Complaint to TGA: Sawyer Extractor™ Pump for Snake Bite

I submit that this is a "critical" complaint because it undermines accepted public health messages and is likely to lead to harm or injury if the claims are relied upon.

Publications:

- https://outdooryou.com.au/view/?id=36
- https://youtu.be/hM0FFpy-J_E
- https://survivalsuppliesaustralia.com.au/products/sawyer-extractor-kit.php
- https://nethos.com.au/index.php?rt=product/product&product_id=146
- https://backpackinglight.com.au/sawyer-venom-extractor-kit.html
- https://pinterest.com.au/pin/413205334553309465/
- Etc.

Date/Edition: 30/07/2018

Product: Sawyer Extractor Pump Kit (Not found on the ARTG)

Sponsor: Sawyer in Australia (Outdoor You) Yankul PTY LTD, PO BOX 348, Lancelin, Western Australia, 6044, info@sawyeraustralia.com.au

Claims

- "The Sawyer ExtractorTM Pump vacuum was specifically designed to provide the most powerful suction available for the safe extraction of venoms and poisons."
- "Removes poisons from snake bites, bee and wasp stings, mosquito bites & more"
- "The Extractor most effectively retrieves venom from extremities and areas of the body outside muscle areas."
- "The ONLY suction device proven to remove snake venom."
- "Can safely and quickly remove significant quantities of venom."

I allege that this product (and its promotion) breaches the Therapeutic Goods Act 1989, s.41ML and the Therapeutic Goods Advertising Code 2015, s.4(1)(a), s.4(1)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(2)(d), 4(2)(f), 4(2)(h), 5(2) and 6(3)(d).

Research

I have appended two relevant articles:

- Snakebite Suction Devices Don't Remove Venom - They Just Suck
- Suction for Venomous Snakebite - A Study of "Mock Venom" Extraction in a Human Model.

In short, the promotion of this device is misleading, deceptive and dangerous.

During July 2005 – June 2015, 1548 patients with snakebite were recruited from 171 hospitals in all Australian states and territories. Pressure bandages with immobilization (PBI) were applied to 1304 patients (84%). Systemic envenoming occurred in 835 patients. There were 23 deaths, a median of two per year (range, 0–6).[1]

Recommended First Aid for Snake Bites:[2]

- Do NOT wash the area of the bite or try to suck out the venom!
- It is extremely important to retain traces of venom for use with venom identification kits.
- Do NOT incise or cut the bite or apply a high tourniquet!
- Cutting or incising the bite won't help. High tourniquets are ineffective and can be fatal if released.
- Stop lymphatic spread - bandage firmly, splint and immobilize.

