NEW PERSPECTIVES ON EXTERNAL IMMOBILIZATION OF THE CERVICAL SPINE

Proefschrift

ter verkrijging van de graad van doctor aan de Radboud Universiteit Nijmegen op gezag van de rector magnificus prof. dr. J.H.J.M. van Krieken, volgens besluit van het college van decanen in het openbaar te verdedigen op maandag 18 december 2017 om 10:30 uur precies

door

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INTRODUCTION TO EXTERNAL IMMobilization OF THE CERVICAL SPINE
Introduction to External Immobilization of the Cervical Spine

The cervical spine is the critical connection between heart and mind. Any damage to the cervical spinal cord can be lethal. Although incidence is relatively low, with approximately four people in a population of 100,000 per year, the impact of spinal cord injury on an individual patient is high. Excluding those who die from an incident, each year approximately 12,000 people sustain a spinal cord injury in the US. The incidence of traumatic spinal cord injury in the Netherlands was estimated to be approximately 12 people per million.

As a first step in therapy, it is common in the case of (possible) cervical injury, to immobilize the vertebral column and spinal cord. According to Advanced Trauma Life Support (ATLS) guidelines, annually in the US, over five million people are temporarily immobilized for the suspicion of cervical fractures after a high energy trauma. This immobilization comes at an estimated annual cost of more than 75 million USD.

The ATLS protocol is not only applied in the US; it is the gold standard for primary trauma care in most western countries, including the Netherlands. A study performed in the Netherlands showed that, between 2008 and 2013, in more than 95% patients transported to the hospital after a high energy trauma, the cervical spine was immobilized. According to the Dutch Trauma Registry in 2015 more than 40,000 patients were transported by an ambulance and admitted to a Dutch hospital after a trauma.

This incidence of external immobilization of the cervical spine is even higher if other indications, like cervical radiculopathy, temporary stabilization after elective spinal surgery, and cervical mechanical instability caused by pathological tumors are included. To better understand the goals and biomechanical principles of external cervical immobilizers, it is important to understand the normal motion and anatomical restrictive structures of the cervical spine.

Figure 1.1 Pre-hospital immobilization of the spine after a high energy trauma. Note the use of a spine board, rigid collar and manual support by Emergency Medical Services Workers (right below).
New Perspectives on External Immobilization of the Cervical Spine

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Introduction to External Immobilization of the Cervical Spine

The normal motion of the cervical spine is created by movement of the seven cervical vertebrae (C1-C7) and their connection to the skull base (C0) and first thoracic vertebrae (Th1). They facilitate flexion, extension, rotation and lateral bending of the head in relation to the body. Cervical motion increases the field of optical view and reduces shock forces to the brain. Furthermore, the bony spinal channel protects the vulnerable spinal cord from external forces.

The normal motion of the cervical spine is complex and can be compared with a chain with different mechanical properties at each level. The atlanto-occipital joint (C0-C1) is responsible for most of the flexion and extension of the upper cervical spine, while little rotation occurs at this level. This in contrast to the atlanto-axial joint (C1-C2) which allows more than 50% of rotation of the cervical spine. The pre-axial levels C0-C1 and C1-C2 allow minimal lateral bending which is made possible by the lower cervical levels (C2-C7). During lateral bending, the oblique shape of the posterior facet joints causes intervertebral rotation.

The chain of cervical joints results in an average range of motion in the sagittal plane (flexion-extension) of 122° (SD 18°), in the coronal plane (left to right lateral bending) of 88° (SD 16°), and in the axial plane (left to right rotation) of 144° (SD 20°).

Anatomical structures restricting cervical movement

The normal cervical range of motion is limited by the muscle tension, bony structures and intervertebral ligaments.

Of these limiting factors in a conscious human, muscle tension is the most important. As cervical muscles are flexible, they are seldom ruptured, even in high energy trauma accidents. In case of spinal injury, the conscious patient will generally perceive cervical pain, which leads to increased muscle tension. As a consequence, a conscious patient with a recent cervical spine injury will not permit much cervical motion, while if the patient becomes unconscious, the muscle tension is lost.

