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## The efficacy of Similasan #2 eyedrops for the relief of simple allergic conjunctivitis

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# The efficacy of Similasan #2 eyedrops for the relief of simple allergic conjunctivitis

## Abstract

Seasonal allergy sufferers have a wide choice of over the counter products to choose to alleviate their symptoms. Similasan #2 is a homeopathic over the counter product marketed to alleviate allergy symptoms. Homeopathy is the belief that "like cures like." Antigens, if taken in minute doses, will stimulate the bodies immune system. This double blind, matched group, clinical study compares the efficacy of Similasan #2, Visine AC, and sterile saline to alleviate various ocular signs and symptoms caused by seasonal allergies. Subjective and objective measurements were taken. The results showed that Visine AC, objectively, reduced conjunctival injection at a statistically significant level. Similasan #2 for allergies do demonstrate a reduction in allergic symptoms but not at any statistically significant levels. No other signs nor symptoms showed statistical significance.

## Degree Type

Thesis

## Degree Name

Master of Science in Vision Science

## Committee Chair

Kenneth Eakland

## Subject Categories

Optometry

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THE EFFICACY OF  
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SIMPLE ALLERGIC CONJUNCTIVITIS

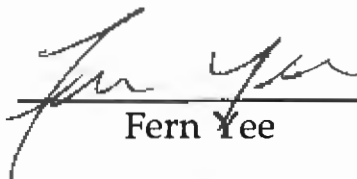
BY  
FERN YEE  
JOHN PRESS

A thesis submitted to the faculty of the  
College of Optometry  
Pacific University  
Forest Grove, Oregon  
for the degree of  
Doctor of Optometry  
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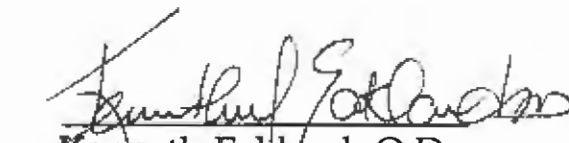
Advisor:

Kenneth Eakland, O.D.

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## Abstract

Seasonal allergy sufferers have a wide choice of *over the counter* products to choose to alleviate their symptoms. Similasan #2 is a homeopathic *over the counter* product marketed to alleviate allergy symptoms. Homeopathy is the belief that "like cures like." Antigens, if taken in minute doses, will stimulate the bodies immune system.

This double blind, matched group, clinical study compares the efficacy of Similasan #2, Visine AC, and sterile saline to alleviate various ocular signs and symptoms caused by seasonal allergies. Subjective and objective measurements were taken.

The results showed that Visine AC, objectively, reduced conjunctival injection at a statistically significant level. Similasan #2 for allergies do demonstrate a reduction in allergic symptoms but not at any statistically significant levels. No other signs nor symptoms showed statistical significance.

## Biography

Fern Yee was graduated from Pacific University College of Optometry in 1993. She came to Oregon from Saskatoon, Saskatchewan, Canada after completing a Bachelor of Science degree in biology in 1988 from University of Saskatchewan.

Outside of optometry, she likes to keep active by participating in sports such as volleyball and running. She also enjoys music, photography and traveling.

Her interests within optometry lie in the areas of ocular disease and behavioral optometry with a focus towards being a full scope optometrist. She hopes to return to Canada to practice.

John Press was graduated from the University of Virginia in 1982 with a Bachelor of Arts in physics. Afterwards he joined the US Coast Guard and spent five years on active duty. John then began optometry school and was graduated from Pacific University College of Optometry in 1993.

John is married to the former Tanya Orlando. They have two children, Eric and Shea. He enjoys spending his time with his family, engaging in such activities as camping, gardening, and golfing (sometimes all at once). They reside in Grayland, Washington.

John was accepted into the US Army Health Profession Scholarship Program during his first year of optometric study. He and his family will be in Berlin, Germany for his first tour of duty.

## ACKNOWLEDGEMENTS

We would like to thank the Similasan corporation for providing a sample of their product for our use in our thesis study. We would also like to thank Dr. Ken Eakland for his helpfulness throughout the study and Dr. Bob Yolton for his guidance in statistical analysis.



## INTRODUCTION

Modern medicine is making remarkable strides in search of cures for existing medical conditions. Paralleling this growth is the resurgence of natural remedies. The public is becoming re-acquainted with treatment options not derived from synthetic chemical substances. An increasing patient population is turning back to a system of health-oriented medicine that stresses the maintenance of health and disease prevention. (Murray, 1991). Homeopathy is the study of medicine that treats a disease with a dilute, potentised agent, or drug, that will produce the same symptoms as the disease when given to a healthy individual. (Murray, 1991). Thus, products that are considered homeopathic often contain a plethora of plant, mineral and chemical substances. These medicines are used to treat a wide variety of human disease conditions.

Seasonal allergies are a very common affliction within the general population. This study will concentrate on the ocular symptoms that are manifest with seasonal allergies and the degree to which they are alleviated employing a homeopathic medicine, "Similasan #2 for Allergies."

"Anaphylaxis is an allergic response due to exposure to an antigen." (Busse, 1976). There are vast chemical and environmental contaminants that can serve as antigens and produce such a response; drugs, foods, plants, pollen, animals, dust, and insect venom's to name only a few. Anaphylaxis occurs when the antigen stimulates the production of the IgE antibody, from which there are four types of hypersensitivity that results from an antigen.

### **Type I Hypersensitivity (Immediate or Anaphylactic)**

Type I reactions are triggered when an allergen attaches to two IgE molecules on a circulating basophil. The attachment results in a physical change of the cell thereby causing mast cell degranulation. Mast cells contain histamine, serotonin, heparin, neutral proteases, acid hydrolases and chemotactic factors responsible for the tissues' reaction to the antigen. Type I hypersensitivity reactions result from exposure to an allergen. This form represents the most common type of allergic response within ocular tissue.

### **Type II Hypersensitivity**

Type II reactions result when an antibody attached to an intruding cell membrane. Cell lysis occurs as macrophages identify the antibody tagged cell and destroy the cell by phagocytose. Presently, there are no ocular diseases that are a result of this type of hypersensitivity.

### **Type III Hypersensitivity**

Type III reactions require complement-mediated antibodies and may involve soluble or diffusible antigens. Intraocular inflammatory disease can be a result of type III reactions. (Allansmith, 1990).

### **Type IV Hypersensitivity (Cell-mediated or Delayed reaction)**

Type IV reactions are due to a previous exposure to lymphokines and the interaction of primed T-lymphocytes and antigen. Approximately 24-48 hours after exposure to the antigen an allergic reaction will result. These are most commonly seen in drug allergies, graft rejections and poison ivy. (Allansmith, 1990).

## **Ocular Symptoms of Allergies**

There are many ocular signs and symptoms that manifest in response to an allergic reaction. Presentation may be unilateral or bilateral with itching as the primary presenting symptom. Visual acuity is generally stable and unaffected but can fluctuate, usually secondary to tearing. The bulbar conjunctival injection varies from pink to red. Both the palpebral and bulbar conjunctiva are chemotic, with chemosis varying from mild to severe. There is often a papillary response of the tarsal conjunctiva. Discharge is usually watery with mucous strands. There can be accompanying lid edema and hyperemia. (Disease classnotes, 1992).

The primary allergies that affect ocular tissues are Type I and IV hypersensitivity. Type I reactions are frequently seasonal allergies associated with recurrent systemic allergic rhinitis. (Disease class notes, 1992). A person with Type I hypersensitivity is usually aware of their condition and frequently has a positive family history of allergies.

The severity of the symptoms that present are dependent upon the individual's own immunological response to the allergen. All of the signs and symptoms listed above may not all be present in a mild case of ocular allergies. Therefore, since the degree of presentation is variable this will indicate the aggressiveness of treatment in order to alleviate the symptoms.

## **TREATMENT**

Ocular allergies can present a wide spectrum of complications for the patient varying from a mild to a considerable threat to vision. (Bartlett, 1990). The primary concern in treatment is to identify and eliminate the allergen.

However, identification of the allergen is not as easy as it sounds and other treatment options may need to be taken to alleviate the allergy symptoms. Non-pharmacological based treatment options can include filtering methods to eliminate the allergen from the environment and to keep areas free of dust. The use of air

conditioning to regulate the humidity, thus, inhibiting the growth of dust mites and fungi may also be beneficial. (Bartlett, 1990).

Itching, a primary feature of allergies, is often easily relieved using cold compresses. Soaking solutions are commonly used in conjunction with compresses. This method usually has a large safety margin. (Bartlett, 1990). This is the easiest symptom to alleviate but the drawback is that compresses only provides symptomatic rather than long term relief. Repeated applications may be necessary. (Bartlett, 1990). The solutions used, along with cold compresses, are listed below, and may be of further benefit for symptomatic relief.

**Table 1**

<b>Active Ingredient</b>	<b>Concentration (Aqueous Solution)</b>
Aluminum acetate (Burrow's solution)	1:40 to 1:20
Potassium permanganate 0.1%	1:7
Sodium chloride	3 Tbsp: 1 qt. water
White vinegar	2 oz.: 1 qt. water (Bartlett, 1990).

Vasoconstrictors are also employed in management of ocular allergies. Their mechanism of action is by binding to the alpha receptors on blood vessels stimulating the adrenergic agonists, leading to vasoconstriction of conjunctival blood vessels. (Disease classnotes, 1992). Phenylephrine, naphazoline, tetrahydrozoline, oxymetazoline and ephedrine are effective local vasoconstrictors when applied topically to the conjunctiva. All of these are available commercially except for ephedrine.

**Table 2**  
**Ophthalmic decongestant preparations**

Generic Name	Trade Name	Manufacturer	Concentration (%)
Phenylephrine hydrochloride	Relief	Allergan	0.12
	Prefrin Liquifilm	Allergan	0.12
	Prefrin-A <sup>a</sup>	Allergan	0.12
	AK-Nefrin	Akorn	0.12
	Isopto Frin	Alcon	0.12
	Zincfrin	Alcon	0.12
Naphazoline hydrochloride	Albalon Liquifilm	Allergan	0.1
	Albalon-A <sup>a</sup>	Allergan	0.05
	Clear Eyes	Ross	0.012
	Degest 2	Barnes Hind	0.012
	Naphcon-A <sup>a</sup>	Alcon	0.025
	Allerest Eye Drops	Pharmacraft	0.012
	Vasoclear	Iolab	0.02
	Vasocon-A <sup>a</sup>	Iolab	0.05
Oxymetazoline	AK-Con Ophthalmic	Akorn	0.1
	OcuClear	Schering	0.025
Tetrahydrozoline hydrochloride	Murine Plus	Ross	0.05
	Optigene 3	Pfeiffer	0.05
	Soothe Eye Drops	Alcon	0.05
	Visine	Leeming	0.05

<sup>a</sup>Decongestant/antihistamine combination.