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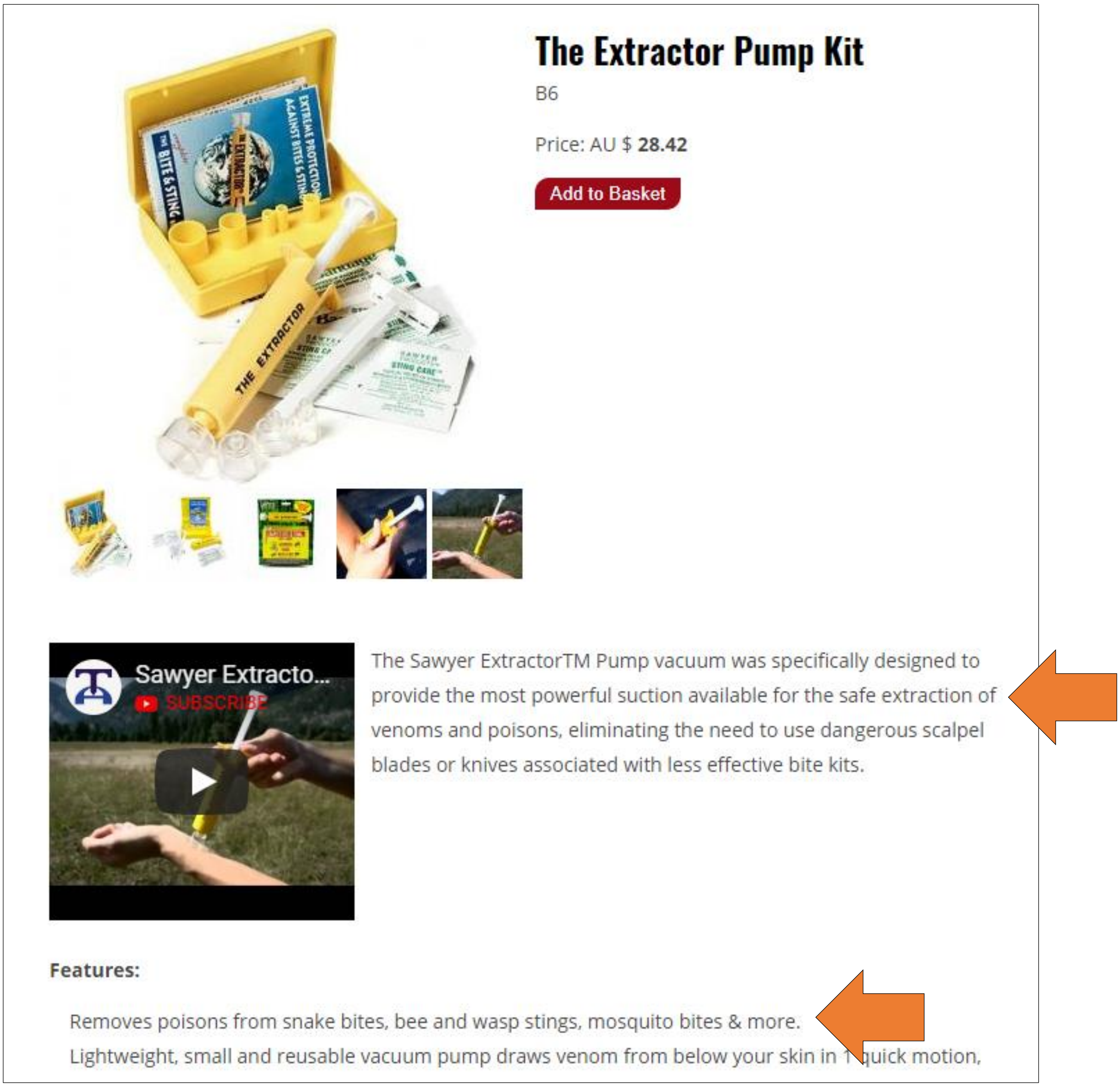
[1] https://www.mja.com.au/journal/2017/207/3/australian-snakebite-project-2005-2015-asp-20
[2] http://anaesthesia.med.usyd.edu.au/resources/venom/snakebite.html

- The lymphatic system is responsible for systemic spread of most venoms. This can be reduced by the application of a firm bandage (as firm as you would put on a sprained ankle) over a folded pad placed over the bitten area. While firm, it should not be so tight that it stops blood flow to the limb or to congests the veins. Start bandaging directly over the bitten area, ensuing that the pressure over the bite is firm and even. If you have enough bandage you can extend towards more central parts of the body, to delay spread of any venom that has already started to move centrally. A pressure dressing should be applied even if the bite is on the victims' trunk or torso.
- Immobility is best attained by application of a splint or sling, using a bandage or whatever to hand to absolutely minimize all limb movement, reassurance and immobilization (e.g., putting the patient on a stretcher). Where possible, bring transportation to the patient (rather than vice versa). Don't allow the victim to walk or move a limb. Walking should be prevented.

The advertisements:



https://outdooryou.com.au/view/?id=36

Details

Price: $27.95 incl. gst Quantity: 1 Add to Cart

Product Description

This amazing compact extractor/bite and sting kit is compact and has all the essential contents to ensure you have everything you need to deal with a variety of bites and stings. Whether from venomous snakes, bees or wasps, or mosquitos and other insects, this kit can help you extract poisons and irritants from your skin to reduce the effects they may cause. This kit provides the most powerful suction available for the safe extraction of venoms and poisons, eliminating the need to use dangerous scalpel blades or knives associated with less effective bite kits. This kit can save your life!