In the comatose patient, the motion of the cervical spine depends on restriction by the bony structures and ligaments. Ligaments are strong limiters of intervertebral motion, independent of patient’s state of consciousness. Children and young adults have flexible ligaments, however as age increases, ligament elasticity decreases. Hence, age has a significant influence on the normal range of motion. During extreme cervical motion, especially in the elderly, ligaments can overstretch or even rupture. A rupture of the transverse ligament of C2 can cause mechanical instability of the atlantoaxial junction, while injury to the interspinous ligaments can allow the cervical spine to flex beyond normal ranges (Figure 1.2). Imaging techniques like conventional radiography can only detect mechanical instability in extreme positions of the cervical spine, which in these cases is not always possible.

The bony structures of the cervical column are the final structures to limit cervical motion. Its integrity can be altered by degenerative, auto-immune, infectious, neoplastic diseases or fractures. Due to its rigidity, bony structures can fracture during kinetic energy transfer. A fracture of the dens of C2 can be the cause of abnormal shifts of C1 in relation to C2, while injury of the vertebral body can induce axial instability with changed cervical motion.

To summarize, a disturbed function of muscle tension, ligaments or bony structures can result in abnormal motion of the cervical spine, endangering the spinal cord.

Figure 1.2 Increased intervertebral flexion after a rupture of the intraspinous ligaments.
Introduction to External Immobilization of the Cervical Spine

**Goals of cervical immobilization**

The following section introduces a number of reasons for restricting the movement of the cervical spine.

**Prevention of additional spinal cord injury**

To prevent (additional) spinal cord injury, the current ATLS and American Association of Neurological Surgeons (AANS) guidelines advise spinal immobilization of all trauma patients with a mechanism of injury having the potential to cause cervical spinal injury. Although there is no evidence for this practice, it is believed that during transport and in the emergency room, additional spinal cord injury can be prevented with the use of a semi rigid collar and a spine board. As there is no validated instrument available to assess spinal cord injury in the pre-hospital setting, and no prospective randomized studies are performed, the actual effectiveness of external immobilization can be questioned.

**Temporary reduction of mechanical forces enabling injured structures to heal**

To temporarily relieve injured structures from mechanical forces, enabling them to heal, external immobilization can be used; a range of collars and orthotic devices for this use are advised in protocols and textbooks. It is known that some of these devices restrict the range of motion of the cervical spine. However, it is unknown whether external immobilizers actually relieve the injured structures and whether patients have a better outcome with immobilization compared with functional movement.

**Reduction of pain**

In an attempt to reduce pain, some clinicians advise patients with spinal pathology, such as disc degeneration to restrict cervical movement using immobilizers. Although in one prospective randomized study it was shown that semi-rigid collars in combination with physiotherapy was better than a ‘wait-and-see’ policy in early cervical radiculopathy, it remains unclear whether external immobilization reduces neck pain resulting from degenerative disc diseases.

**Positioning of the head in relation to body**

In patients with muscle tension disorders, external immobilizers can help to keep the head upright in relation to the body. For example, patients with amyotrophic lateral sclerosis and Duchenne are known to have problems keeping their head upright. There is scientific evidence and clinical experience showing that for patients with muscle strength disorders, external supports attached to chairs can be of great help to position the head, and thus to immobilize the cervical spine.

**Awareness of (possible) spinal injury**

Sometimes the goal of external immobilization is to visually remind the patient and all those involved in care that the patient has sustained an injury to the cervical spine. This might be the patient’s own choice to warn others regarding the dysfunction of the cervical spine. It might also be the choice of a medical health care worker to remind other healthcare workers that the cervical spine is still injured. However, as a consequence of increased awareness of possible neck injury, patients can also perceive prolonged pain.

