

Grid Challenge test to evaluate Safe Sea protection level against Olindias.

Purpose

The purpose of this study was to test the protection levels of a jellyfish sting inhibitor called "Safe Sea" against the Atlantic Olindias in Argentina,

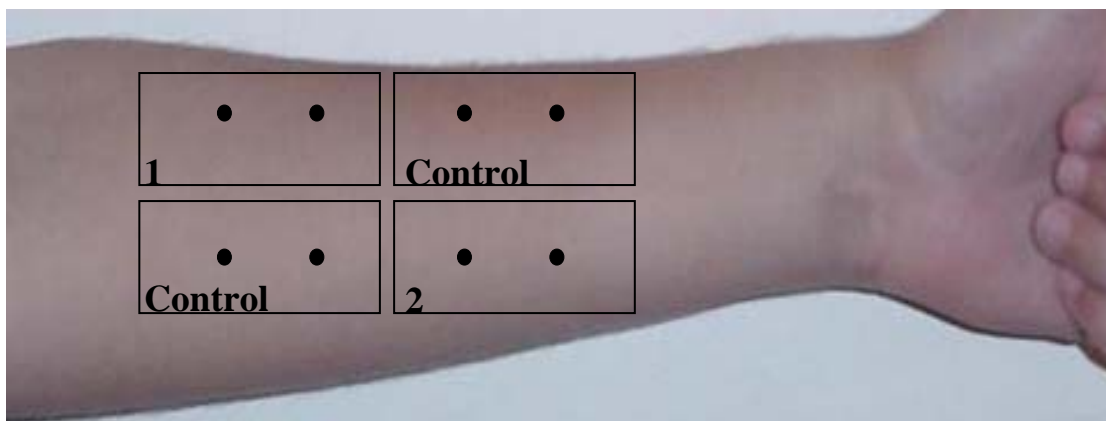
Envenomation by cnidarians is a worldwide problem. Cnidarians are equipped with stinging cells, each of which contains a stinging apparatus capable of delivering toxins into the victim when activated. Safe Sea inhibits the stinging mechanism based on patented technology.

Safe Sea have been successfully tested on the Atlantic *Chrysaora* (sea nettle), the dangerous species of the Atlantic *Chiropsalmus* (Box jellyfish) and Atlantic *Rhopilema*. However, no trials have been done to monitor Safe Sea efficacy against *Olindias* Sp.

Testing Protocol:

The test performed on both arms of each volunteer. Inner arms was marked and divided into 4 grids for conducting 8 independent experiments on each subject (see photo below). Two grids on each arm used as a controlled unprotected skin and the rest of the grids were lotioned with Safe Sea. The size of every grid was of 50 squares Centimeter. 0.1 Gram of Safe Sea applied onto each grid 10-15 minutes before the tests or before any exposure of the hand into Sea water. Ten minutes following the application of Safe Sea the test was initiated. After wetting the grids with 1 ml of seawater, 1-2mm of *Olindias* tentacles were applied on each grid. The tentacle was left on the skin for 15 second to induce maximum contact and maximum sting.

Demonstration of grids marks for the tests.



Data collection:

The degree of inflammation was evaluated and scored according to the following criteria: 0 (no change), 1 Erythema (skin color change only), 2 (edema), 3 Vasculation (blister or ulcer formation). These measurements were taken at the same time points.

Table of results:

Subject Name _____

	Control Unprotected	Safe Sea Protected
Left hand 1		
Left hand 2		
Right hand 1		
Right hand 2		
*Total		

Infection score level

No reaction=0

Erythema = 1

Edema= 2

Vesiculation= 3

*Total represents the sum of on each column.

Data Analyses:

Comparison between the Sum No. of control Unprotected grids and the Sum No of Safe Sea protected grids gave an indication on the protection level of Safe Sea against the sting of Olindias Sp.

Results:

Study population: Twenty three (23) subjects were enrolled in the study. Their mean age 26.7 years range 10-61 years. All volunteers completed the study.

Skin Reaction

Control unprotected skin:

Different level of skin reaction was developed at 77 grids out of the total 92. Skin reaction to the level of Vasculation was developed at 17 unprotected grids. The total median reaction score per subject was at the level of 7. The most common skin reaction at the unprotected grids was edema (score 2).

Safe Sea treated skin:

No visible signs of sting were notable in 53 Safe Sea protected grids. Only 2 grids score skin reaction of 3. The total median reaction score per subject was at the level of 2. The most common skin reaction at the unprotected grids was no reaction (score 0).

p-values were <0.0001 demonstrating a statistically significant difference between the two groups.

Table 2: Summary of results

Subject	Total unprotected	Total Protected
1	10	2
2	11	7
3	9	5
4	9	4
5	8	5
6	5	1
7	11	4
8	0	1
9	9	2
10	4	3
11	3	0
12	1	0
13	4	0
14	6	0
15	4	2
16	8	0
17	10	3
18	4	3
19	9	2
20	5	3
21	6	4
22	7	2
23	9	2
Median	7	2
Average	6.608695652	2.391304348
P-Value	<0.0001	

Conclusion:

Exposure of the skin to Olindias tentacles resulted in the untreated arms in Edema or even skin blisters.

In contrast under the same conditions Safe Sea inhibited sting in most subjects.

Under this tests condition Safe Sea significantly inhibits the development of skin reaction resulting from contact with the Olindias tentacles.

CONFIDENTIAL

This report was submitted under complete confidentiality. It should be present and use only for internal evaluation.