

New Spinal Immobilizer Vest for Prehospital Emergency Care

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Abstract

Post-traumatic spine immobilization plays an important role in the prevention of spinal cord injury. The splints are used today by the emergency department to immobilize the spine include a backboard and a immobilizer vest. A backboard bed usually is used for those injured in the open environment and a immobilizer vest, commonly is used for those injured in enclosed spaces such as a car. This study aims to design and manufacture a new spine immobilizer vest (NSIV) with features such as being lightweight and low volume, disposable and hygienic, very low cost, recyclability and the ability to be fitted in all emergency centers for replacing the old immobilizer vest. The design and construction of the NSIV was done in two stages. In the first step, with the help of measures obtained from measuring different people, the design and fabrication of prototype lattice polypropylene sheets were successfully designed and manufactured, and after the test on it, the necessary corrections were done. In the second step, the dimensions of the prototype were completed and were designed computerized and accurate with the help of AutoCAD software and precise cut molding was also made that was used to produce new spinal immobilizer vest (NSIV).

Keywords: backboard; disposable; immobilizer; spine; splint; vest

Introduction

According to the World Health Organization(WHO) as many as 500,000 people worldwide suffer from spinal cord injuries each year, which most of these spinal cord injuries are related to traffic accidents that are preventable. People with spinal cord injuries are 2 to 5 times more likely to die prematurely, with worse survival rates in low- and middle-income countries. Males are most at risk of spinal cord injury between the ages of 20-29 years and 70 years and older, while females are most at risk between the ages of 15-19 years and 60 years and older. Studies report male to female ratios of at least 2:1 among adults. The first essential measures for improving the survival, health and participation of people with spinal cord injury is pre-hospital management. quick recognition of suspected spinal cord injury, rapid evaluation and initiation of injury management, including immobilization of the spine. [1]

Results of a investigation shows the overall global incidence of TSI was 10.5 cases per 100,000 persons, resulting in an estimated 768,473 [95% confidence interval, 597,213–939,732] new cases of TSI annually worldwide. The incidence of TSI was higher in low- and middle-income countries (8.72 per 100,000 persons) compared with high-income countries (13.69 per 100,000 persons). Road traffic accidents, followed by falls, were the most common mechanism of TSI worldwide. Overall, 48.8% of patients with TSI required surgery [2]. These injuries can be greatly prevented by the use of standard procedures and the use of appropriate equipment outside the hospital by the emergency team. One of the equipments that is often used by emergency teams after events and accidents is splint. It is essential to use a splint to immobilize the limb, and the emergency team need a variety of splints. The splint immobilizes limb after injury. Movement of the injured limb can cause serious damage to the bones and soft tissue including arteries, veins, tendons, ligaments, peripheral nerves, and most importantly damage to the spinal cord which can cause death or paralysis of the lower extremities. The splint fixes the injured limb and relieves pain and allows the healing process to begin.

Seventeen randomized, controlled trials compared different types of immobilization devices, including collars, backboards, splints, and body strapping. For immobilization efficacy, collars, spine boards, vacuum splints, and abdominal torso strapping provided a significant reduction in spinal movement.

Adverse effects of spinal immobilization included a significant increase in respiratory effort, skin ischemia, pain, and discomfort [3]. Therefore, immobilizing is necessary to prevent these injuries. The splints have different types depending on the site of injury, including the lower extremities, upper extremities, neck and spine splints. Lower extremity splints are used to fix fractures and dislocations of the ankle, leg, knee, thigh. Upper extremity splints are also used for dislocation or fracture of the fingers, wrist, forearm, elbow, arm and shoulder. Splints usually are used to immobilize the upper and lower limbs but immobilization of the vertebral column and neck is more important.

A study that used healthy volunteers and video motion-capture methods found the motion of cervical spine (C-spine) was greater when volunteers were extricated onto a spine board than when they were able to exit the vehicle on their own, wearing a cervical collar (C-collar) for stabilization. [4]

Since the past the splints have undergone a great deal of change in materials, shape and use. In the past, upper and lower extremities were used to be fixed with the wooden splinters, which are almost obsolete today and can be used except where no other splinters are available. In recent years a variety of wire, metal and plastic have been used. Each of these splints has its own advantages and disadvantages. For example, the metal splint is bulky and does not let the patient take radiography. The inflatable splint is also expensive and not fixity enough to be affordable.