Kit Contents

* Includes Extractor Pump
* 4 x Plastic Cups
* 1 x Razor
* 3 x Sterile Adhesive Bandages
* 2 x Alcohol Wipes
* 2 x Insect Bite Antiseptic and Pain Reliever Towelettes
* 1 x Plastic Case

Short Videos

Product Features

* Removes poisons from snake bites, bee and wasp stings and Mosquito bites
* Lightweight, small and reusable vacuum pump draws venom from below your skin in one motion, the pump is really easy to operate with only 1 hand
* 4 x different size plastic cups for use and effective suction on a variety of sting or bite sizes.
* Effectiveness of the Extractor varies with the location of the bite; the Extractor most effectively retrieves venom from extremities and areas of the body outside muscle areas

https://survivalsuppliesaustralia.com.au/products/sawyer-extractor-kit.php

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30 July 2018

Snakebite Suction Devices Don't Remove Venom: They Just Suck

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See related article, p. 181.

[*Ann Emerg Med.* 2004;43:187-188.]

It was only a few decades ago that incision and suction were recommended snakebite first aid. However, concerns arose about injuries and infections caused when laypersons made incisions across fang marks and applied mouth suction. Meanwhile, several snakebite suction devices (eg, Cutter's Snakebite Kit, Venom Ex) were evaluated, and it was determined that they were neither safe nor effective.[1] So, recommendations changed, and mechanical suction without incision was advocated instead.[2-5] It seemed intuitive that suction alone would probably remove venom and should not cause harm. However, when the techniques were studied rigorously, quite the opposite was discovered.

One of the most popular suction devices, the Sawyer Extractor pump (Sawyer Products, Safety Harbor, FL), operates by applying approximately 1 atm of negative pressure directly over a fang puncture wound (or wounds) without making incisions. The manufacturer instructs that the device be applied within 3 minutes of the snakebite and left in place for 30 to 60 minutes. For many years, most agreed (including the Wilderness Medical Society and the American Medical Association) that the Extractor might be beneficial and would probably cause no harm.[2-5] Others suggested that it could exacerbate tissue damage, adding insult to injury after viper envenomation.[6-9] In this issue of *Annals*, the Extractor's inefficacy has been further confirmed with a well-designed study and fully detailed manuscript.[10]

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In their prospective experimental trial, a human model was used to test the amount of radioactively labeled mock venom that could be removed by an Extractor after subcutaneous injection with a 16-gauge hypodermic needle. The investigators measured radioactive count as an approximation of the amount of venom removed. The bottom line: the Extractor removed 0.04% to 2.0% of the envenomation load. The authors conclude that this is a clinically insignificant amount and that the Extractor is essentially useless. The main limitation of their study is that they could not use real venom.

The study by Alberts et al[10] corroborates other studies that have tested the efficacy and safety of the Extractor. Using a porcine model and real rattlesnake venom in a randomized, controlled trial, Bush et al[11] measured swelling and local effects as outcome variables after application of an Extractor to artificially envenomated extremities. The conclusion of the study was that the Extractor did not reduce swelling, but resulted in further injury in some subjects. Specifically, circular lesions identical in size and shape to the Extractor suction cups developed where the devices had been applied. These lesions subsequently necrosed, sloughed, and resulted in tissue loss that prolonged healing by weeks. Similar injuries after Extractor use have been noted in human patients.[1,12]