Published with permission from Jaanus SD, Pagano VT, Bartlett JD. Drugs affecting the autonomic nervous system. In: Bartlett JD, Jaanus SD, eds. Clinical ocular pharmacology, 2<sup>nd</sup> ed. Boston: Butterworth, 1989;69-148.

However, side effects do result from constant use of ocular decongestants. Phenylephrine causes mydriasis which may precipitate an angle closure glaucoma attack. Rebound hyperemia may also occur with prolonged use. (Disease classnotes, 1992). Xerosis and stinging are other side effects which may result from adrenergic agonists.

Antihistamines are often used to prevent the symptomatic effects of histamine. During the immune response, mast cells are activated and histamine is released. Histamine results in increased vascular permeability, intense itching, vasodilatation leading to the physiological changes associated with allergies. (Bartlett, 1990)

Cromolyn sodium is a widely used ophthalmic preparation. Its action inhibits mast cell degranulation and proves to be very effective in treating those with allergic conjunctivitis. (Bartlett, 1990). Ocular symptoms are decreased with the use of cromolyn sodium and those patients using this preparation often require decreased use of antihistamines as well.

There is another school of thought that takes us away from familiar modes of therapy and back to more traditional roles, that of naturopathy. "Naturopathic medicine has a belief in the ability of the body to heal itself if given the proper opportunity." (Murray, 1991). Vitalism is key to the naturopathic approach and regards symptoms presented are due to the patients' attempt to defend against the intruder rather than in response to the organism itself. (Murray, 1991). This mode of therapy includes changes in their dietary habits, nutritional supplements and botanical medicines. The botanical products used in the treatment of allergic conjunctivitis are listed below along with the suggested dosage.

**Table 3**

<b>Botanical Medicine</b>	<b>Dosage</b>
Ephedra sinica	Crude herb or tea 0.5-1 gm
Glycyrrhiza glabra	Dried root or tea 1-2 gm
Scutellaria baicalensis	Tincture(1:5), 4-6ml
Angelica sinensis	Fluid extract(1:1), 0.5-2.0ml
	Powdered solid extract (4:1), 250-500 mg. (Murray, 1991).

Ephedra(*Ephedra sinica*) has found to contain a physiologically active alkaloid that has been effective in the treatment of mild to moderate asthma and hay fever. (Murray, 1991). "If ephedra is used long term the effectiveness will diminish due to weakening of the adrenal glands due to the ephedrine. Hence, it may be necessary to use ephedra in combination with adrenal gland supportive herbs like *Glycyrrhiza glabra* and *Panax ginseng* along with Vitamin C, magnesium, zinc, vitamin B6 and pantothenic acid." (Murray, 1991). The ocular side effects that it may cause are mydriasis and contact lens staining. (Bert, 1992).

Another medicinal plant used is *Scutellaria baicalensis* (Chinese Skullcap) and is said to contain anti-arthritic and anti-inflammatory effects. "Chinese skullcap does not appear to have any adverse effects at therapeutic levels ." (Murray, 1991).

*Angelica* (*Angelic sinensis*) has proven to be very effective in the management of allergic symptoms and has long been used by Chinese herbalists. It inhibits the production of IgE antibodies which are elevated in those people with allergic complaints. (Murray, 1991).

Liquorice (*Glycyrrhiza glabra*) is used extensively because it increases the half-life of cortisol therefore increasing the anti-inflammatory action of cortisol in addition to decreasing some potential side effects of the hormone. (Murray, 1991). Liquorice contains properties similar to steroids therefore may cause cataracts, glaucoma, herpes simplex, keratitis, photophobia and retinal thrombosis. (Bert, 1992).

There are other botanical products used in the management of asthma and allergic conditions; chili pepper (*Capsicum frutescens*), skunk cabbage (*Symphlocarpus factida*), green tea (*Thea sinensis*) and onions and garlic (*Allium spp*). Skunk cabbage contains volatile or aromatic oils and may produce the following ocular side effects; increased tearing, irritation, contamination of the contact lenses, and CNS effects. (Bert, 1992). The botanical medicine to be used is dependent upon the symptoms presented, the action of the plant and prescribing the correct dosage level.

These are some of the more traditional and botanical remedies available in the treatment of ocular allergic conjunctivitis and in the management of allergic symptoms. Our thesis investigates the effectivity of a homeopathic eye drop, Similasan #2, to alleviate the ocular symptoms presented with seasonal allergies. The active ingredients used in Similasan #2 are Apis HPUS 6X 30.333%, Euphrasia HPUS 6X 30.333%, Sabadilla HPUS 6X 30.333%. Apis is a whole bee extract and provides relief in acute burning and edema of the eyelids. Euphrasia, also known as eyebright, fights against infections of the eyelid, the external eyelid, the conjunctiva and the tear ducts. Euphrasia is said to possess anti-catarrhal properties and may cause possible drying of the eye or decreased tearing. (Bert, 1992). Sabadilla is dried ripe seed of the Lily family. It provides relief for acute ocular irritation, sneezing, and runny nose. (Gaier, 1991 and Jouanny, 1984). These three medicinal agents are common homeopathic remedies given to alleviate allergic symptoms. (Jouanny, 1984 and Ullman,1988).

## **METHODS**

### **Subjects**

The sample population is comprised of volunteers who were manifesting ocular symptoms of allergic conjunctivitis. The volunteers were placed into three categories depending on their initial subjective assessment of their allergic symptoms. The recruitment process employed the use of research announcements placed in several news media sources and local physicians' offices. For project participation the subjects were given a complimentary, comprehensive vision exam and a sample of the product they preferred upon completion of their trial. Subjects were rejected from the study if they were currently taking medication for their allergies which alleviated their ocular signs. There were 25 subjects of which 2 failed to complete the study because of failure to return after the five day trial period.



## PROCEDURE

A double blind matched group study was performed. Each subject was evaluated in three separate phases. The first examination was a preliminary assessment of the degree of severity of the objective and subjective ocular variables. The same examiner was used throughout the duration of the study. After the preliminary examination, the patient was put into one of three groups and then given an unmarked bottle of one of three products for a period of five days. The product was prescribed for use four times a day. As in the initial assessment, the patient was then re-examined immediately after the instillation of one drop in each eye, 0.5 hours and after five days. The categories under examination are listed in Table 4. The examiner used a Mentor biomicroscope and fluorescein strips for the completion of his evaluation.

**Table 4**

<b>Objective (examiner)</b>	<b>Subjective (patient)</b>
Follicles/papillae	Itching
TBUT	Burning
Injection	Tearing
Chemosis	Swelling
	Redness
	Runny nose
	Sneezing

## RESULTS

The Kruskal-Wallis one-way analysis of variance by ranks was used to determine if there was statistical significance between each of the three matched groups at the pre-trial, immediate, 0.5 hour, and 5 day trials. The Mann-Whitney U Test was then used to discern which group was significant and performed by comparing each group to the other at each significant trial period.

At the start of the trials, there was no statistical significant difference between groups for the each of the signs and symptoms investigated, that is, the groups were

matched. The subjective findings were variable and showed no statistical significant differences between the three matched groups. The objective finding of conjunctival injection did show statistical significance ( $p \leq 0.05$ ). Visine AC was shown to reduce injection at the immediate, 0.5 hour and 5 day trials as shown below:

Group	Trial	p
Visine AC vs Control	Immediate	0.016
Visine AC vs. Control	0.5 hour	0.003
Visine AC vs. Control	5 day	0.003
Visine AC vs. Similasan #2	Immediate	<0.02
Visine AC vs. Similasan #2	0.5 hour	<0.05

No other objective findings showed any statistical significance.

## DISCUSSION

Similasan #2 for allergies did provide subjective relief of swelling immediately upon instillation of the drop and up to 0.5 hours after, but, not at a statistically significant level. Similasan #2 did not prove to be as effective in long term relief of swelling as did Visine A.C. (Graph 1). All three products demonstrate a decrease in the relief of itching, however, Similasan #2 shows the most significant change. (Graph 2). Objectively, injection was relieved by all three products but Visine A.C. proved to be the most effective and Similasan #2 to be the least. (Graph 3). In the areas of TBUT, chemosis, papillae, tearing, sneezing, reduction of stinging, runny nose and burning, all products did not provide any significant relief.

In any following studies to determine the efficacy of Similasan the wording should be changed to grade the effectiveness for the patient evaluation. The term "Degree of Relief" at the subjective post-instillation trials may have been difficult for subjects to interpret, thus confounding their assessment. During the initial patient

assessment, the subject was asked to the degree to which the symptoms were affecting them presently. Thus, the intrinsic difference between "degree of symptoms" and degree of relief" negated any correlation in patient responses.

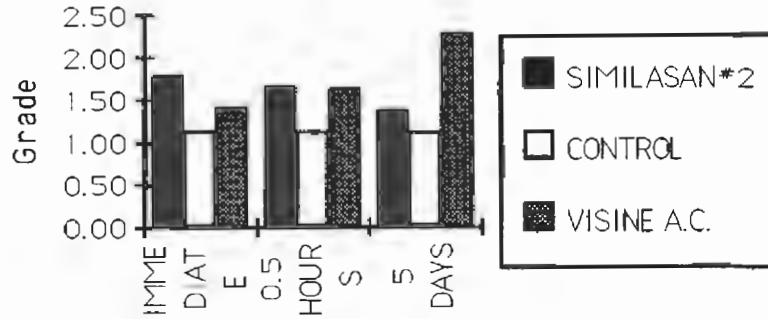
A larger patient population is needed because relief is provided in the other categories examined. However, not enough to illustrate any significance, thus, a larger sample would be necessary to prove or to disprove any significant findings.

At the completion of the evaluation, the volunteer was given a sample of Similasan #2 along with a complimentary vision exam. A randomized questioning of the volunteers were asked to determine if the homeopathic eye drop was effective in relieving their allergic signs. Again, the responses were conflicting, some found it to be an excellent product and some did not.

It is under our recommendation that Similasan #2 is certainly a viable option for those peoples suffering from allergic symptoms but cannot be guaranteed as a "cure-all" for their symptoms. We have not found it to be detrimental by any means and does provide some degree of relief. We do not advise against its usage as treatment modality for ocular allergic conditions and will recommend its use to those people looking for alternative modes of treatment.