There are many different types of plastic splints, one of which is compact and available, making it more widely used. Many types of neck collar are also used to stabilize the neck, especially the Philadelphia open trachea neck collar.

Two types of splints are often used to immobilize the spine: a backboard bed and immobilizer vest.

A backboard bed is used for injuries and accidents when the injured is lying outdoors in supine position. For example, in falling from a height or motorcycle accident or accident that occurs in an open space backboard can be used. If the injured is kept inside the vehicle or mine or any

confined space as he/she is seated, the backboard bed cannot be used and the immobilizer vest must be used to stabilize the spine and move him/her out. immobilizer vest stabilizes the hip-to-head. Available old vests that are often imported have many disadvantages and problems especially in low- and middle-income countries, despite these problems, the role of emergency and pre-hospital care for injured spinal cord patients is not quite promising and satisfied, because no use of this vest, increases the risk for spinal cord injuries and causes more serious injuries such as death or paralysis and disabilities.

The project began with the design and construction of a new spinal immobilizer vest (NSIV). Following the increase in accidents, especially traffic accidents, and problems with spine stabilization and fixation, it was necessary to build NSIV. The purpose of this research project was to design and manufacture of a new splint, by doing so, we can play an important role in preventing spinal cord injuries and disabilities, and eventually replace the old one with the proposed one. The design is based on the assumption that when it is built, we can gain the special advantages of the splint such as disposability, lighter and compact size, recyclability, shooting capability, high stabilization and cheaper than current models.

Rigid cervical collars, long backboards, and straps remain the standard implements for immobilizing supine patients. Tape, foam blocks, and towels can complement the basic items and improve stability. Padding may improve positioning and comfort. Intermediate-stage devices include the short backboard and newer commercial devices. Properly used, all provide reasonable immobilization of the sitting patient [5].

To determine the amount of occipital padding required to achieve neutral position of the cervical spine when a patient is immobilized on a flat backboard. Neutral position was defined as the normal anatomic position of the head and torso that one assumes when standing looking straight ahead [6].

The original spinal longboard has been used in conjunction with the hard collar, blocks, and straps to achieve immobilization of the spine. There is currently evidence of the potential harm especially pressure sores over the sacrum. This particularly true in the case of spinal injury with no protective

sensation. The soft vacuum mattress offers a more gentle surface which protects from the effects of pressure sores while at the same time offers enough support if extended above the level of the head [7].

Spinal immobilisation using hard trauma boards and rigid cervical collars has traditionally been the standard response to suspected spinal injury patients even though the risk may be extremely low [8]. Field spinal immobilization using a backboard and cervical collar has been standard practice for patients with suspected spine injury since the 1960s. The backboard has been a component of field spinal immobilization despite lack of efficacy evidence. While the backboard is a useful spinal protection tool during extrication, use of backboards is not without risk, as they have been shown to cause respiratory compromise, pain, and pressure sores. Backboards also alter a patient's physical exam, resulting in unnecessary radiographs. Because backboards present known risks, and their value in protecting the spinal cord of an injured patient remains unsubstantiated, they should only be used judiciously [9]. Although using of backboard is not impossible now, NISV can be an appropriate appliance to instead the backboard.

The American College of Surgeons Committee on Trauma (ACS-COT), American College of Emergency Physicians (ACEP), and the National Association of EMS Physicians (NAEMSP) have previously offered varied guidance on the role of backboards and spinal immobilization in out-of-hospital situations. This updated consensus statement on spinal motion restriction in the trauma patient represents the collective positions of the ACS-COT, ACEP and NAEMSP. It has further been formally endorsed by a number of national stakeholder organizations. This updated uniform guidance is intended for use by emergency medical services (EMS) personnel, EMS medical directors, emergency physicians, trauma surgeons, and nurses as they strive to improve the care of trauma victims within their respective domains [10]. Spinal immobilization does not cause a change in vital signs despite a significant increase in pain and discomfort. Since no relationship appears to exist between immobilization and abnormal vital signs, abnormal vital signs in a clinical situation should not be considered to be the result of immobilization [11].