**Evaluation of external immobilization of the cervical spine**

The evaluation of the results of cervical immobilization depends on the primary question: was the external immobilization able to achieve its primary goal (as noted in the previous section)? Although frequently applied, there is little scientific evidence showing that immobilizers of the cervical spine are effective in achieving their primary goals. One of the fundamental aspects needed to answer this primary question, is to know what the ability to restrict cervical movement of a specific type of external immobilizer is. To better understand how cervical immobilizers restrict cervical movement, a closer insight into the biomechanical principles of these immobilizing techniques is needed.

**Biomechanical principles of external cervical immobilization**

The cervical spine can be immobilized either internally or externally. With internal immobilization techniques, devices are placed under the skin, either ventrally, dorsally of the spine, or both. As this thesis focuses on external immobilization of the cervical spine, these internal immobilization techniques fall outside its scope.

The biomechanical principle of external cervical immobilization techniques is to apply pressure on, or through the skin, in different anatomical zones (Figure 1.3). When these different support areas are interconnected, they are able to limit cervical movement. Theoretically, in a patient without muscle tension, an absolute rigid connection between the skull base (C0) and the first thoracic vertebrae (T1) will result in complete immobilization of the cervical vertebrae. However in practice, it is not possible to achieve a good grip on these structures alone. Therefore, other anatomical support areas are used to achieve indirect immobilization: the head, the neck and thorax.

**Supporting areas of the head**

The anatomical zones of the head can be separated into the occiput, parietal bone, frontal bone, upper jaw and lower jaw. The occipital area of the skull usually has little subcutaneous fat which enables pressure forces from the external devices to reach the skull base,
Introduction to External Immobilization of the Cervical Spine

The cervical spine is covered with skin and cervical muscles and local pressure can easily be applied. However, if external pressure alone is applied to the cervical area, increased motion can be expected at the ends of fixation. This mechanism of increased motion can be compared with a chain passing through a rigid tube: the enclosed parts of the chain will move less, while an increase of motion can be expected at the ends of the pipe. This so called “chain through pipe” or “junctional angulation” phenomenon is depicted in Figure 1.5. In clinical practice, most fractures occur at the upper and lower parts of the cervical spine. Therefore external pressure on the cervical area alone is, from a biomechanical point of view, not ideal.

To summarize, with the exception of the lower jaw, pressure on areas of the head are essential to achieve good external immobilization of the cervical spine.

Support areas of the neck

The anatomical zones of the neck can be divided into two areas: front and back. The front of the cervical spine is covered with soft structures, including the carotid arteries, jugular veins, esophagus and trachea. External pressure in this area can compromise these vital structures. Therefore, ideally, pressure is to be avoided in these regions. The back of the upper jaw area

Figure 1.3 Areas for external pressure to achieve immobilization of the cervical spine.

Figure 1.4 Flexion of the upper cervical spine during opening of the mouth without (left) and with (right) pressure on the lower jaw.

Figure 1.5 The “chain through pipe” or “junctional angulation” phenomenon: parts of the chain will move less while an increase of motion can be expected at the levels at the ends of the pipe.
Support areas of the thorax
The thoracic zones can be split into the anterior thoracic area and the posterior thoracic area and the shoulder girdles. The anterior thoracic area is relatively large; however, breasts can reduce the surface suitable for mechanical support on the front of the thorax. The subcutaneous fat layer at the sternum is relatively thin in most people. The dorsal side of the thorax is large and the sub-cuts and muscle groups can be thick and are used to sustain local pressure. As the ribs are directly attached to the thoracic spine, from a biomechanical point of view, thoracic support is a useful area for external immobilization of the cervical spine. The shoulder girdle areas are mobile in relation to the thoracic ribs and spine. Due to this mobility, immobilizing devices resting on the shoulder girdle areas, can have problems achieving the desired stability. The support pressure of a collar is lower in depressed shoulders, and increases as the shoulder girdles are elevated (Figure 1.6).