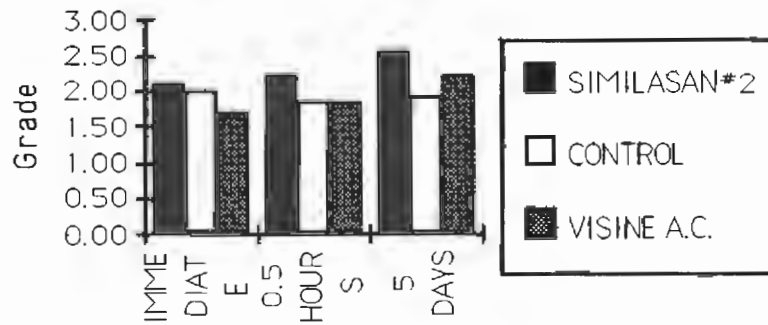
Graph 1

PATIENT DEGREE OF RELIEF FROM SWELLING



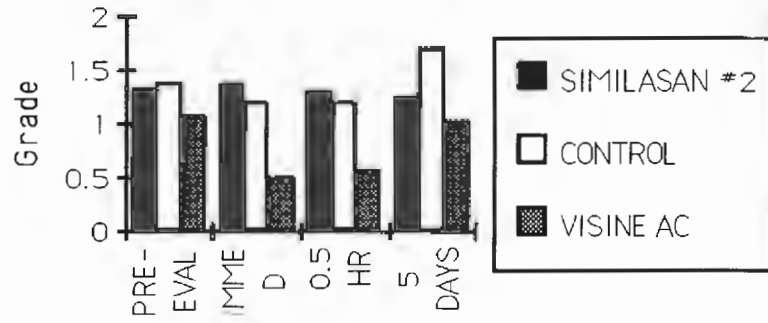
Graph 2

PATIENT DEGREE OF RELIEF FROM ITCHING



Graph 3

EXAMINER EVALUATION OF  
INJECTION



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## APPENDIX A

NAME \_\_\_\_\_  
DATE \_\_\_\_\_  
TRIAL \_\_\_\_\_

### PATIENT EVALUATION FORM-PRE

The following criteria will be used to scale the degree which your allergic symptoms are affecting you.

ABSENT                  VERY SLIGHT                  SLIGHT                  MODERATE                  SEVERE  
1                                  2                                  3                                  4                                  5

	BASELINE
REDNESS	
SWELLING	
ITCHING	
STINGING	
BURNING	
RUNNY NOSE	
SNEEZING	
TEARING	



NAME \_\_\_\_\_  
 DATE \_\_\_\_\_  
 TRIAL \_\_\_\_\_

**PATIENT  
 POST-EVALUATION FORM-IMMED**

The following criteria will be used to scale the **degree of relief** the drops provided for you.

NONE            SLIGHT            MODERATE            GOOD            EXCELLENT  
 1                    2                    3                    4                    5

	RIGHT EYE IMMEDIATE	LEFT EYE IMMEDIATE	RIGHT EYE 0.5 HOURS	LEFT EYE 0.5 HOURS
REDNESS				
SWELLING				
ITCHING				
STINGING				
BURNING				
RUNNY NOSE				
SNEEZING				
TEARING				

NAME \_\_\_\_\_

DATE \_\_\_\_\_

TRIAL \_\_\_\_\_

**PATIENT  
POST-EVALUATION FORM-5 DAY**

The following criteria will be used to scale the **degree of relief** the drops provided for you.

NONE  
1

SLIGHT  
2

MODERATE  
3

GOOD  
4

EXCELLENT  
5

	RIGHT 5 DAY- OD	LEFT 5 DAY- OS
REDNESS		
SWELLING		
ITCHING		
STINGING		
BURNING		
RUNNY NOSE		
SNEEZING		
TEARING		

NAME \_\_\_\_\_  
 DATE \_\_\_\_\_  
 TRIAL \_\_\_\_\_

EXAMINER  
 PRE-EVALUATION

	OD BASELINE	OS BASELINE
PAPILLA		
TBUT		
INJECTION		
CHEMOSIS		
TEAR PRISM		

Papilla

- 1- absent
- 2- slight
- 3- moderate
- 4- severe

TBUT- Time (sec)

Injection/chemosis

- 1-absent
- 2-slight inj. s chemosis
- 3-mod. inj. s chemosis
- 4-mod. inj. c chemosis
- 5-svre inj. c chemosis

Tear prism  
 measurement

NAME \_\_\_\_\_

DATE \_\_\_\_\_

TRIAL \_\_\_\_\_

EXAMINER  
POST-EVALUATION-IMMED

	OD IMMEDIATE	OS IMMEDIATE	OD 0.5 HOURS	OS 0.5 HOURS
PAPILLA				
TBUT				
INJECTION				
CHEMOSIS				
TEAR PRISM				

Papilla

- 1- absent
- 2- slight
- 3- moderate
- 4- severe

TBUT- Time (sec)

Injection/chemosis

- 1-absent
- 2-slight inj. s chemosis
- 3-mod. inj. s chemosis
- 4-mod. inj. c chemosis
- 5-svre inj. c chemosis

Tear prism  
measurement

NAME \_\_\_\_\_

DATE \_\_\_\_\_

TRIAL \_\_\_\_\_

EXAMINER  
POST-EVALUATION-5 DAY

	5 DAY- OD	5 DAY- OS
PAPILLA		
TBUT		
INJECTION		
CHEMOSIS		
TEAR PRISM		

Papilla

- 1- absent
- 2- slight
- 3- moderate
- 4- severe

TBUT- Time (sec)

Injection/chemosis

- 1-absent
- 2-slight inj. s chemosis
- 3-mod. inj. s chemosis
- 4-mod. inj. c chemosis
- 5-svre inj. c chemosis

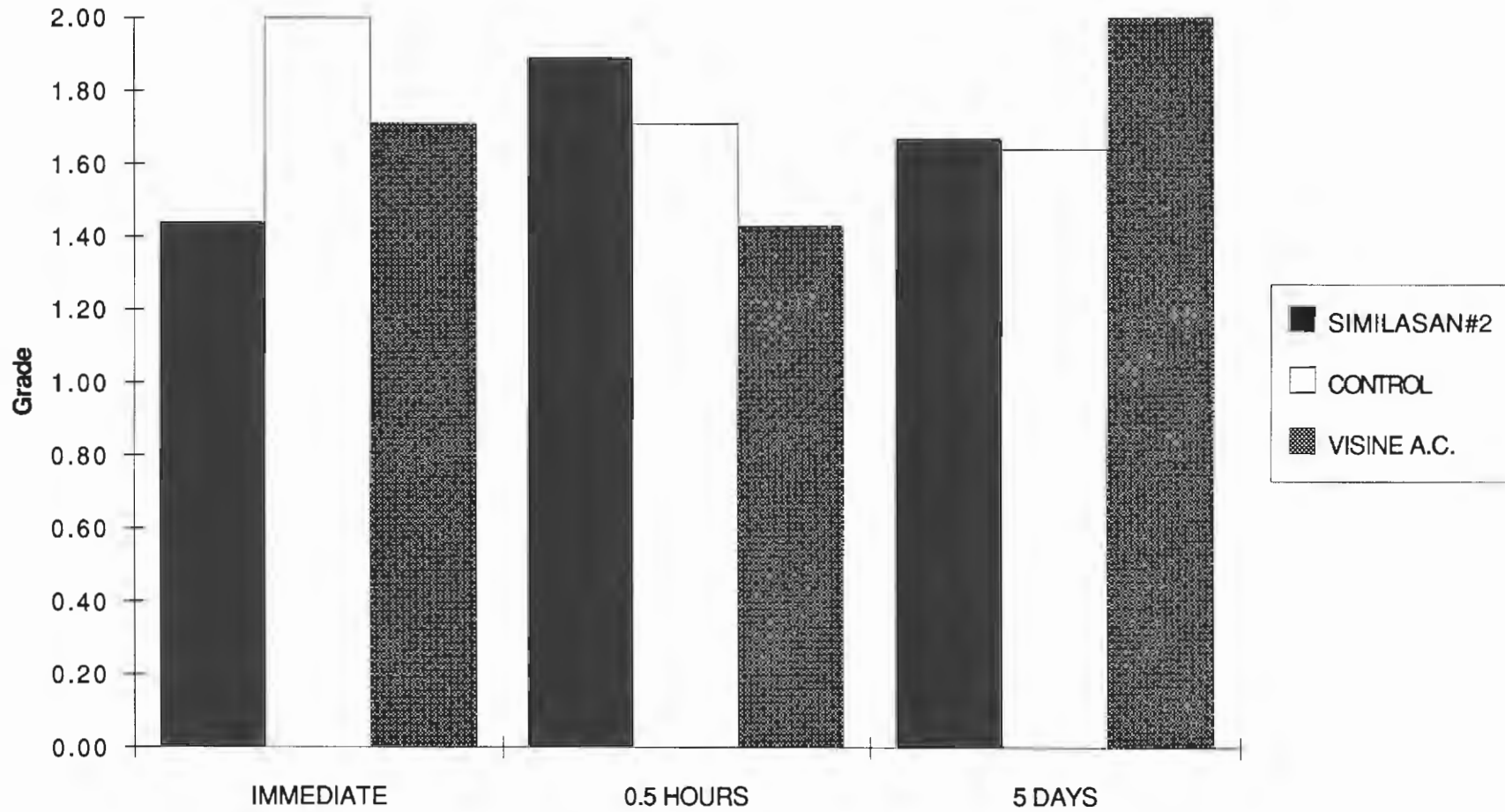
Tear prism  
measurement

## **APPENDIX B**

Patient's subjective data for burning

<b>BURNING</b>	<b>TRIAL C</b>	<b>VISINE A.C.</b>		
<b>NAME</b>	<b>PRE-EVALUATION</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAYS</b>
1	1	1	1	4
2	3	4	3	2
3	3	1	1	1
4	3	2	1	3
5	3	2	1	2
6	3	1	2	1
7	4	1	1	1
<b>AVERAGE</b>	<b>2.86</b>	<b>1.71</b>	<b>1.43</b>	<b>2.00</b>
	<b>TRIAL B</b>	<b>SALINE</b>		
1	2	2	1	2
2	4	3	2	1
3	1	1	1	1
4	2	1	1	2
5	1	1	1	1
6	4	5	4	2.5
7	4	1	2	2
<b>AVERAGE</b>	<b>2.57</b>	<b>2.00</b>	<b>1.71</b>	<b>1.64</b>
	<b>TRIAL A</b>	<b>SIMILASAN#2</b>		
1	1	1	1	1
2	4	1	1	1
3	1	1	1	1
4	3	1	3	1
5	4	4	5	3
6	1	1	1	1
7	2	2	2	2
8	1	1	2	2
9	1	1	1	3
<b>Average</b>	<b>2.00</b>	<b>1.44</b>	<b>1.89</b>	<b>1.67</b>