A thick soft pad lies between vest and head for protecting head in anatomic position and prevention pressure sore in occipital area, also it is possible to cover full surface with foam easily.

Immobilization of the spine of patients with trauma at risk of spinal damage is usually performed using a rigid long spineboard or vacuum mattress, both during prehospital and in-hospital care. However, disadvantages of these immobilization devices in terms of discomfort and tissue-interface pressures have guided the development of soft-layered long spineboards [12].

NSIS decrease the risk of pressure ulcer and traumatic pain, because immobilize the spine and distribute the pressure in all skin surface.

Rigid spinal immobilization is not without risk to the patient. It has been shown to decrease forced vital capacity in both the adult and pediatric populations,² compromise vascular function and increase risk of pressure ulcers,³⁻⁴ and can confound emergency department assessment of traumatic injuries by causing pain. Utilization of spinal immobilization when not indicated can lead to moderate to severe pain.⁵ Due to the potentially injurious nature of spinal immobilization, judicious use has become the standard recommendation [13].

It is better the NSIV used with a Philadelphia open trachea neck collar for making the most stabilization in neck region and supporting head and neck by soft foam to prevent pressure ulcer and comfort the neck and head. Also adjusting straps in thorax area can reduce the pressure.

Current immobilization techniques of the cervical spine are associated with complications including pressure ulcers, discomfort, and elevated intracranial pressures with limited access to the thorax and airway. In this study, a newly developed craniothoracic immobilizer (Pharaoh mattress) for critical care patients with cervical injury was tested for its restriction of cervical movement, peak interface pressures, comfort, and radiolucency, and compared with headblocks strapped to a spineboard. Cervical movement was measured by roentgen stereophotogrammetric analysis in 5 fresh frozen cadavers. Peak interface and discomfort pressures were measured in 10 healthy volunteers. Radiographic absorption was calculated by measuring the total emission radiation with and without immobilizer. The Pharaoh

mattress caused a mean restriction of 59% (SD: 15) flexion–extension, 77% (SD: 14) lateral bending, and 93% (SD: 3) rotation, compared with the unrestricted situation. No significant differences in restriction of cervical movement were found between headblocks strapped to a spineboard and the Pharaoh mattress. The mean peak pressures on the Pharaoh mattress were significantly lower than on the spineboard. Healthy volunteers gave significantly lower numeric discomfort scores on the Pharaoh mattress than on the spineboard. The Pharaoh mattress absorbed more x-rays than the spineboard. The Pharaoh mattress provides similar restriction of cervical movement compared with headblocks strapped to a spineboard but with lower interface pressures and increased comfort. This new mattress could be useful for immobilization of the cervical spine in critical care patients with mechanically instable spinal fractures [14].

Method of implementation and design:

In this study, the design and manufacture of the NSIV is discussed. The difference between this type of stabilizing vest and the various types currently used is its design, construction and material type.

The material used, must first be selected to produce the prototype. We were looking for a hygienic, disposable and most importantly, cheap and available material for making NSIV.

It should be capable of covering the spine. In the old model, wood pieces were used in a cloth base, that the disadvantages are high weight and volume, time consuming and costly production and high cost. So we had to look for a light, compact, and cheaper material. The use of metallic wire splint was rejected because of its heavy and inability in photography. Also, the use of wooden splints was not considered due to the heavy and expensive ones. Inflatable splint, also in addition to inadequate support, are also expensive. The only material that could be considered was the high strength, lightweight, compact, inexpensive plastic material. Among the plastic materials polyethylene sheets and solid polypropylene sheets as well as polypropylene lattice sheets were examined. Solid materials were excluded because of their heavy weight, lack of flexibility and lack of suitable coverage. But polypropylene lattice materials were considered. Its properties can be described as proper strength, despite being lightweight and reasonably priced. So a thicker type was chosen. The sheet with thickness of 8mm had the necessary strength and was not bendable. We considered the distance between the fold lines 5cm, which fortunately yielded the desired result. So for making this kind of vest, lattice polypropylene sheets, also known as Carton Plast sheets, were used. The next step is to design the splint on pattern cardboard according to the shape and anatomical dimensions of the body in the required areas. Designing the shape of the splint on the cardboard pattern according to the anatomical shape and dimensions of the body was required in the areas, that with the help of external sample and measuring the length and width of the body at the start and end points and randomly in different people (10 people) with different physical typical, was done to get a proper pattern. To prepare the design and construction pattern first, the physical dimensions of 10 adults selectively, from short to tall were examined. These measurements include:

Distance between the tip of the head to the buttocks in the sitting position (Table 1).

Table (1) Distance between the tip of the head to the buttocks in the sitting position.

Distance(cm)	Person Number
89	1
88/5	2
88/5	3
88	4
87/5	5
87	6
87	7
86	8
85	9

84	10
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Table (2) Head circumference

Head Circumference(cm)	Person Number
57/5	1
57/5	2
57/5	3
57	4
57	5
57	6
57	7
57	8
56/5	9
57	10

Table (3) Distance between tip to shoulder

Distance(cm)	Person Number
28	1
27/5	2
27	3
26	4
25	5
24/5	6
24/5	7
24	8
24	9
23/5	10

Table (4) Distance between end of neck from top to shoulder to armpit

Distance(cm)	Person Number
23/5	1
23	2
23	3
22	4
22	5
21	6
20	7
19	8
18/5	9
18	10

Table (5) Waist circumference

Distance(cm)	Person Number
115	1
110	2

105	3
100	4
100	5
95	6
85	7
85	8
80	9
75	10

To obtain the initial vertical splint length of 10 subjects, the distance from the tip to the buttocks was measured, with an average of 87 cm. After designing and structuring the initial pattern, the result was that it had to reduce 5 cm from this number, because the 5 cm end of the head was non-contact with the splint and covered with a sponge pad to soften the back and prevent painful pressure. So the real number for designing was chosen for the 82cm.

To calculate the width of the splint at the head and forehead area, the head circumference was measured in these 10 subjects to reach an average of 57cm, this number is consistent with medical findings. Of course, for the splint design, we should reduce 10 centimeters from this number because the location of the strips is on the forehead. So the actual number is 47 centimeters.

To get splint size from head to neck and shoulder, measurements were taken on these subjects, and we got an average of 25.4cm that here too with a terminal 5cm fraction we reached the actual number 20.5cm for the initial design.

In order to cover the splint on the body, the splint should be cut at the shoulders, because the shoulders prevent them from wearing and for this purpose, it was necessary to remove from splinters about the distance from the neck to the armpit which reached a mean of 21cm by measurement.

To obtain the vest length in the abdomen, an average waist circumference of 95 cm was obtained with a 15 cm reduction the actual number was 80 cm to attach the front straps.

The distance between the waist area and the buttock area in the sitting position was necessary because in this case the legs in front part prevented the splint from closing, this number was measured at the back of the subjects and the average was 15 cm. However, the number tilted to zero in the front so that the splint could be firmly closed in the abdomen.

After achieving all requirement sizes, dimension of prototype was obtained and the autocad plan was prepared. (Figure 1).