In another study, Extractors were applied to 2 human patients immediately after rattlesnake envenomations, and the device was left in place until its cup filled with serosanguinous fluid 5 times, although the authors do not specify the volume(s) of fluid obtained. The concentration of venom was measured in the fluid removed using an enzyme-linked immunosorbent assay.[13] There were no control subjects, and this study has only been published in abstract form. Ironically, this abstract is cited amongst the main supporting evidence for the Extractor.[4,14] However, a closer review of the results reveals that the concentration of venom in the serosanguinous fluid removed was only about 1/10,000th the concentration of rattlesnake venom. Alberts et al[10] similarly noted that although a relatively large volume of bloody fluid was pulled from the puncture site, it contained virtually no venom. Most interestingly, Alberts et al found that the amount of venom in the fluid that spontaneously oozed from the wound was greater than the amount of venom in the Extractor aspirate. It is possible in these 2 experiments that the fluid obtained came from superficial tissues, and that the strong suction exerted by the device collapses the distal portion of the fang tract where the venom is deposited, thereby reducing the amount of venom that would spontaneously ooze out. This suggests, like the study by Bush et al,[11] that the Extractor might make the envenomation worse by paradoxically increasing the amount of venom left in the wound.

Although each of these 3 studies was done independently of each other and using different methodology, they arrive at the same conclusion: the Extractor does not work, and it could make things worse. The only study that suggests the Extractor removes a clinically important amount of venom is an uncontrolled experiment using a rabbit model.[15] Unfortunately, this study was only published as an abstract, and the methodology is not described in detail. Furthermore, its results are suspect for many reasons. Rabbits have a very thin subcutaneous layer, unlike humans (and pigs).[16] Most snake envenomations are thought to occur in the subcutaneous layer.[17] It is possible that in Bronstein et al's[15] investigation the injected venom collected just under the rabbit's skin, where it was easily suctioned back out by the device. Because this inadequately documented single abstract reports a finding that is vastly different from all the other studies that follow, its conclusions are questionable and may be erroneous.

If there was controversy before, the study by Alberts et al[10] adds to the growing pile of evidence against the Extractor. This study should change our practice. We should stop recommending Extractors for pit viper bites, and the manufacturer should certainly stop advertising that they are recommended medically as the only acceptable first aid device for snakebites.

Because it is becoming clear that this gadget does not work, future investigations should focus on other first aid techniques, such as pressure-immobilization or others yet to be discovered. Meanwhile, the best first aid for snakebite is a cell phone and a helicopter.

The author reports this study did not receive any outside funding or support.

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Suction for Venomous Snakebite: A Study of "Mock Venom" Extraction in a Human Model

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See related article, p. 187.

Study objective: We determine the percentage of mock venom recovered by a suction device (Sawyer Extractor pump) in a simulated snakebite in human volunteers.

Methods: A mock venom (1 mL normal saline solution, 5.0 mg albumin, 2.5 mg aggregated albumin) radioactively labeled with 1 mCi of technetium was injected with a curved 16-gauge hypodermic needle 1 cm into the right lateral lower leg of 8 supine male volunteers aged 28 to 51 years. The Sawyer Extractor pump was applied after a 3-minute delay, and the blood removed by suction was collected after an additional 15 minutes. A 1991 Siemens Diacam was used to take measurements of the radioactive counts extracted and those remaining in the leg and body.

Results: The "envenomation load," as measured by mean radioactivity in the leg after injection, was 89,895 counts/min. The mean radioactivity found in the blood extracted in the 15 minutes of suction was 38.5 counts/min (95% confidence interval [CI] –33 to 110 counts/min), representing 0.04% of the envenomation load. The postextraction leg count was less than the envenomation load by 1,832 counts/min (95% CI –3,863 to 200 counts/min), representing a 2.0% decrease in the total body venom load.

Conclusion: The Sawyer Extractor pump removed bloody fluid from our simulated snakebite wounds but removed virtually no mock venom, which suggests that suction is unlikely to be an effective treatment for reducing the total body venom burden after a venomous snakebite.

[*Ann Emerg Med.* 2004;43:181-186.]

INTRODUCTION

Recommendations about first aid for venomous snakebites have changed throughout the past few decades and remain an area of controversy. The techniques considered as possible first-line therapies include tourniquets or constriction bands, cryotherapy, electric shock therapy, compression, and immobilization (Australian method), as well as incision and suction. Most of these techniques have fallen out of favor with many experts because they lack strong scientific support and are fraught with potential complications.[1-5] Incision and suction, in particular, was at one time considered the standard of care but is now believed to pose more risk than benefit to the victim.