### PATIENT DEGREE OF RELIEF FROM BURNING

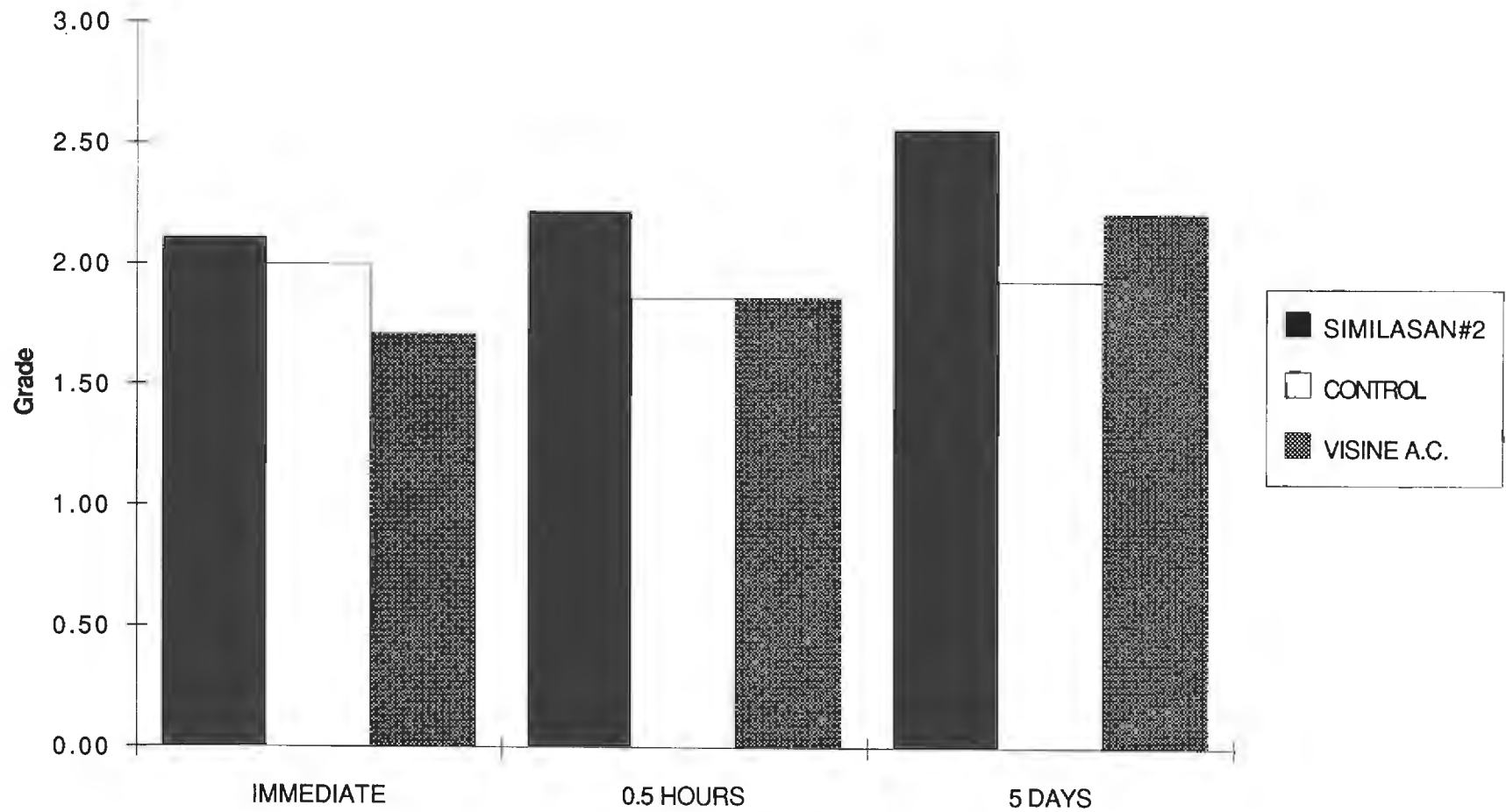




Patient's subjective data for itching

<b>ITCHING</b>	<b>TRIAL C</b>	<b>VISINE A.C.</b>		
<b>NAME</b>	<b>PRE-EVALUATION</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAYS</b>
1	3	1	3	5
2	4	4	2	2
3	4	2	3	1
4	2	1	1	4
5	3	1	1	1.5
6	1	1	1	1
7	5	2	2	1
<b>AVERAGE</b>	<b>3.14</b>	<b>1.71</b>	<b>1.86</b>	<b>2.21</b>
	<b>TRIAL B</b>	<b>SALINE</b>		
1	3	1.5	1	2
2	4	2	2	1
3	4	2	2	2
4	5	1	1	1
5	2	1	1	3
6	2	5	4	2.5
7	4	1.5	2	2
<b>AVERAGE</b>	<b>3.43</b>	<b>2.00</b>	<b>1.86</b>	<b>1.93</b>
	<b>TRIAL A</b>	<b>SIMILASAN#2</b>		
1	1	1.5	1	1
2	4	1	1	1
3	5	4	4	4
4	4	2	3	2
5	4	3.5	3	2
6	3	2	2	4.5
7	2	3	3	3.5
8	2	1	2	2
9	1	1	1	3
<b>Average</b>	<b>2.89</b>	<b>2.11</b>	<b>2.22</b>	<b>2.56</b>

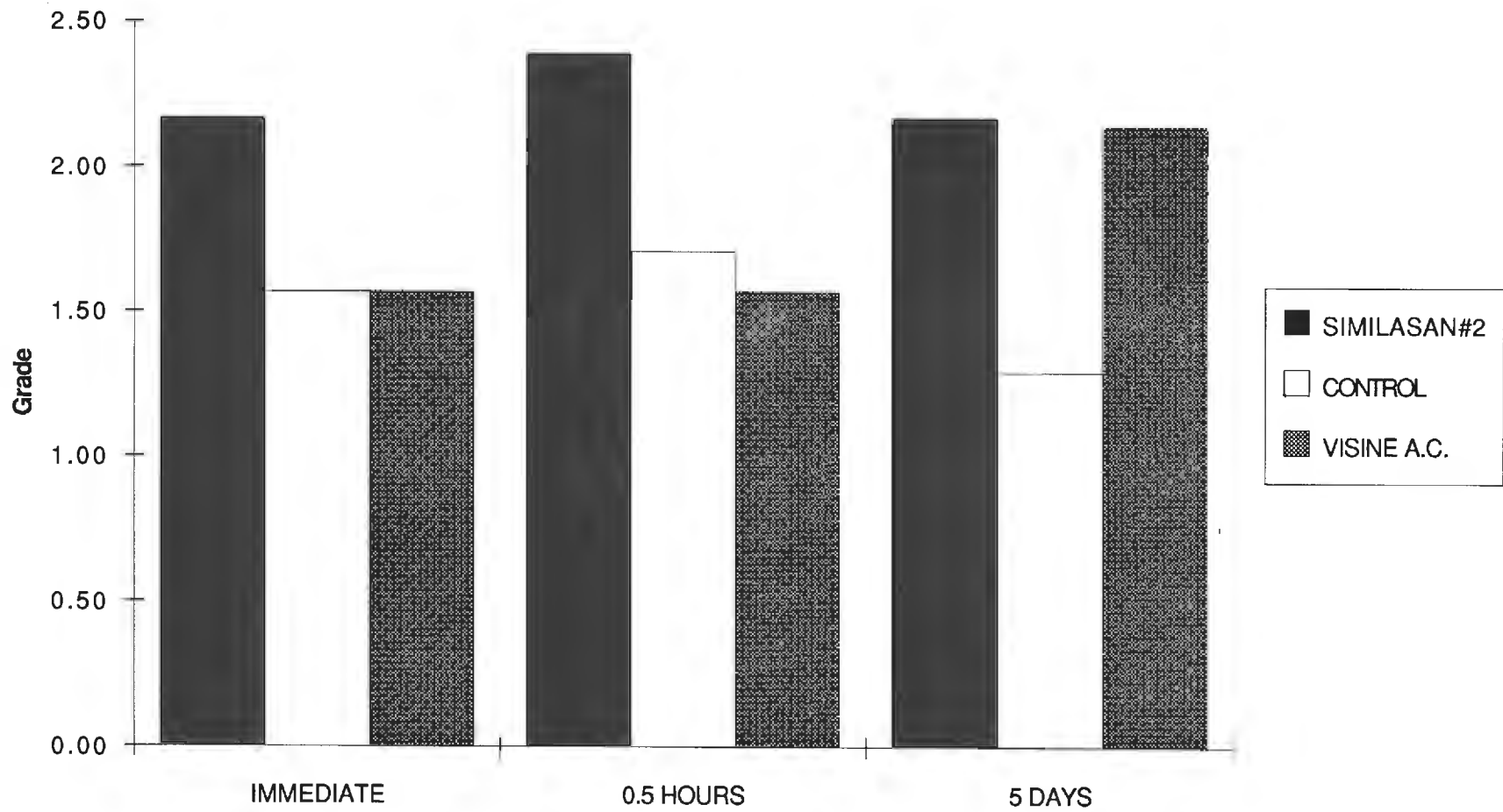
### PATIENT DEGREE OF RELIEF FROM ITCHING



Patient's subjective data for redness

<b>REDNESS</b>	<b>TRIAL C</b>	<b>VISINE AC</b>		
Subject	PRE-EVALUATION	IMMEDIATE	0.5 HOURS	5 DAYS
1	2	1	1	4
2	4	4	4	4
3	1	1	1	1
4	3	2	2	2
5	1	1	1	2
6	2	1	1	1
7	3	1	1	1
<b>AVERAGE</b>	<b>2.29</b>	<b>1.57</b>	<b>1.57</b>	<b>2.14</b>
	<b>TRIAL B</b>	<b>SALINE</b>		
1	1	1	1	1
2	3	1	1	1
3	3	1	1	1
4	5	4	3	2
5	3	2	2	1
6	2	1	3	1
7	4	1	1	2
<b>AVERAGE</b>	<b>3.00</b>	<b>1.57</b>	<b>1.71</b>	<b>1.29</b>
	<b>TRIAL A</b>	<b>SIMILASAN#2</b>		
1	2	1.5	1	1.5
2	4	1	1	1
3	4	5	5	5
4	4	2	4	2
5	2	4	4	2
6	1	1	1	1
7	3	2	2	2
8	1	1	2	2
9	2	2	1.5	3
<b>Average</b>	<b>2.56</b>	<b>2.17</b>	<b>2.39</b>	<b>2.17</b>