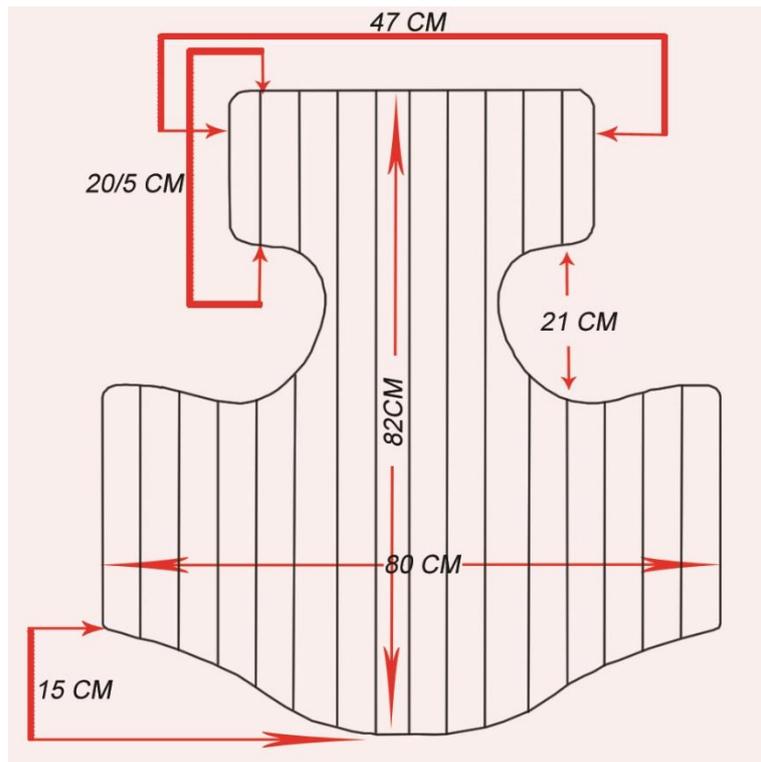


Figure (1) Autocad plan of NSIV with all measurements.

Then, by preparing a plastic lattice sheet (8mm thick cartonplast), we first adjust the sheets dimensions and then cut the pattern onto the sheet. Then, on the sample along the spine, we cut lines (folds) 5 cm apart to fold our lines so that they could be rounded on the body.

Next, strips (5 cm wide) were stitched on the sample. Then, the number and length of each strip were determined according to the anatomy of the body at the forehead, chin, chest, waist and lower leg and the strips were stitched onto the splint sheet with a special sewing machine.

In order to withstand the weight of the patient and for lifting the injured, two sets of staples are sewn under the armpit and sides. (Figure 2)

Also for protecting head in anatomic position and prevention pressure sore in occipital area, a thick soft pad lies between vest and head.



Figure (2) NSIV with its pad

After preparing the splint, it was tested on a number of individuals. The result showed that the prototype had to be modified in some cases. For example, the length of some strips, the angle, and the location were not exactly accurate.

Modified sample were designed and fabricated and tested by re-measurements. To test this sample after complete correction, the sample splint transferred at the Shiraz Emergency Center SEC and the Shiraz Corps Rescue Center SCRC to assess the specimen. Assessments indicated slight problems with the length of the lower adhesions and the long axis of the armpits, which were re-approved and corrected. (Figure 3).



Figure (3) putting NSIV in car

After making the prototype in terms of weight, volume, solidity, and final price, we took a closer look and found that it was lighter, smaller, compact, cheaper and more immobilization than the current prototype.

To mass-build this splint the manual method cannot be used. So the production method was changed. We first designed the template using the AutoCAD program with the help of a template delivery mechanism and template maker then, with the help of laser die-cut molds were prepared for cutting sheet. This method has a higher accuracy than the manual method and is considered less time-consuming to construct.

Sheets were cut using a heavy press machine (40 ton) after preparing die-cut mold. The samples were delivered for sewing. It should be noted that the tape cutter has been used for precise and rapid cutting of the strips. The samples were checked for accuracy and strength of tape stitching and sheath integrity and were packed in cellophane coatings.

The number of samples produced was 70, which was delivered to the Emergency and Airspace Rescue Center. For final approval of this product, it is necessary to submit the sample to the General Directorate of Medical Devices until after its review by medical universities construction permits become issued in Iran.

Conclusion:

The results of the production of emergency disposable splint were very useful and effective. By producing this product, we achieved the following conclusions:

- 1- The problem of budget shortages for emergency centers was resolved to purchase exterior typical because the typical made internally were much cheaper.
- 2- The sample made (compared to the foreign sample) is disposable, so it is hygienically highly effective in controlling the transmission of infection in open wounds or communicable diseases.
- 3- The method of production of this product is easy and fast (compared to similar old sample).
- 4- The materials of this product are chip and available.
- 5- In terms of employment, workforce is effective.

- 6- Sample control or modification can be done by experts.
- 7- In emergencies such as floods, earthquakes, etc., the community needs can be met as soon as possible.

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