Graduated compression sock for stump oedema volume reduction in amputees

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Abstract: Stump oedema volume reduction post amputation is extremely important for proper prosthetic fitting and comfort of the patient. In India, elastic bandaging techniques consisting of oblique turns that alternatively ascend and descend after encircling the lower limb are most prevalent. Evidence available is against the use of these techniques as it is highly unreliable. It is a manual procedure wherein most patients do not understand the need to apply less pressure at the proximal end and more at the distal end of the stump. Interacting with numerous patients it was understood that they wouldn't be able to afford compression socks which are widely used as stump oedema control modality elsewhere. Therefore, in order to address the need for a compression gradient for stump oedema volume reduction, along with the need to cut maximum costs to enable usage by the poor sections of society in India, simple new designs were needed. This paper aims to introduce a graduated compression sock for the Indian scenario, which is cost effective, efficient, durable, washable, comfortable and sweat absorbent for stump oedema volume reduction in amputees. Initial design ideas involved bands of different elastic yarn content with no latex present that couldn't be taken forward due to manufacturing constraints. Implementation of the next set of proposed designs was done using crepe bandages (which have the required medical clearances). With these designs the required pressure gradient was achieved and measured.

Keywords
Elastic crepe bandages, amputees, stump, trans-tibial amputees, oedema, rehabilitation engineering, post-operative phase.

1. INTRODUCTION
Amputation is the surgical removal of all or part of a limb or extremity**.** For this research trans-tibial amputation was considered, as it is the most prevalent. It is the amputation of the lower leg between the ankle and knee, also called below knee amputation. The different stages after amputation are amputation dressing, acute postsurgical, pre-prosthetic, prosthetic prescription/fabrication, prosthetic training, community integration, vocational rehabilitation and follow-up. The area of stump oedema volume reduction falls under the pre-prosthetic phase which deals with residual – limb shaping, shrinking and increasing muscle strength.

After the operation for amputation, the tissue on the residual limb normally swells up. This swelling (oedema) is a normal reaction to the operation. Oedema forms following an amputation due to an inflammatory response. Exudate arises from soft tissue and medullary bone, as well as bleeding, causing the stump to swell. Amputees are often predisposed to oedema due to pre-existing vascular disease, and a reduced capacity for venous return. There is also an increased risk of dependent oedema due to immobility of the limb and the patient in general, and the effects of gravity during prolonged sitting. A patient who has undergone recent amputation is subjected to three different kinds of prosthesis: immediate post-operative fitting prosthesis (used immediately after amputation), temporary prosthesis (used during rehabilitation) and permanent prosthesis (worn after rehabilitation phase is completed and gait analysis is done). In order to fit the permanent prosthesis over an amputated part, there has to be sufficient oedema stump volume reduction. To achieve a pressure gradient, such that there is lesser pressure at the proximal end compared to the distal end of the stump sock.

The oedema reduction modalities used currently both within the country and abroad are: rigid dressings / removable rigid dressings immediately post-operatively, stump bandaging, use of stump shrinkers, compression therapy – pumps, elevation, massage, newer techniques involving use of silicone or polyurethane sleeves / liners, and use of temporary or interim prostheses. This does not guarantee a required compression gradient.

2. METHODOLOGY
At first the existing solutions and techniques had to be studied. Then the specific problems with each of these were evaluated. Based on these shortcomings, new designs were conceptualised. Elastic crepe bandages were chosen as the basic material as it has the required medical clearances. The plan for prototyping, testing and evaluation was generated. Solidworks software was used for initial basic designs. Once the prototypes were ready, testing phase was initiated by using an FSR (Force Sensing Resistor), an Arduino circuit and weights. The outputs for each prototype and its band were then tabulated and plotted as a graph. This further led to improved results and conclusions.

3. ENGINEERING SPECIFICATIONS

3.1 Materials for Prototype

Elastic crepe bandage (constituents – elastic yarn, polyester, latex, rubber, cotton) having the required properties of elasticity, comfort, ease of availability, and sweat absorbance especially necessary in the Indian scenario were used. Elastic bands of different lengths and widths were made use of in making the prototypes. Also used were elastic threads.

3.2 Prototypes

The designs translated into three prototypes. In the first one, (as shown in Figure1) elastic bands of different widths were arranged in a particular sequence to ensure an overall pressure gradient. These bands were stitched one after the other with minimal gap between the folds of elastic crepe bandages. The crepe and elastic bands chosen not only varied in width but also in length, according to the circumference of that part of the stump.