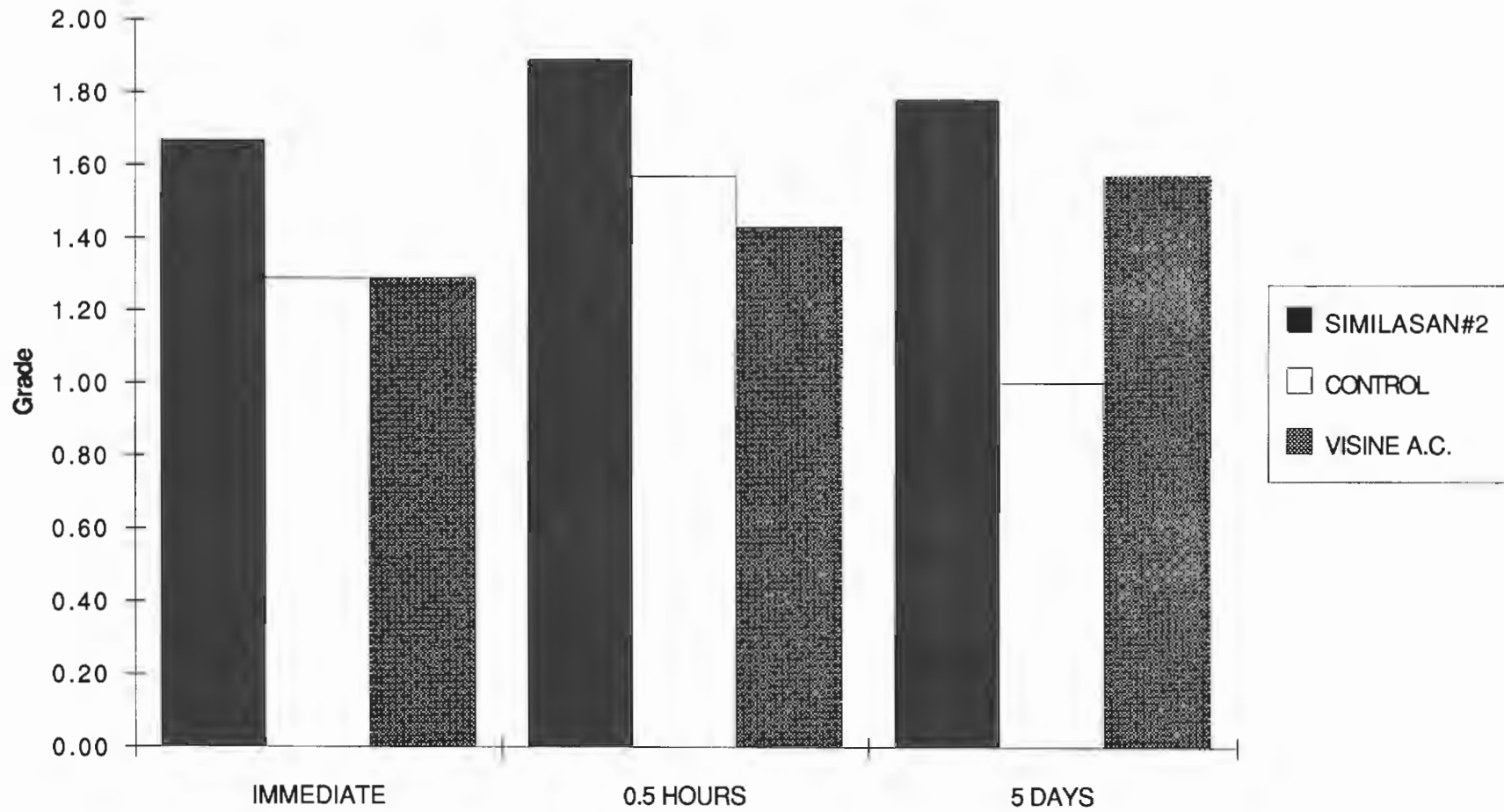
### PATIENT DEGREE OF RELIEF FROM REDNESS



Patient's subjective data for runny nose

<b>RUNNY NOSE</b>	<b>TRIAL C</b>	<b>VISINE A.C.</b>		
<b>NAME</b>	<b>PRE-EVALUATION</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAYS</b>
1	4	1	3	4
2	3	1	1	1
3	4	3	2	1
4	4	1	1	1
5	2	1	1	1
6	2	1	1	2
7	4	1	1	1
<b>AVERAGE</b>	<b>3.29</b>	<b>1.29</b>	<b>1.43</b>	<b>1.57</b>
	<b>TRIAL B</b>	<b>SALINE</b>		
1	3	1	1	1
2	3	1	1	1
3	2	1	1	1
4	3	1	1	1
5	4	3	3	1
6	2	1	3	1
7	2	1	1	1
<b>AVERAGE</b>	<b>2.71</b>	<b>1.29</b>	<b>1.57</b>	<b>1.00</b>
	<b>TRIAL A</b>	<b>SIMILASAN#2</b>		
1	1	1	1	1
2	4	1	1	1
3	5	2	2	3
4	4	1	1	1
5	4	1	2	1
6	4	3	3	3
7	4	4	1	4
8	2	1	1	1
9	1	1	1	1
<b>Average</b>	<b>3.22</b>	<b>1.67</b>	<b>1.44</b>	<b>1.78</b>

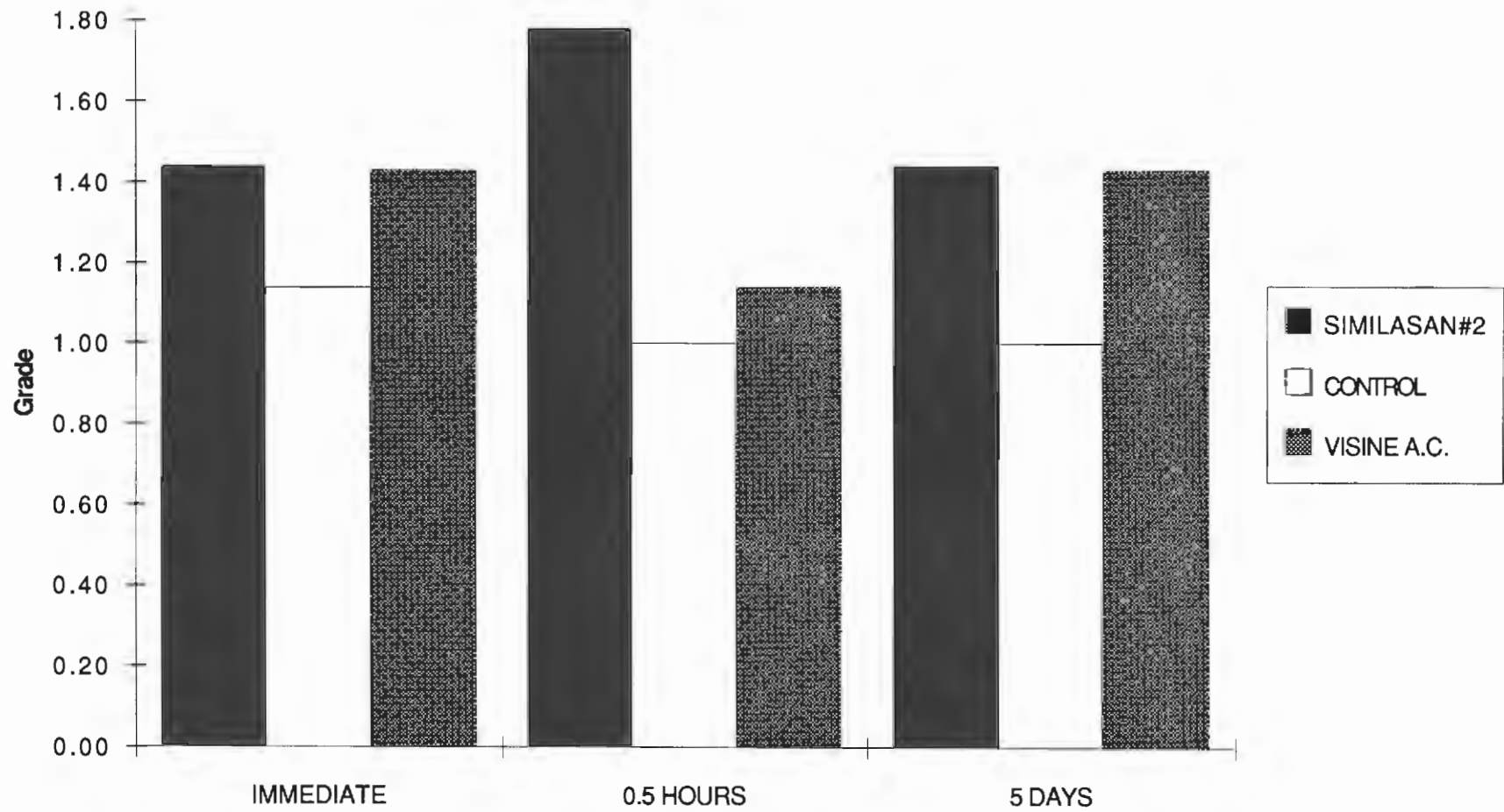
### PATIENT DEGREE OF RELIEF FROM RUNNY NOSE



Patient's subjective data for sneezing

<b>SNEEZING</b>	<b>TRIAL C</b>	<b>VISINE A.C.</b>		
<b>NAME</b>	<b>RE-EVALUATIO</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAYS</b>
1	4	1	2	4
2	4	3	1	1
3	3	2	1	1
4	4	1	1	1
5	1	1	1	1
6	1	1	1	1
7	3	1	1	1
<b>AVERAGE</b>	<b>2.86</b>	<b>1.43</b>	<b>1.14</b>	<b>1.43</b>
	<b>TRIAL B</b>	<b>SALINE</b>		
1	1	1	1	1
2	3	1	1	1
3	3	1	1	1
4	4	1	1	1
5	2	2	1	1
6	1	1	1	1
7	2	1	1	1
<b>AVERAGE</b>	<b>2.29</b>	<b>1.14</b>	<b>1.00</b>	<b>1.00</b>
	<b>TRIAL A</b>	<b>SIMILASAN#2</b>		
1	1	1	1	1
2	2	1	1	1
3	3	1	4	1
4	4	1	1	1
5	4	3	3	1
6	4	1	1	3
7	3	3	3	3
8	3	1	1	1
9	1	1	1	1
<b>Average</b>	<b>2.78</b>	<b>1.44</b>	<b>1.78</b>	<b>1.44</b>

