

PREVENTING PAIN FROM PRESSURE ON SUBCUTANEOUS NEUROFIBROMAS

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INTRODUCTION

Neurofibromatosis Type 1 (NF1) is a neurological genetic disorder that affects 1 in 3,000 people worldwide [1], making it more common than multiple sclerosis and cystic fibrosis combined.

Nearly all persons with NF1 deal with pain on a daily basis. Cutaneous and subcutaneous tumors called neurofibromas, affect 94% of people with NF by the time they are 30 years old [2]. Pressure on these neurofibromas pinch the underlying nerve, causing significant pain. The sensation is described as a “sharp pain” and can arise from constant or sudden pressure on or near a neurofibroma [3].

Reducing the intensity or duration of the pain has a positive impact on the quality of life for patients. Unfortunately, neurofibromas are difficult to remove with current medical technology such as surgery or radiation therapy, [4] and removal is not always permanent [4]. Assistive technology is therefore necessary to lessen the pain from neurofibromas that cannot be removed. The two primary approaches are physically preventing pressure and treating pain with painkillers. This paper focuses on the former approach and describes the preliminary design of a device to reduce the pain that persons with NF experience from pressure on neurofibromas.

DESIGN CRITERIA

In addition to reducing the pain felt by a person with NF, the device needed to meet a number of criteria. It needed to be portable, fit comfortably on neurofibromas of different sizes on different areas of the body, and be easily attachable to the body. Additionally, the device needed to be comfortable, unrestrictive, and affordable. For wide adoption, its appearance had to be such that a user would feel comfortable wearing it in public. Finally, in response to the growing importance of corporate social responsibility, the device design needed to follow ‘Cradle to Cradle’ [5] principles, using non-toxic, biodegradable or recyclable materials.

DESIGN

Concept

There were several possible solutions to the formulated problem. To arrive at the best solution, various concepts were generated and then evaluated against customer needs.

The main approaches considered included attempting to treat the pain experienced when a neurofibroma is hit, modifying an existing device (such as belts, knapsacks and watches) to reduce any inadvertent pressure which could be placed on neurofibromas, or developing a bandage-like device to prevent pressure on neurofibromas anywhere on the body.

The bandage-like device was chosen as it had the broadest potential benefit. Any development in the bandage-like device could be easily applied toward the modification of existing devices. As well, it is a proactive solution as it attempts to reduce pressure before pain is incurred on a neurofibroma rather than to treat the pain experienced.

As shown in Figure 1, the bandage-like device was to consist of a primary energy-absorbing or force-distributing material, and auxiliary outer-packaging and adhesive materials. The bandage-like device would be constructed such that energy from a bump or strike would be absorbed by the primary bandage material. Force would be distributed over a sufficiently large area such that the amount of pressure acting on the neurofibroma is minimized.

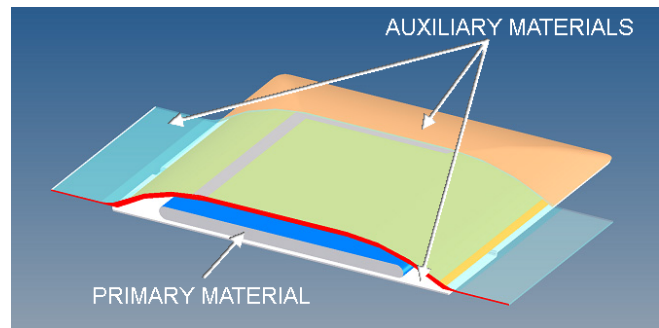


Figure 1: Cross-section of bandage-like device.

Primary component material

It was difficult to measure pain directly [6]. However, pressure on nerves and nerve endings is known to cause pain [6]. For preliminary design purposes, it was assumed that a greater reduction in pressure would result in a greater reduction in pain. Thus, testing was performed to determine the most effective material for distributing the force of an applied impact away from a neurofibroma.

The materials evaluated were gelatine, soft foam, petroleum jelly, water and air. A pressure sensor was placed under a thin plastic packet of each material. Two different loads were applied to each packet. The first load was relatively small in area and mass, simulating a small, pointed tap. The second load was larger in area and mass, simulating a larger, distributed impact to a neurofibroma. The resulting force on the sensor underneath the tested materials was measured to assess the pressure that would be transmitted to the neurofibroma. The area of the pressure sensor was smaller than that of an average subcutaneous neurofibroma, which is approximately 1 inch in diameter [7]. However, since the area was kept constant for each material tested, the assumption was made that differences in measured values distinguished the relative effectiveness of each material.

Table 1 summarizes the results of the materials test. Since the measured force of soft foam was the same under both loads, results were normalized to those of soft foam.

Table 1: Force Test Results Normalized to Soft Foam

Material	Small Area	Large Area
Gelatin	0.2	0.6
Soft Foam	1.0	1.0
Petroleum Jelly	1.2	0.4
Water	< 0.1	0.2
Air	4.5	< 0.1

It was found overall that water performed best, with the lowest force measures relative to soft foam. Water has the advantage of being among the most benign materials and therefore meets environmental design criteria. In future designs, some substance may have to be added to the water to prevent microorganisms from growing.