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Capsule Summary

What is already known on this topic

There are conflicting animal and preliminary human data that high-pressure suction applied to the fang marks shortly after pit viper envenomation may remove venom. The methodology of most of these studies is very poor.

What question this study addressed

This study examined the amount of radiolabeled "mock venom" that could be removed from the soft tissue of human volunteers in a simulated snakebite using a commonly available suction device.

What this study adds to our knowledge

Application of the suction device for 15 minutes shortly after the simulated snakebite was able to remove an average of 0.04% (maximum 1%) of the mock venom from the leg.

How this might change clinical practice

The use of mechanical suction as a first aid measure for pit viper envenomation is dubious because the amount of venom that is removed is clinically insignificant. The marketing of suction devices to the public for first aid treatment of snakebites is probably not appropriate.

The possibility of damaging underlying structures, introducing infection, and causing significant bleeding makes this approach ill advised in untrained hands. However, suction through the fang wound, without incision, could potentially remove venom without any morbidity to the victim.

In the United States, a product that is found in many retail, camping, and sports stores, called the Sawyer Extractor pump (Sawyer Products, Safety Harbor, FL) is touted by the manufacturer as "recommended medically as the only acceptable first aid device for snakebites." This device applies approximately 1 atm of suction (750 mbars),[6] can be carried in a first aid kit, and avoids the possible dangers of mouth suction. As the manufacturer claims, many experts consider this device an appropriate first aid measure. However, support for this device is not universal.[2,3,7-13] The scientific data supporting the device come from 2 published abstracts that have not yet led to peer-reviewed publications.[6,7] In this study, we use an experimental model in human beings to determine whether the mechanical force of suction applied by the Sawyer Extractor pump can aid in the removal of mock venom in a simulated snakebite.

METHODS

This was a prospective human trial approved by the institutional review board of the Community Medical Center of Central California, Fresno, CA. Participants were chosen from a pool of male volunteers, and written consent was obtained before the study.

Mock venom was made from the Technetium Tc 99m HSA Multidose kit (Medi-Physics, Inc., Amersham Healthcare, Arlington Heights, IL). Each injection from this kit contained 1 mL of normal saline solution with 5.0 mg albumin, 2.5 mg aggregated albumin labeled with 1 mCi of technetium-99m, and a maximum of 0.11 mg of stannous chloride. According to the manufacturer, more than 90% of the technetium in this product is bound to albumin. Because this kit is designed for use in human beings, the labeled protein is well tolerated in body fluids and tissues. This proteinaceous substance served as our mock venom and was injected in the right leg of volunteers. The injection was consistently performed on the lateral side of the lower third of the right calf by using a slightly angulated 16-gauge hypodermic needle to the depth of 1 cm. At this depth, the needle appeared to enter the subcutaneous fat of the leg.

After the leg was injected, the wound was allowed to bleed for a period of 3 minutes, at which time the Sawyer Extractor pump was placed on the wound. We chose to use a 3-minute delay because the manufacturer's instructions specify that the optimal time for placement is within 3 minutes. Three minutes is also a realistic time for a snakebite victim to locate and apply this device. The blood that oozed from the wound was collected before the start of suction to prevent any mock venom that bled from the injection from being counted as removed by suction. The bloody fluid removed by the Sawyer Extractor pump was then collected by maintaining constant suction for 5 minutes over the puncture wound. The fluid obtained was collected in the device's suction cup and placed under the Siemens Diacam (Siemans, Malvern, PA) for counting. Immediately after the first suction cup was removed, a second session of constant suction was performed for an additional 10 minutes and analyzed in the same manner.

