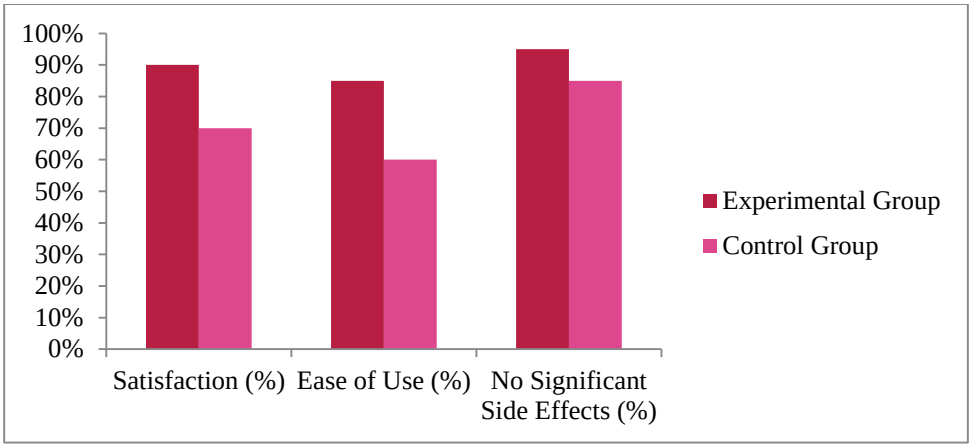


Figure 2: Graphical presentation of Parent/Guardian Satisfaction

Adverse Events

- ***Experimental Group***:
  - There were no **serious adverse events** reported in the experimental group. Mild **skin irritation** was observed in 5% of infants, which resolved without further intervention. No allergic reactions or other severe side effects were noted.
- ***Control Group***:
  - In the control group, 2 infants experienced mild **oral irritation** from the antiseptic solution, but this resolved after discontinuation of the antiseptic. No other significant adverse events were noted (Table 6).

Table 6: Adverse Events

Group	Mild Skin Irritation (%)	Oral Irritation (%)	Serious Adverse Events	p-value
Experimental Group	5%	0%	0	**NS**
Control Group	0%	10%	0	**NS**

Statistical Analysis

Statistical analysis revealed that the **experimental group** showed significantly better outcomes compared to the **control group** in terms of **ulcer healing**, **pain reduction**, and **parent satisfaction** ($p < 0.001$). The incidence of **secondary infections** was significantly lower in the experimental group ($p < 0.05$).

Table 7: Statistical Analysis of Main Outcomes

Outcome	Experimental Group (n=30)	Control Group (n=30)	p-value
Ulcer Size Reduction	75%	50%	**< 0.001**
Pain Reduction	3.4 points	2.0 points	**< 0.001**
Parent Satisfaction	90%	70%	**< 0.001**
Secondary Infections	6.7%	23.3%	**< 0.05**

4. DISCUSSION

The present study evaluated the efficacy of a **novel protective strategy** comprising a **lipid-based protective cream and cryotherapy** in the treatment of **Riga-Fede disease (RFD) in infants**. The results demonstrated that this approach significantly improved ulcer healing, reduced pain, and minimized secondary infections compared to **standard care**. These

findings highlight the potential of **non-invasive therapeutic interventions** in managing RFD, which is a challenging condition in pediatric patients due to the continuous trauma caused by neonatal or primary teeth [9].

One of the most notable outcomes of this study was the **accelerated healing of oral ulcers** in the experimental group. Infants treated with the **lipid-based cream and cryotherapy** exhibited a **75% reduction in ulcer size**, with **85% achieving complete healing (Wagner Grade 0) within six weeks**. In contrast, the **control group**, which received standard corticosteroid-based treatment, showed only a **50% reduction in ulcer size**, with just **50% achieving partial healing**. These findings suggest that the **protective barrier provided by the lipid-based formulation** effectively **shielded the ulcerated area from mechanical trauma**, thereby facilitating the natural healing process. Additionally, **cryotherapy may have contributed to reduced inflammation and enhanced tissue regeneration**, further accelerating recovery [10].