### PATIENT DEGREE OF RELIEF FROM SNEEZING

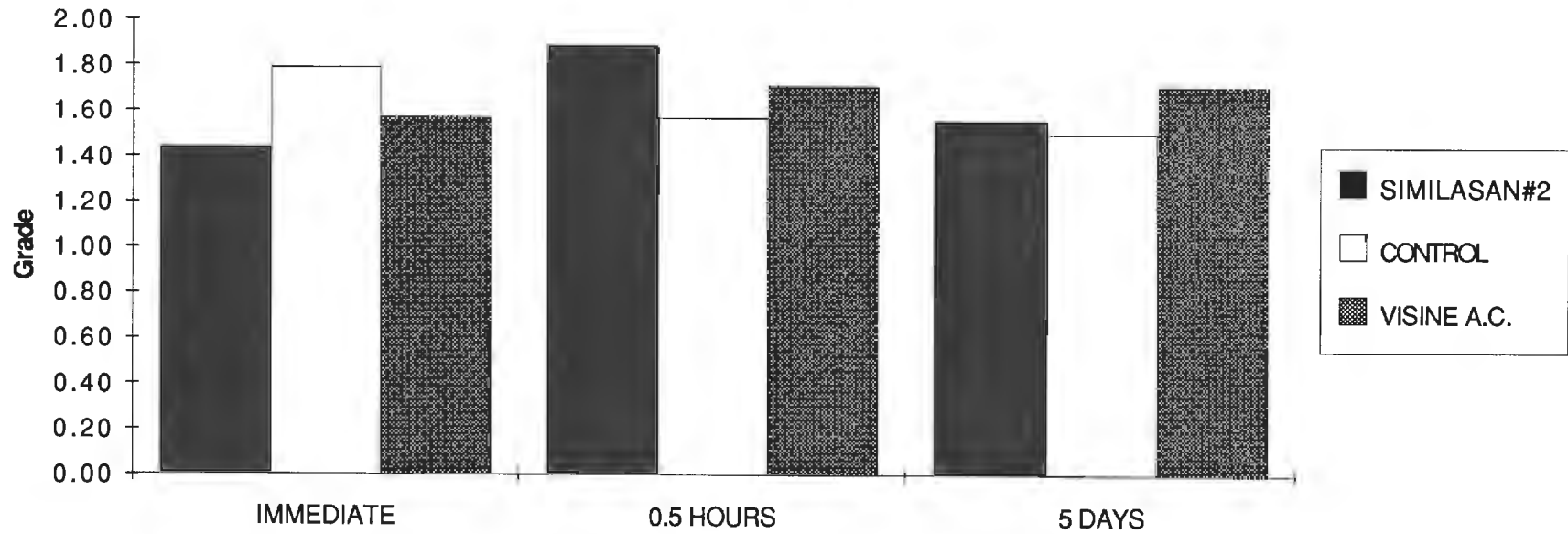




Patient's subjective data for stinging

<b>STINGING</b>	<b>TRIAL C</b>	<b>VISINE A.C.</b>		
<b>NAME</b>	<b>PRE-EVALUATION</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAYS</b>
1	2	1	1	3
2	2	3	3	2
3	2	1	1	1
4	2	2	2	2
5	3	1.5	1	2
6	3	1	2	1
7	4	1.5	2	1
<b>AVERAGE</b>	<b>2.57</b>	<b>1.57</b>	<b>1.71</b>	<b>1.71</b>
	<b>TRIAL B</b>	<b>SALINE</b>		
1	1	1	1	2
2	4	2	1	1
3	2	1	1	1
4	2	1	1	1
5	1	1	1	1
6	3	5	4	2.5
7	4	1.5	2	2
<b>AVERAGE</b>	<b>2.43</b>	<b>1.79</b>	<b>1.57</b>	<b>1.50</b>
	<b>TRIAL A</b>	<b>SIMILASAN#2</b>		
1	1	1	1	1
2	4	1	1	1
3	1	1	1	1
4	3	1	3	1
5	4	3	4	2
6	2	2	2	1
7	2	2	2	2
8	1	1	2	2
9	1	1	1	3
<b>Average</b>	<b>2.11</b>	<b>1.44</b>	<b>1.89</b>	<b>1.56</b>

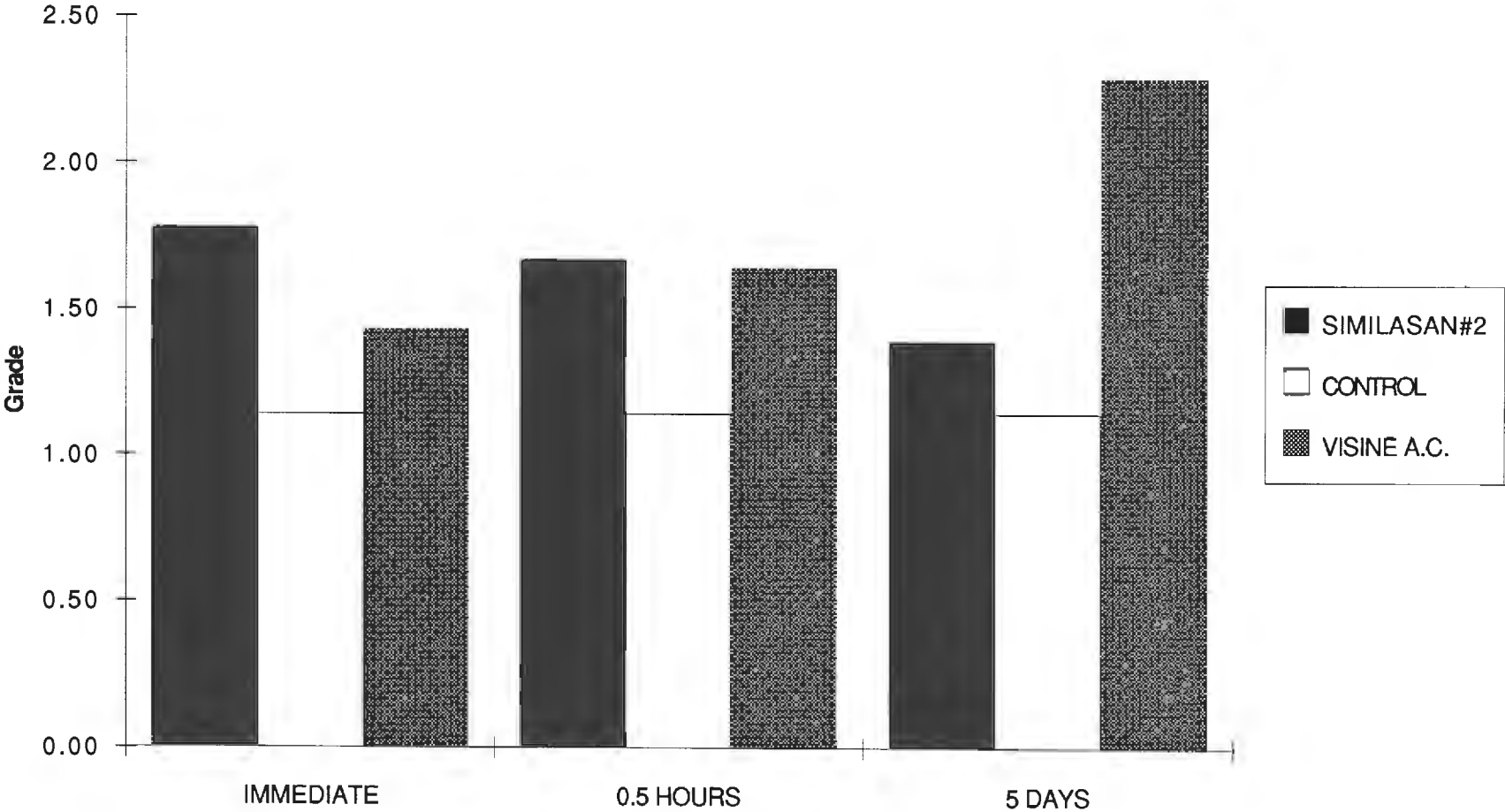
### PATIENT DEGREE OF RELIEF FROM STINGING



Patient's subjective data for swelling

<b>SWELLING</b>	<b>TRIAL C</b>	<b>VISINE A.C.</b>		
Subject	PRE-EVALUATION	IMMEDIATE	0.5 HOURS	5 DAYS
1	2	1	1	5
2	2	4	4	4
3	1	1	1	1
4	2	1	2	2
5	2	1	1.5	2
6	2	1	1	1
7	3	1	1	1
<b>AVERAGE</b>	<b>2.00</b>	<b>1.43</b>	<b>1.64</b>	<b>2.29</b>
	<b>TRIAL B</b>	<b>SALINE</b>		
1	1	1	1	1
2	2	1	1	1
3	3	1	1	1
4	4	2	1	1
5	1	1	1	1
6	2	1	2	1
7	2	1	1	2
<b>AVERAGE</b>	<b>2.14</b>	<b>1.14</b>	<b>1.14</b>	<b>1.14</b>
	<b>TRIAL A</b>	<b>SIMILASAN#2</b>		
1	1	1	1	1
2	4	1	1	1
3	1	4	4	1
4	2	1	1	1
5	2	3	2	2
6	1	1	1	1
7	3	3	3	2.5
8	1	1	1	2
9	1	1	1	1
<b>Average</b>	<b>1.78</b>	<b>1.78</b>	<b>1.67</b>	<b>1.39</b>