In addition to measuring the blood collected with the Sawyer Extractor pump at 5 and 15 minutes, we measured the radioactivity in the syringe before and after injection, in the injected leg before and after suction, in the blood that oozed from the wound after 3 minutes, in the pelvis of the volunteer, in the chest of the volunteer, and in the background of the research area. One measurement was made for each data point. The location of all the mock venom could thereby be accounted for, as indicated by the sum of the radioactive counts. To ensure accuracy, we calibrated the Siemens Diacam. A series of 6 radioactive dilutions was used to determine what level of radioactivity over background the Diacam could detect. All counts measured were corrected for radioactive decay by using the physical decay chart for technetium-99m.[14] All results are expressed as a percentage of the total radioactivity, with 95% confidence intervals (CIs) indicated.

RESULTS

The age of our volunteers ranged from 28 to 51 years. All 8 volunteers had significant "envenomations," with a mean of 89,895 counts/min in the leg after injection. Seven volunteers were injected with a single kit, whereas 1 volunteer was injected by using a different kit with serendipitously lower radioactive counts (Table). After adding the material from the 5-minute and 10-minute suction sessions, the mean radioactivity found in the blood extracted in the 15 minutes was 38.5 counts/min (95% CI –33 to 110 counts/min; Figure), which represents 0.04% of the average injected counts or "venom" load that was initially in the leg before suction. The maximum radioactivity removed from any 1 leg was 159 counts/min, or 1.0% of the envenomation load for that individual.

The counts in the body (leg, lung, and pelvis) after extraction were less than the pre-extraction counts by a mean of –1,832 counts/min (95% CI –3,863 to 200 counts/min; Figure), which represents the maximum amount of mock venom that the Sawyer Extractor pump was able to remove from the body. When analyzing the data from this standpoint, we observed a mean 2.0% reduction in the total body "venom" load, with the maximum being 7.0% in 1 volunteer.

Our independent testing of the Siemens Diacam by using dilutions revealed that no significant radioactivity was missed because of machine error. We could easily detect 0.1% of the "venom" injected, which represented 258 counts/min on average above a background of approximately 1,750 counts/min.

Table.
Mock venom radioactive counts.

Volunteer	Envenomation Load	Pre-extracted Body Venom Load Minus Postextracted Body Venom Load	Measured Extracted Venom	Spontaneous Wound Ooze
1	86,834	691.80	–13.30	1,547.9
2	105,636	251.46	151.41	–5.03
3	91,200	5,394.56	76.80	934.37
4	84,005	880.13	–41.41	–3.017
5	92,893	–425.60	59.51	93.538
6	130,043	934.96	–44.93	979.6
7	113,344	5,984.34	–39.22	1,200.9
8	15,205	943.06	159.20	69.399
Mean	89,895	1,831.84	38.51	602.21

DISCUSSION

Venomous snakebite is a medical emergency and occurs approximately 8,000 times a year in the United States.[15,16] Fortunately, mortality in the United States is rare and ranges from 1 to 15 deaths a year, with 5.5 deaths recently reported by Langley et al.[15,17,18] Local injury resulting in long-term morbidity, however, is much more common and can occur in as many as 10% of all bites.[8] Suction is intuitively attractive because removal of venom would be expected to protect the victim from further harm.

Venom is a proteinaceous fluid; however, it also contains a wide variety of compounds, including inorganic substances, metals, free amino acids, peptides, nucleosides, carbohydrates, lipids, and biogenic amines.[19-24] The major toxic component of venom in most species is thought to be a peptide or polypeptide.[19] Exact replication of an innocuous mock venom is not feasible. We instead chose to simulate the proteinaceous character of venom by using a mixture of soluble albumin with an aggregated albumin that has particle sizes ranging from 10 µm to 150 µm.

The volume of venom injected during a snakebite varies widely and tends to increase with the size of the snake.[21] We chose to model our experiment with data for the western diamondback rattlesnake. This species is commonly implicated in venomous snakebites and, according to some experts, probably has been responsible for more deaths than any other species in the United States.[21] It represents a good model for our experiment because it can be a large snake with large wide fangs and copious amounts of venom. Intuitively, it would seem that these factors would favor removal of venom. One study concluded that a 60-cm western diamondback would yield approximately 0.1 mL of venom, whereas a 150-cm snake would inject 1.27 mL of venom.[21] According to this study, we chose to inject 1 mL of our mock venom solution.