In the second prototype, elastic thread was used in gauging the elastic crepe bands in a tailoring machine. Three elastic crepe bands each having more than three layers of elastic thread gauged on to the back side (facing the skin on stump) were attached together as per required measurements.

The circumference of both prototypes was lesser at the distal end of the stump and higher at the proximal end i.e. there was a circumference gradient lengthwise.

Figure 1: Prototype - I

3.3 Calibration and Testing

A FSR (Force Sensing Resistor) was used to measure the pressure exerted by the prototype in different regions when donned. . Other sensors for example, piezoelectric sensors were not optimal for our requirement as they weren't flexible, reliable and easy to use like FSRs. An Arduino board connected to the computer recorded the values for the same. Different weights (50 gm, 20 gm, 10 gm, and 5 gm) were initially used to calibrate the FSR as these were in the optimal pressure range. A negative cast made to a patient's measurement was used for initial testing. All the bands of the Prototype-I were checked for pressure values by inserting the Force Sensing Resistor.

Table 1. Test results of each band of the Prototype-I

	FSR Analog Output (Averaged)	Force (N)	Pressure (Pa)	Pressure value (mmHg)
Band 1	679	1.9	995.3814302	7.465
Band 2	720	2.45	1283.51816	9.62717
Band 3	742	2.75	1440.683649	10.80601
Band 4	757	2.95	1545.460642	11.5919
Band 5-6	820	3.9	2043.151357	15.3248

4. RESULTS AND DISCUSSIONS

There are loopholes in the existing solutions for stump volume reduction post amputation. Not only is the method followed in India not completely effective, its cost could be largely reduced. People use crepe bandages to make a figure 8 or ace wrap around the stump. They aren't aware that a pressure gradient has to be applied while wrapping it around their stump. It is extremely important that the pressure applied in the distal end of the stump is high and decreases as it reaches the proximal end. This research aimed to lessen the manual conditions and depend less on people's ability to judge the pressure to be applied. The solution for oedema volume reduction outside India is the use of compression socks. The cost of this product is more than what poor people could be comfortable with. Using easily available materials and simple designs we aimed to reduce cost of the finished product. Thus, cost, pressure gradient, elasticity, durability, washability, sweat absorbance, and aesthetic appeal were the factors looked into.

It was observed that the second prototype was flimsy and didn't pass the subjective evaluation itself. The first prototype however, excelled in every feature. Not only was it well below Rs.100, it was also washable, comfortable/easy to wear, sweat absorbent and aesthetically appealing.

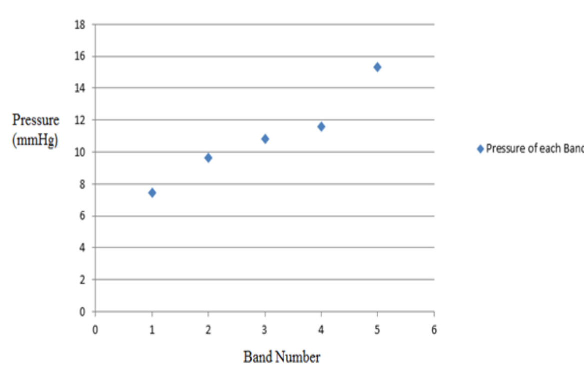

Figure 2: Pressure of each band in prototype – I clearly showing a pressure gradient from proximal to distal end

It also achieved the required pressure gradient requirement as can be seen in Figure2. This graph shows the pressure range for each of the individual band when the sock is donned on. Thus the pressure decreases from band 6 to band 1, 16mmHg to 7mmHg (approximately). The band numbering can also be referred from Figure 1. Thus as the circumference increases, pressure applied decreases from proximal to the distal end of the stump.

Apart from the above mentioned features it was found to be durable too. A durability test was carried out on it. Boxes with side 1 cm and area of 1 cubic square were drawn on each band using a black marker (as shown in Figure1). It was then donned on the negative cast and left for 60 hours. It was observed that after 60 hours a change of 0.9 – 1 mm increase on one of the band's horizontal black lines had occurred. The prototype has to be worn by patient for about 10- 14 days only and thus, this negligent change shows that prototype – I has good durability.

Therefore, this is a good and plausible solution for post-operative oedema reduction in amputees.

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