Current problems with external cervical immobilization and outline of this thesis
As stated above, there is limited scientific evidence that external immobilization is effective in achieving its primary goals, including prevention of additional spinal cord injury. The current guidelines are based on anatomical and mechanical considerations, and assumptions from clinical practice.13
Lack of a review of all cervical immobilizing techniques and their ability to restrict cervical movement

Although a number of review studies compared different cervical collars, no systematic review of all different types of immobilizers is available. Using the newly validated classification system described in chapter 2, a systematic literature study on all external cervical immobilizers and their ability to restrict cervical movement was performed.

Chapter 3 describes a systematic review of the different types of external cervical immobilizers and their ability to restrict cervical movement.

Lack of knowledge of frequently used groups of immobilizers and effects on intervertebral movement

As described above, there is limited knowledge of the ability to restrict cervical movement by various immobilizers. Furthermore, no studies have described the intervertebral movement in three dimensions, with frequently used immobilizing techniques.

Therefore, in chapter 4, we compared the ability of different immobilizers to restrict cervical movement, including: a rigid collar, sterno occipital mandibular immobilizer, halotraction, head blocks strapped to a spine board, and halovest. Intervertebral movement as a result of controlled forces was measured with radiostereometric analysis in three directions in cadavers.

Absent rationale for the use of a rigid collar in addition to head blocks

As recommended by the ATLS guidelines from 2008 to 2013, more than 80% of the patients in the region of Gelderland Zuid received a rigid collar combined with spine board with straps, and head blocks. This combination of techniques was advised by the American Association of Neurological Surgeons (AANS), based on an article by Podoloski in 1983, in which the range of cervical motion with rigid collars and a combination with sandbags were compared, using a goniometer.

Chapter 5 describes the value of the addition of a rigid collar with head blocks strapped to a modern spine board.

Lack of information of new pre-hospital immobilizing techniques

There is no good rationale for the use of a rigid collar in addition to head blocks. Pre-hospital spinal immobilizers of the future, include vacuum mattresses and the use of head blocks strapped to a padded spine board. There are only few studies that compare the characteristics of these immobilizers.

In chapter 6 we compared the results of two types of vacuum mattresses, two types of padded spine boards with head blocks.

Problems with external cervical immobilization in the critical care patient

There are several known risks of external immobilization of the cervical spine, including pressure ulcers, pain/discomfort, and increased intracranial pressures. Therefore, a new anatomically shaped mattress was created to immobilize the cervical spine while improving comfort and access to the face/neck/thorax, and reducing risks of pressure sores.

Chapter 7 presents the first results of the restriction of cervical movement by this so-called Pharaoh mattress, focusing on contact pressures, patient comfort and radiolucency.

The solutions presented in chapters 2 to 7 provide important insights in how to evaluate and improve the results of the primary goals for cervical immobilization. The answers to the research questions might have serious consequences for the way patients with suspected or proven cervical injury are immobilized.

In chapter 8 the results and impact of this thesis on healthcare are discussed and recommendations for future research directions are provided.

A summary of the conclusions of this thesis is given in chapter 9.


A VALIDATED CLASSIFICATION FOR EXTERNAL IMMOBILIZATION OF THE CERVICAL SPINE

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A Validated Classification for External Immobilization of the Cervical Spine