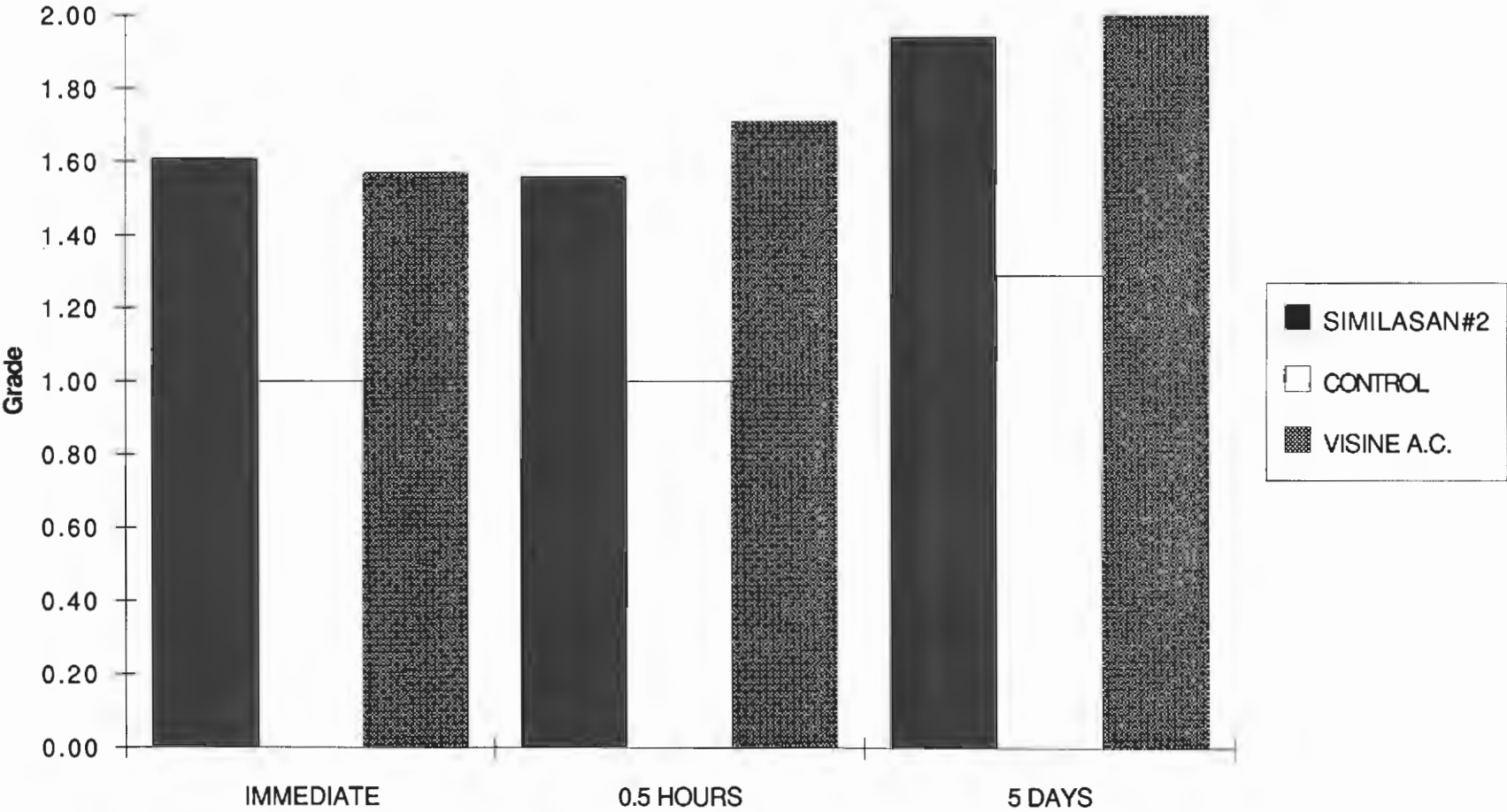
### PATIENT DEGREE OF RELIEF FROM SWELLING



Patient's subjective data for tearing

<b>TEARING</b>	<b>TRIAL C</b>	<b>VISINE A.C.</b>		
<b>NAME</b>	<b>PRE-EVALUATION</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAYS</b>
1	1	1	1	5
2	2	2	4	1
3	3	2	2	1
4	2	1.5	2	2
5	3	2.5	1	3
6	3	1	1	1
7	4	1	1	1
<b>AVERAGE</b>	<b>2.57</b>	<b>1.57</b>	<b>1.71</b>	<b>2.00</b>
	<b>TRIAL B</b>	<b>SALINE</b>		
1	1	1	1	1
2	2	1	1	1
3	2	1	1	1
4	3	1	1	2
5	1	1	1	1
6	2	1	1	1
7	2	1	1	2
<b>AVERAGE</b>	<b>1.86</b>	<b>1.00</b>	<b>1.00</b>	<b>1.29</b>
	<b>TRIAL A</b>	<b>SIMILASAN#2</b>		
1	1	1.5	1	1
2	4	1	1	1
3	1	1	1	5
4	3	2	3	2
5	4	2	2	3
6	3	1	1	1
7	2	4	3	2.5
8	1	1	1	1
9	1	1	1	1
<b>Average</b>	<b>2.22</b>	<b>1.61</b>	<b>1.56</b>	<b>1.94</b>

### PATIENT DEGREE OF RELIEF FROM TEARING



## APPENDIX C

Examiner objective data for Similasan

<b>TRIAL A: Similasan</b>				
<b>PAPILLA</b>	<b>PRE-EVALUATION</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAY</b>
Subject				
1	2	2	2	2
2	2	2	2	2
3	2	2	2	0.5
4	1.5	1.5	1.5	0.75
5	2	2	2	2
6	1	1	1	1
7	2	2	2	1
8	2	2	2	1
9	1.5	1.5	1.5	1
<b>average</b>	<b>1.78</b>	<b>1.78</b>	<b>1.78</b>	<b>1.25</b>
<b>TBUT</b>				
1	9.5	10	10	8
2	10	10	10	9.5
3	10	10	10	10
4	10	10	8	10
5	10	10	10	8
6	10	10	10	9
7	10	10	10	10
8	10	10	10	7.5
9	10	10	10	10
<b>average</b>	<b>9.94</b>	<b>10.00</b>	<b>9.78</b>	<b>9.11</b>
<b>INJECTION</b>				
1	1	1	1	1.5
2	0.5	0.5	0.5	1
3	2	2.5	2.5	1
4	2	2	2	1.75
5	1	1	1	1
6	1.75	1.75	1.25	1
7	1	1	1	1.5
8	1	1	1	1
9	1.75	1.75	1.5	1.5
<b>average</b>	<b>1.33</b>	<b>1.39</b>	<b>1.31</b>	<b>1.25</b>
<b>CHEMOSIS</b>				
1	0	0	0	1
2	0	0	0	0.5
3	1	1	1	0
4	1	1	1	1
5	0	0	0	0
6	1	1	1	1
7	1	1	1	1
8	1	1	1	1
9	0	0	0	0
<b>average</b>	<b>0.56</b>	<b>0.56</b>	<b>0.56</b>	<b>0.61</b>



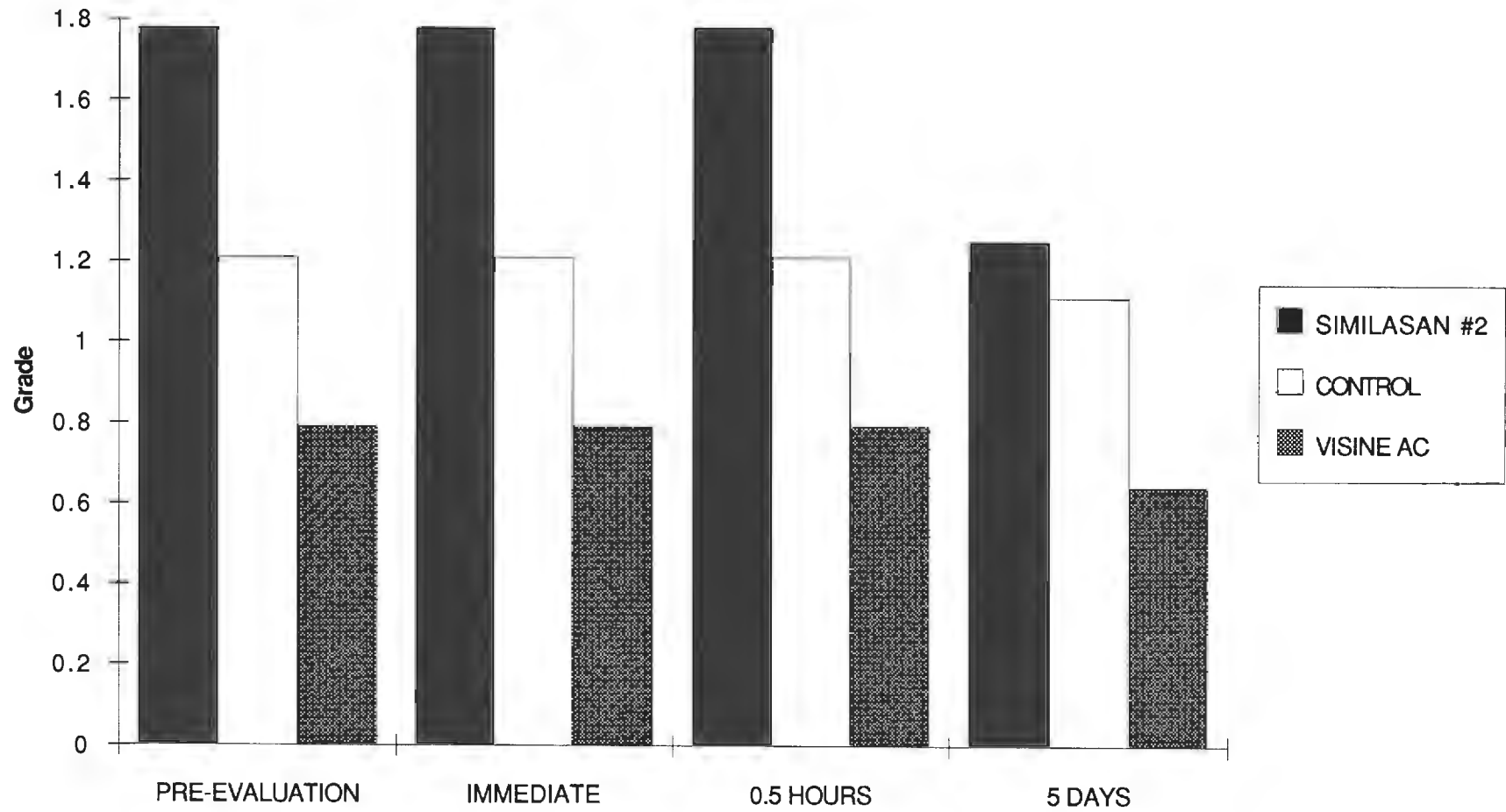
Examiner objective data for Control

<b>TRIAL B: Control</b>				
<b>PAPILLA</b>	<b>PRE-EVALUATION</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAY</b>
Subject				
1	0.5	0.5	0.5	0
2	0	0	0	2
3	2	2	2	1
4	2	2	2	0.75
5	2	2	2	2
6	1	1	1	1
7	1	1	1	1
<b>average</b>	<b>1.21</b>	<b>1.21</b>	<b>1.21</b>	<b>1.11</b>
<b>TBUT</b>				
1	4	10	5	5.5
2	3.5	3.5	8	5
3	10	10	10	10
4	10	10	7	9
5	9	10	10	10
6	7.5	10	5.5	7.5
7	10	10	10	10
<b>average</b>	<b>7.71</b>	<b>9.07</b>	<b>7.93</b>	<b>8.14</b>
<b>INJECTION</b>				
1	1.25	1.25	1.25	1
2	1.5	1.25	1.25	3
3	2	2	2	2
4	1.5	1	1	1.5
5	1	1	1	1.5
6	1	1	1	1.5
7	1.5	1	1	1.5
<b>average</b>	<b>1.39</b>	<b>1.21</b>	<b>1.21</b>	<b>1.71</b>
<b>CHEMOSIS</b>				
1	0.5	0.5	0.5	0.5
2	0	0	0	1
3	0	0	0	0
4	1	1	1	1
5	0	0	0	1
6	1	1	1	0
7	2	2	1	1
<b>average</b>	<b>0.64</b>	<b>0.64</b>	<b>0.50</b>	<b>0.64</b>