In our study, we chose to use the western diamondback fang dimensions as measured by Klauber.[25] For 51 western diamondbacks, fang lengths ranging from 9.6 to 12.9 mm were measured. We therefore chose 1 cm as our standard depth of injection. Although an appropriate fang length, this choice may favor a positive outcome for the Sawyer Extractor pump because, in an actual snakebite strike, the momentum of the snake would probably compress the soft tissue of the victim, which would lead to a deeper deposition of venom than the actual fang length.

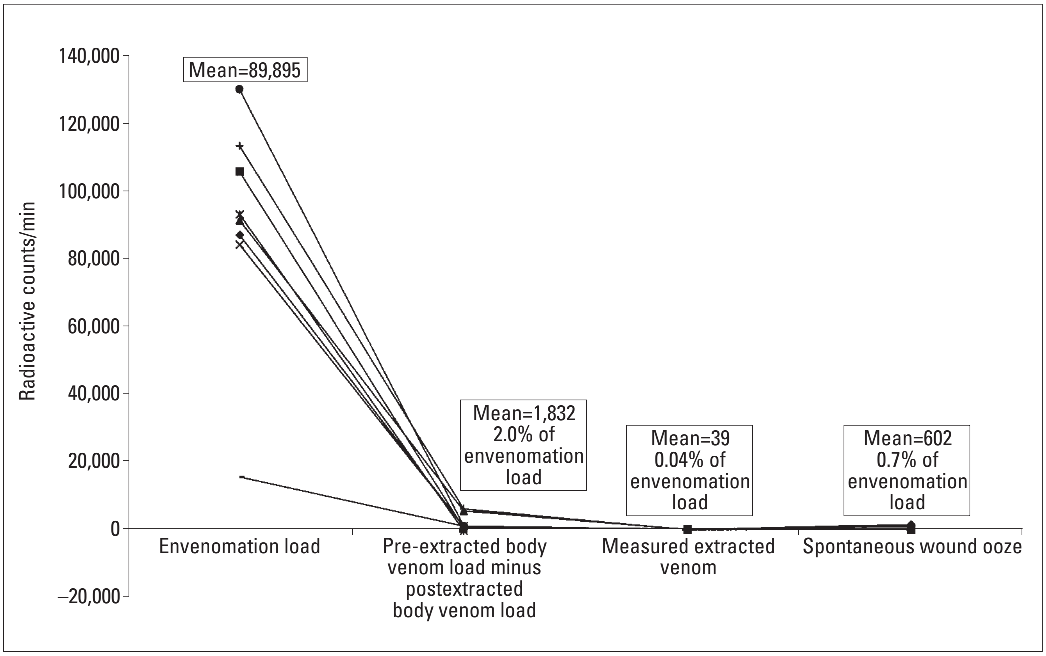
In a study of maximum fang width, values from 0.5 mm to 4.7 mm were obtained for the proximal fang, with an average value of 1.23 mm.[25] We therefore decided to use a 16-gauge needle because it has a width of 1.7 mm. These needles were curved in a rough approximation of fang diagrams.[25] We used 1 puncture instead of 2 punctures to minimize the trauma to our participants. Although this is a less common presentation of a snakebite, we have encountered this presentation in our clinical practice, and its occurrence is reported in the literature.[26,27]

Our results bring into question previous studies, which found benefit in the use of the Sawyer Extractor pump. These studies are found in 2 published abstracts by Bronstein et al.[6,7] The first abstract involved simulated envenomations into rabbits with I^{125}-radiolabeled *Crotalus viridis helleri* venom.[7] The Sawyer Extractor pump was placed and removed 23% of the venom in the first 3 minutes and 34% of the venom throughout 30 minutes of suction, as identified by a γ counter.