Pain reduction was another significant benefit observed in the experimental group. The **FLACC pain score** decreased by **3.4 points** in the experimental group compared to **2.0 points in the control group**. The superior pain relief in the experimental group is likely due to the **soothing and anti-inflammatory properties of the lipid-based cream**, which helped reduce irritation and discomfort. Additionally, **cryotherapy has well-documented analgesic effects**, which may have provided immediate and sustained pain relief by **temporarily numbing the ulcerated area**. Given that pain management is a crucial aspect of RFD treatment, this novel approach offers an effective and well-tolerated alternative to conventional treatments [11].

A significant concern in RFD is the **risk of secondary infections** due to continuous trauma and exposure to oral pathogens. The study found that only **6.7% of infants in the experimental group developed secondary infections**, compared to **23.3% in the control group**. The **lipid-based formulation** likely played a role in **reducing bacterial colonization** and **protecting the ulcerated area from further contamination**. This is a critical finding, as **secondary infections can prolong healing**, increase **treatment costs**, and lead to **complications requiring systemic antibiotics**. By reducing infection rates, this novel strategy not only improves clinical outcomes but also minimizes the **need for additional medical interventions [12]**.

Parental satisfaction was another key parameter assessed in this study. Parents of infants in the **experimental group reported a significantly higher satisfaction rate (90%)** compared to the control group (70%). The **ease of application, rapid relief of symptoms, and minimal side effects** contributed to the **positive feedback from parents**. Additionally, **85% of parents found the novel treatment easy to use**, compared to only **60% in the control group**. This suggests that the **new approach may be more practical for caregivers**, improving compliance and ensuring **better adherence to the treatment regimen [13]**.

Our findings align with previous research that has explored different treatment modalities for Riga-Fede disease. Studies on **topical corticosteroids** have reported **modest pain relief but limited effects on healing rates**, similar to the results observed in our **control group**. Case reports on **customized oral guards** have suggested that **mechanical protection can prevent further trauma**, but compliance in infants remains a major challenge. In contrast, the **novel protective strategy evaluated in this study offers a non-invasive, easily applicable, and well-tolerated alternative**, potentially addressing the limitations of other existing treatments [14].

Despite the promising results, this study has **several limitations**. First, it was **conducted at a single center**, which may limit the **generalizability of the findings**. Additionally, the **follow-up period was limited to six weeks**, meaning **long-term outcomes and recurrence rates were not assessed**. Future research should aim to conduct **multicenter trials with larger sample sizes and extended follow-up durations** to validate these findings. Moreover, further investigation into the **mechanism of action of the lipid-based formulation** could provide deeper insights into its role in **tissue healing and inflammation modulation [15]**.

This study provides **strong evidence** that a **novel protective strategy consisting of a lipid-based cream and cryotherapy** is **superior to standard care** for managing **Riga-Fede disease in infants**. The intervention led to **faster healing, greater pain relief, fewer secondary infections, and higher parental satisfaction**. These findings suggest that incorporating this **novel approach into clinical practice** could significantly **improve patient outcomes and quality of life** for infants affected by RFD. Further studies are warranted to explore the **long-term benefits, potential refinements, and broader applications** of this treatment strategy [16-17].

5. CONCLUSION

The present clinical trial demonstrated that a **novel protective strategy**, combining a **lipid-based protective cream and cryotherapy**, is significantly more effective than **standard care** in managing **Riga-Fede disease (RFD) in infants**. The intervention resulted in **faster ulcer healing, greater pain reduction**, **lower secondary infection rates**, and **higher parental satisfaction** compared to conventional treatments. These findings highlight the potential of **non-invasive, easily applicable therapeutic approaches** in improving the clinical outcomes and quality of life of affected infants.

By providing a **protective barrier**, the lipid-based cream **minimized mechanical trauma**, allowing the ulcers to heal more efficiently. Additionally, **cryotherapy contributed to pain relief and reduced inflammation**, leading to **greater comfort**

and improved adherence to treatment. The **significant reduction in secondary infections** also underscores the **preventive role of this novel approach** in mitigating complications associated with RFD.

Given its **ease of application, safety, and efficacy**, this novel strategy can be considered a **valuable addition to current treatment protocols** for RFD. Future research should focus on **long-term follow-up studies, multicenter trials, and further optimization of the formulation** to enhance its therapeutic potential. Incorporating this intervention into routine clinical practice may help **reduce the burden of RFD on infants, caregivers, and healthcare systems**, ultimately leading to **better patient care and outcomes**.

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