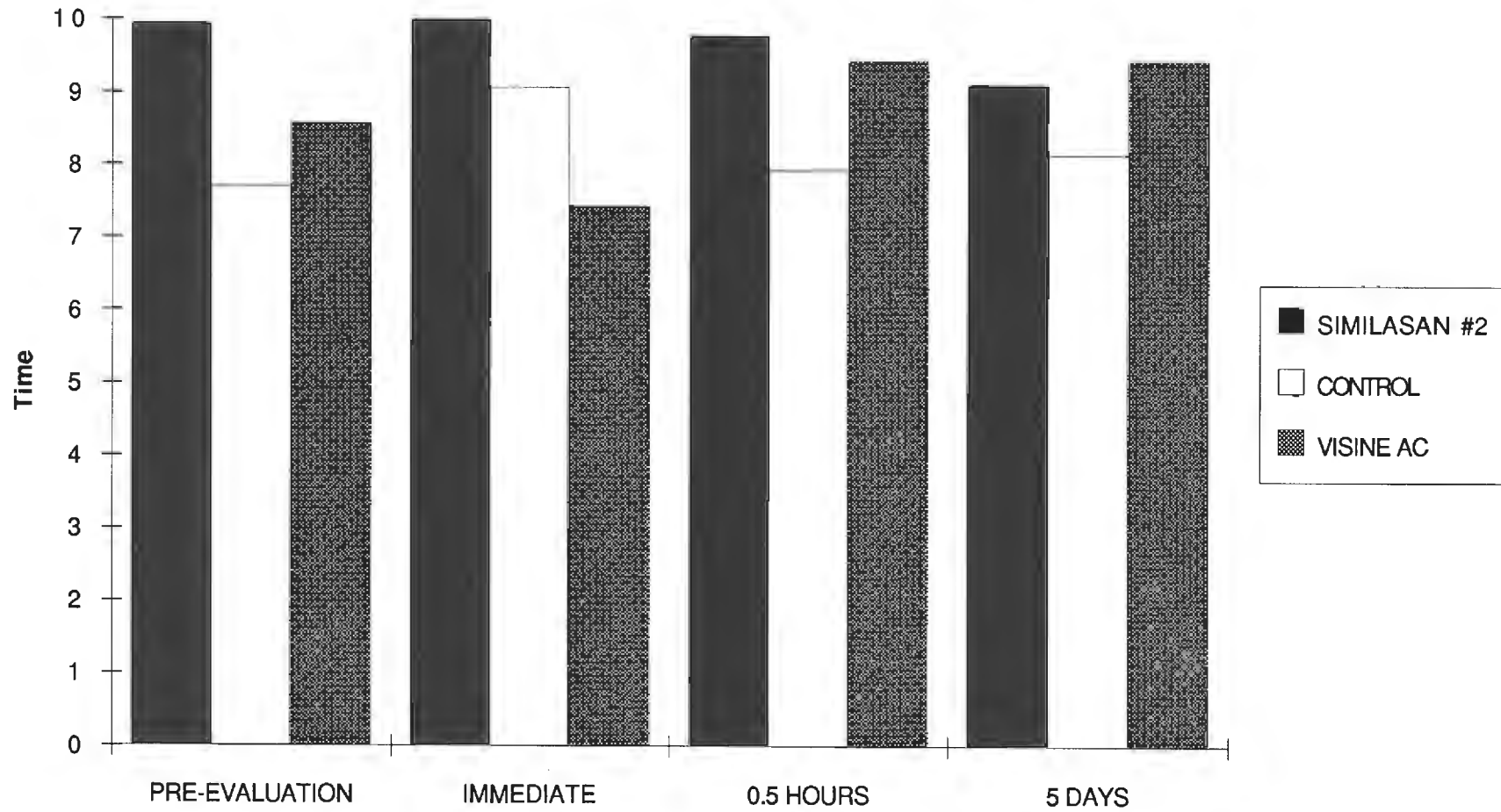
Examiner objective data for Visine AC

<b>TRIAL C: Visine AC</b>				
<b>PAPILLA</b>	<b>PRE-EVALUATION</b>	<b>IMMEDIATE</b>	<b>0.5 HOURS</b>	<b>5 DAY</b>
Subject				
1	0	0	0	0
2	2	2	2	1
3	0	0	0	0
4	1.5	1.5	1.5	0.5
5	0	0	0	1
6	0	0	0	0
7	2	2	2	2
<b>average</b>	<b>0.79</b>	<b>0.79</b>	<b>0.79</b>	<b>0.64</b>
<b>TBUT</b>				
1	3	3	7	9
2	10	10	10	10
3	10	1	10	7
4	10	10	9	10
5	10	10	10	10
6	10	10	10	10
7	7	8	10	10
<b>average</b>	<b>8.57</b>	<b>7.43</b>	<b>9.43</b>	<b>9.43</b>
<b>INJECTION</b>				
1	1.5	0	0.5	1.5
2	1	1	1	0.75
3	1	1	1	1
4	1	0	0	1
5	1	0.5	0.5	1.5
6	1	0.5	0.5	1
7	1	0.5	0.5	0.5
<b>average</b>	<b>1.07</b>	<b>0.50</b>	<b>0.57</b>	<b>1.04</b>
<b>CHEMOSIS</b>				
1	1	1	1	0
2	0	0	0	0
3	0	0	1	0
4	1	1	1	0
5	0	0	0	1
6	0	0	0.5	1
7	0	1	1	1
<b>average</b>	<b>0.29</b>	<b>0.43</b>	<b>0.64</b>	<b>0.43</b>

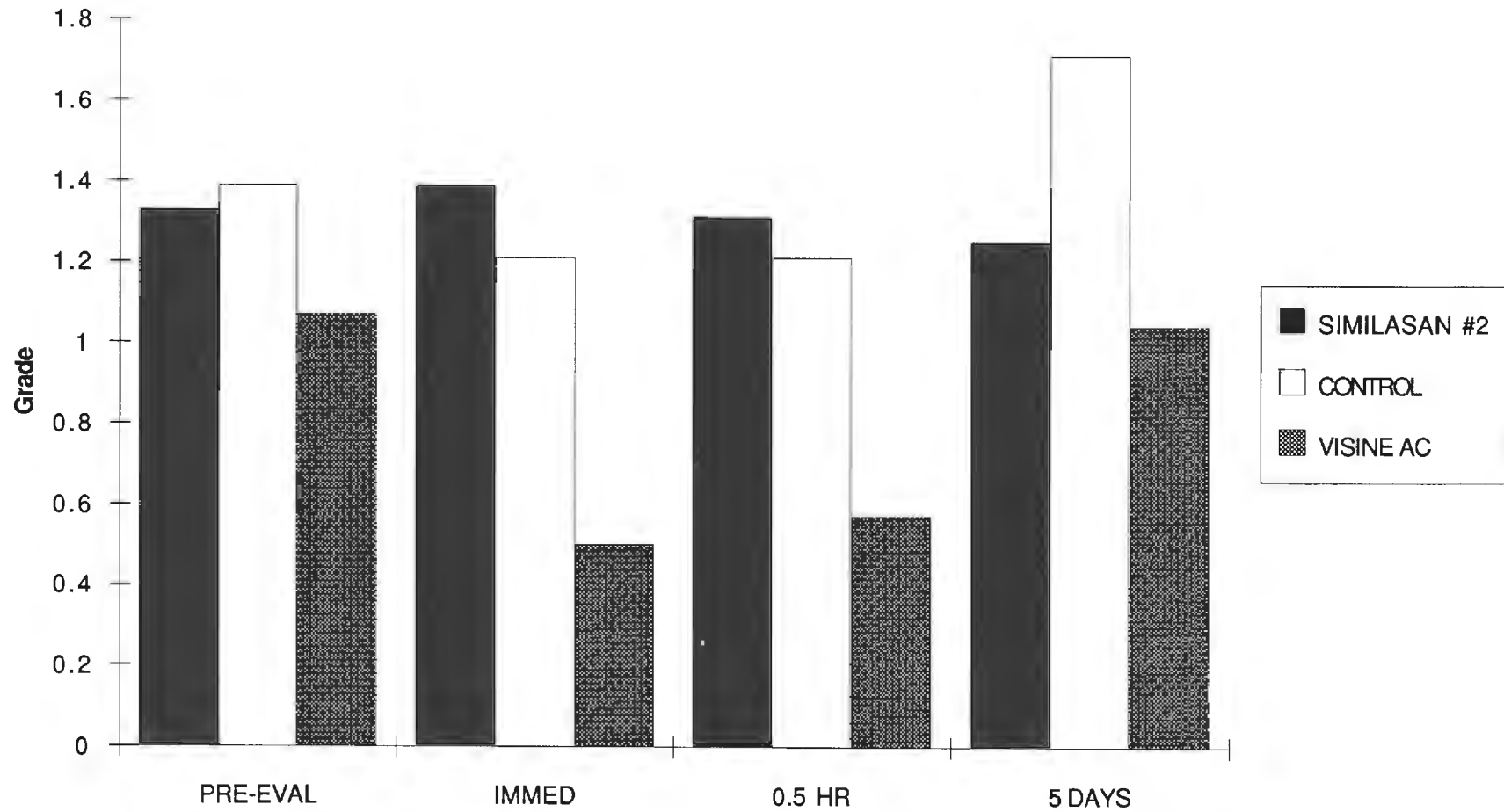
### EXAMINER EVALUATION OF PAPILLA



### EXAMINER EVALUATION OF TBUT



### EXAMINER EVALUATION OF INJECTION



## EXAMINER EVALUATION OF CHEMOSIS