The second abstract by the same author was published a year later and applied the Sawyer Extractor pump to 3 people bitten by *Crotalus atrox* at a "rattlesnake rodeo."[6] Although the amount of venom is not known with certainty, this rattlesnake has an estimated lethal dose of 100 mg of venom for an adult human.[21] The extraction of microgram amounts of venom per milliliter, as demonstrated in this second study, would require huge volumes of fluid to be extracted to be of clinical significance. In fact, with the concentration of venom obtained in the first period of suction, more than 3.6 L of fluid would need to be removed to obtain 100 mg of venom, which is especially important, considering the reduction of venom concentration extracted over time in Bronstein et al's[6] study.

Recent studies by Bush et al[8,13] used the Sawyer Extractor pump in a porcine model and showed no benefit in preventing local tissue injury after injection with rattlesnake venom and perhaps some injury pattern associated with the device. Our study results, if extrapolated to a real snakebite scenario, show that no clinically relevant amounts of venom can be retrieved from a snakebite by using suction. The Sawyer Extractor pump continued to pull bloody fluid from our puncture site during the 15 minutes of the test; however, only 0.04% of the total "venom" injected was present in that Sawyer Extractor pump fluid. Instead of sucking out the "venom" in the subcutaneous layer, the Sawyer Extractor pump may collapse the deep wound and remove the superfi-

Figure.
Mock venom radioactive counts. Residual measurements do not total 100% because of measurement error and corrections for decay and background counts.



cial capillary blood that contains virtually no venom. A larger amount of mean radioactivity (602 counts/min) was present in the spontaneous wound ooze than in the fluid removed by the Sawyer Extractor pump (38 counts/min).

We also compared the leg counts after envenomation, but before suction, with the total body counts after suction. This calculation affords the most favorable analysis for the Sawyer Extractor pump because it assumes that the device is completely responsible for the decrease in envenomation load and does not take into account other unidentified variables. It is, nonetheless, only an extrapolation and not a direct measurement of venom extracted as described previously. With this "most favorable scenario," the total body counts after extraction were less than the pre-extraction leg counts by a mean of –1,832 counts/min (95% CI –3,863 to 200 counts/min). When the data were analyzed from this standpoint, there was a mean 2.0% reduction in the total body "venom load," with the maximum individual case being 7.0%, which also would most likely represent a clinically insignificant amount of venom removed.

If the use of the Sawyer Extractor pump fails to remove significant venom from a snakebite, then its application may cause more harm than good. Applying the device can increase local tissue damage, as well as worsen the situation of a snakebite victim by wasting valuable time.[8,13] Some snakebite victims may also misunderstand the product and seek no further medical attention.

There are a number of limitations to our test of the effectiveness of the Sawyer Extractor pump in a venomous snakebite scenario. The use of mock venom is an unavoidable limitation to this study. An inert substance with limited effect on the local tissue may behave differently than venom. However, we feel that the mechanical nature of suctioning is probably similar for venom and our proteinaceous fluid. Changing the characteristics of our experiment to include 2 puncture sites instead of 1, a shorter time between injection and Extractor application, different periods of suction, or injection at different depths or different anatomic locations may change the amount of venom removed. Moreover, all of our victims were supine throughout the experiment, which may not reflect the behavior of a true snakebite victim. The effect that body position would have on the retrieval of venom by suction is unknown. Our experiments used only a small number of participants, but the results are so consistent that, intuitively and statistically, we are confident that adding more participants would not change the outcome. Finally, we assume that a 0.04% to 2% decrease in venom is a clinically insignificant amount, although we are not aware of any experimental data to support this supposition.

In summary, we found that the Sawyer Extractor pump was unable to remove significant amounts of mock venom from our simulated snakebites. The potential pitfalls associated with use of the device, in conjunction with our results, suggest that the Sawyer Extractor pump and suction in general are not likely to be useful as first aid for venomous snakebites.

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Author contributions: MBA conceived the study, design, and research. MS supervised the study, data collection, trials, and modification of the study. FL participated strictly as a radiologist to inject radioactive isotope and operate the Diacam scanner. MBA and MS maintained the data and quality control. MBA drafted the manuscript, and MS oversaw the revisions. MBA takes responsibility for the paper as a whole.

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