Abstract

Study Design: Interobserver and intraobserver reliability study.
Objective: To validate a new classification system of external cervical spine immobilization devices by measuring the interobserver and intraobserver agreement.
Methods: A classification system, with five main categories, based on the anatomical regions on which the device supports, was created. Twenty-eight independent observers classified fifty photographs of different devices, designed to immobilize the cervical spine according to the new proposed classification system. At least two weeks later, the same devices were classified again in a new random order. Before and after classification, all participants, answered questions about the usefulness of the proposed classification.
Results: The mean interobserver and intraobserver agreement Fleiss’ kappa was 0.88 and 0.91 respectively. Both are, according to the interpretation described by Landis and Koch, “almost perfect”. A majority of the participants answered that they needed a classification (89%) and considered the classification to be clear (93%). All the participants considered the classification to be useful in clinical practice.
Conclusion: This study showed that the new classification of external cervical spine immobilizers, based on anatomical support areas, has an excellent interobserver and intraobserver agreement. Furthermore the study participants considered the proposed classification to be clear and useful in clinical practice. Since the majority of patients with cervical spine injuries are treated with external immobilization devices, this new classification system can improve the closed treatment of cervical spine injuries in daily clinical practice. Furthermore it makes reproducible comparisons between groups possible, which is essential for further evolution of evidence-based spine care.

Study rationale and context

The majority of the cervical spine injuries are treated external immobilization. At this moment there are more than hundreds of different external devices available to immobilize the cervical spine. These often pre-fabricated devices are made by a variety of manufacturers in an unregulated area of medical practice. No validated classification system for these devices is currently available. The diversity of specific names for all these different immobilizers can be confusing for the clinician and can cause misinterpretation. Furthermore, with the absence of a valid classification system it is impossible to group these devices and report uniform data. The lack of comparable conservative treatment strategies is one of the major obstacles in gathering evidence based treatments for cervical spine injuries. To solve this problem, we introduce a classification system for external cervical immobilization devices. The classification system is based on the anatomical regions on which the device supports. From a hypothetically biomechanical perspective, the more rigid the connection between two regions and the more distance of the spine is bridged, the better the device will restrict motion of the spine. Based on that principle five main categories of devices were assigned: type A: cervical, type B: cervico-thoracic, type C: cranial, D: cranio-thoracic for non-ambulatory patients and type E: cranio-thoracic for ambulatory patients (Figure 2.1). A sub classification is based on material and length of the immobilization device (Figure 2.2).

Figure 2.1 Classification system for external cervical immobilization devices, based on the anatomical regions on which the device supports.
Objective

The primary objective was to validate a new classification system for external cervical spine immobilization devices, based on anatomical support area, by measuring the interobserver and intraobserver agreement. The second objective was to assess the usefulness of the classification system according to different clinicians.

Methods

To determine the interobserver and intraobserver agreement, photographs of different external immobilizers of the cervical spine were classified by observers from different medical fields related to spine care. To assess the usefulness of the classification system different clinicians answered a questionnaire.

Classification system: The new classification system, as described above and depicted in Figure 2.1 and 2.2, was printed on hard copy cards for all observers.

Selection of observers
Twenty-eight healthcare workers, all related to trauma and spine care, participated in this study as observers (Table 2.1). To increase the clinical validity participants were selected from seven different medical professions, with different degrees of education. Apart from information given on the hard copy card, none of the participants received additional information or education about the new classification system.

Clinical usefulness
All participants anonymously answered a questionnaire about their judgement whether this classification system could be useful for their clinical practice (Table 2.2).

Selection of photographs and devices
Fifty photographs of different devices designed to immobilize the cervical spine were selected from websites of medical device manufactures and our own photo database (see appendix 1). The photographs had to meet the following criteria: human adult, anterior-lateral view, daylight photograph, full-colour and relevant anatomy markers visible. Five devices of each category were present (Figure 2.3). The photographs were placed in a random order by Online Research Randomizer Form v4.0.2011 (http://www.randomizer.org).

Assessment process
Based on the classification description as depicted in Figure 2.1 and 2.2, all the participants classified the fifty photographs independently without time limitation on a hard copy form. Before and after the classification of all devices, all participants anonymously answered
Table 2.1 Medical professions of the participants.