Primary component configuration

Once the material was chosen, a similar procedure was used to select among configurations of water pouches. The layout and thickness of the water-packet needed to be tested in order to determine the

optimum design. Since the packet may lie in a vertical position while in use, gravity may have the effect of gathering the water to the bottom of the water-packet, leaving the top vulnerable. This was considered to be more of a problem for the larger enclosures than for the smaller enclosures.

It was decided that cells of water would be made using smaller plastic bags and then placed within larger bags to make the larger sized packets; this would keep some of the water from gathering at the bottom of the device, maintaining a relatively even distribution. Fifteen prototype configurations were considered in the initial stage of testing. Each consisted of different water volumes in small and large plastic enclosures.

First testing was performed with the prototypes flat, in a horizontal position. The result was that 2 small bags (2in x 3in) each with 22.5mL of water inside 1 large bag (3in x 4in) with an additional 15mL of water performed the best of all 15 tested configurations. The best 6 configurations were selected for vertical testing. In the vertical testing, each prototype was clamped in a vertical position against a pressure sensor and a vice was used to apply a horizontal force. The same configuration was again the most effective at reducing the pressure transmitted to the pressure sensor.

To validate the choice of the water pouch configuration, a test subject (user) of 18 years with NF1 placed each of the 6 prototype configurations on the same neurofibroma on his forearm as shown in Figure 2, and evaluated them.



Figure 2: Validation of prototype configuration.

The user first tapped the prototype above the neurofibroma gently and if that did not hurt, he applied greater pressure. He then ranked the level of pain from this pressure on a scale of 1-10. Without the device, the pressure would cause a pain level of 10. All 6 of the devices reduced the level of pain to a 3. The user

said that although the devices worked equally well to reduce pain, the device with 2 small bags each with 22.5mL of water, inside 1 large bag with 15mL of water was the thinnest and most discrete of those that he tried [8]. This prototype was worn for an entire day without discomfort [9].

Auxiliary components

Several factors were considered when developing the remaining auxiliary components of the prototype. These factors included the materials to be used for the outer-package, as well as the size and thickness of the prototype.

The auxiliary material used to house the water-packet was a pouch constructed of cotton on one side (the side in contact with the skin) and a vinyl covering on the other. Cotton is not only comfortable and breathable [10], but absorbs moisture away from the skin which would make the prototype more pleasant on hot days than the plastic against the skin would. Cotton also allows heat transfer from the body to the water-packet, thus preventing freezing in cold weather. Vinyl insulates the water packet from the outside air, having a heat loss rate per hour of only 1.3 BTU [11]. Vinyl also does not rip easily, which helps prevent the water-packet from leaking if pinched by a sharp object [11].

The final design parameter that was addressed was to make the pouch washable. Since the device may be worn for extended periods of time, it is important that the water-packet be easily removable from the pouch for the cleaning of dirt, sweat etc. A small overlapped opening in the cotton material was included such that the water-packet could be removed from the pouch, but would not fall out on its own.

Several alternatives for the adhesive material that would attach the final device to the user were considered. For testing purposes, the adhesive for the prototype was medical tape. Further testing is required to determine the optimum adhesive in terms of its robustness and its effects on neighbouring neurofibromas.

CONCLUSIONS

The functional prototype reduces the pain persons with NF1 experience from pressure on neurofibromas. The principle strength of the design is its simplicity; it is easy to manufacture the device and its size can be easily modified to meet different design criteria.

The final design consisted of three components. The first component was a clear plastic packet divided into two cells, each cell containing 22.5mL of water,

within the larger packet containing 15mL of water. Its purpose was to absorb and distribute applied force away from the target area. The other two components consisted of a fabric pouch and an adhesive. These were used to hold the packet in place over a neurofibroma.

Through the preliminary user testing, the final prototype was shown to successfully meet its main criterion in reducing pain. However, a significant amount of additional testing is required to establish the effectiveness of the device. The design could be refined to extend its application, improve its appearance and durability, and reduce the economic and environmental costs associated with its use.

The prototype is portable and is readily attachable anywhere on the body. The prototype also performs well on the comfort criteria. It is flexible and does not limit mobility. The current level of pain to remove it is comparable to that of removing a bandage. Using improved adhesives or alternative attachment mechanisms could further reduce the discomfort. The prototype is also lightweight (80g). The simple material and manufacturing techniques imply that the device would be readily affordable.

There are a number of problems remaining. First, a stronger more durable packet that does not leak under high pressure is required. Second, alternative quantities of water and packet sub-compartment designs should be investigated to ensure that the current design is optimal. Alternative adhesive materials should be considered for reducing the discomfort experienced when detaching the device from the user. Finally, although the prototype is 0.5cm thick and its nearly flat topology should make it aesthetically unobtrusive, this has yet to be confirmed with multiple users.

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