<table>
<thead>
<tr>
<th>medical profession</th>
<th>number of observers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopedic surgery department</td>
<td></td>
</tr>
<tr>
<td>consultant</td>
<td>2</td>
</tr>
<tr>
<td>resident</td>
<td>2</td>
</tr>
<tr>
<td>General surgery department</td>
<td></td>
</tr>
<tr>
<td>consultant</td>
<td>2</td>
</tr>
<tr>
<td>resident</td>
<td>2</td>
</tr>
<tr>
<td>Intensive care unit</td>
<td></td>
</tr>
<tr>
<td>consultant</td>
<td>2</td>
</tr>
<tr>
<td>resident</td>
<td>2</td>
</tr>
<tr>
<td>nurse</td>
<td>4</td>
</tr>
<tr>
<td>Emergency room</td>
<td></td>
</tr>
<tr>
<td>nurse</td>
<td>4</td>
</tr>
<tr>
<td>Orthopedic appliance technicians</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Pre-hospital health care / ambulance personnel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Total number of observers</td>
<td>28</td>
</tr>
</tbody>
</table>

Table 2.2 Questionnaire and answers related to the proposed classification.

**Before classifying the devices:**

- Did you prescribe or apply an external cervical spine immobilization device during the last year? 28 (100%) 0 (0%)
- Do you know a classification system for external cervical spine immobilization devices? 4 (14%) 24 (86%)
- Are you in need for a valid classification system for external cervical spine immobilization devices? 25 (89%) 3 (11%)
- Is the concept of the classification, as presented in Figure 2.1, clear? 27 (93%) 1 (7%)
- Is the sub classification, as presented in Figure 2.2, clear? 27 (93%) 1 (7%)

**After classifying the devices:**

- too easy: 0 (0%)
- good: 28 (100%)
- too difficult: 0 (0%)

Figure 2.3 Photographs of different cervical spine immobilizers.
the questionnaire about the clinical usefulness of the classification. After at least two weeks (mean 20 days, range 14 to 29 days), the same photographs in a different random order were again classified by the same participants. The observers did not have access to their earlier answers after they completed the forms. The observers were instructed not to communicate with other observers before and between the assessments. All data was blinded and collected by a research fellow.

Analysis
For determination of the interobserver and intraobserver agreement, Fleiss’ multi-rater free-marginal kappa was calculated based on a nominal scale with a qualitative variable using StatTools. The kappa score was interpreted as described by Landis and Koch.

Results

Interobserver variability
The Fleiss’ kappa value of the first round was 0.85 (95%CI: 0.85-0.86) and of the second round 0.91 (95%CI: 0.91-0.92). The mean interobserver agreement of the two rounds was 0.88. The values per photograph are shown in Table 2.3.

Intraobserver variability
The mean Fleiss’ kappa value was 0.91 (range: 0.71-0.98, SD 0.06). The values per medical profession are shown in Table 2.4. Except for one ER nurse (intraobserver agreement: 0.71), all participants scored an intraobserver agreement of 0.80 or higher.

Clinical usefulness
The dichotomous and trichotomous results of the questions are presented in Table 2.2. All observers (100%) prescribed or applied one or more external immobilization devices during the last year. The vast majority of the participants (89%) were in need for a validated classification system for external immobilization of the cervical spine. Four participants (14%) reported to know a validated classification system. However, when asked to report what kind of classification they knew, no valid answer could be given. Before classification of the devices, most of the observers (93%) found the classification and sub-classification to be clear. After using the classification system, all participants (100%) considered the classification system to be useful in clinical practice.

<table>
<thead>
<tr>
<th>Table 2.3</th>
<th>Interobserver agreement kappa per subtype and photograph/device.</th>
</tr>
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<tbody>
<tr>
<td>type</td>
<td>subtype</td>
</tr>
<tr>
<td>A: cervical</td>
<td>A&lt;sub&gt;1&lt;/sub&gt; soft collar</td>
</tr>
<tr>
<td></td>
<td>A&lt;sub&gt;2&lt;/sub&gt; rigid collar</td>
</tr>
<tr>
<td>B: cervical-thoracic</td>
<td>B&lt;sub&gt;1&lt;/sub&gt; high thoracic support</td>
</tr>
<tr>
<td></td>
<td>B&lt;sub&gt;2&lt;/sub&gt; low thoracic support</td>
</tr>
<tr>
<td>C: cranial</td>
<td>C cranial traction</td>
</tr>
<tr>
<td>D: cranial-thoracic non ambulatory</td>
<td>D&lt;sub&gt;1&lt;/sub&gt; board with sandbags</td>
</tr>
<tr>
<td></td>
<td>D&lt;sub&gt;2&lt;/sub&gt; board with head blocks</td>
</tr>
<tr>
<td></td>
<td>D&lt;sub&gt;3&lt;/sub&gt; shaped mattress</td>
</tr>
<tr>
<td>E: cranial-thoracic ambulatory</td>
<td>E&lt;sub&gt;1&lt;/sub&gt; vest without scull pins</td>
</tr>
<tr>
<td></td>
<td>E&lt;sub&gt;2&lt;/sub&gt; vest with scull pins</td>
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<tr>
<th>Table 2.4</th>
<th>Intraobserver agreement kappa of the classification per profession.</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>orthopedic surgeons and residents</td>
</tr>
<tr>
<td>1</td>
<td>0.98</td>
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<td>4</td>
<td>0.91</td>
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<td>mean</td>
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</table>
Discussion

Findings from this study
- 89% of the observers said they were in need for a classification for devices that immobilize the cervical spine.
- According to Landis and Koch the interobserver and intraobserver agreement kappa values of this classification are rated “almost perfect”.
- 93% of the observers rated the classification to be clear, probably due to the simplicity of the system.

Previously published studies
- Currently there are no other validated classification systems for external cervical immobilization devices available.

Strengths of this study
- Introduction of a validated simple and clear classification system for external immobilizers of the cervical spine, considered useful in daily clinical practice by all observers.
- High validity due twenty eight observers, from different medical backgrounds and all related to trauma and spine care.

Limitations
- Although all observers rated this classification to be useful in clinical practice, this has not been proven by this study. Widespread implementation of this classification in clinical practice and research publications is needed to prove its usefulness in the future.
- This study shows excellent interobserver and intraobserver agreement results, however it is not yet proven that this classification correlates with a different range of motion. Nonetheless it is now possible to conduct systematic reviews, comparing different categories of immobilizers and their ability to reduce cervical range of motion.

Clinical relevance and impact
More than 65% of the cervical spine injuries are treated with external immobilization devices. Several hundred different immobilizers are available today. No classification system for closed treatment of spine injuries exists. This new uniform and validated classification for external immobilization of the cervical spine is clinically relevant to improve communication and treatment of patients with cervical spinal injury. Furthermore, with this new validated classification system, it is possible to group external treatment modalities of the cervical spine and to compare their effectiveness and clinical outcomes with other conservative and surgical treatments. This classification is fundamental for better evidence-based treatment of cervical spine injuries in the future.

Summary and Conclusion
- The classification system for external cervical spine immobilization devices, based on anatomical support areas, has an excellent interobserver and intraobserver agreement with Fleiss’ kappa values of 0.88 and 0.91 respectively.
- 93% of the participating clinicians considered the classification for external cervical immobilizers to be clear.
- After using the classification system, all observers considered the classification system to be useful in clinical practice.
- With this validated classification system for external cervical immobilizers, it is possible to compare different treatment-options for cervical spine injuries, essential for future evidence-based practice and research.

References
Appendix 1  Links to photographs of different cervical spine immobilization devices.

<table>
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<th>A1 soft collar</th>
<th>Acces Health Soft collar</th>
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Appendix 1  Continued.

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<td><a href="http://pharmaceuticals.indiabizclub.com/catalog/342604~hard+cervical+collar+%28+nu+ca01%29~new+delhi">http://pharmaceuticals.indiabizclub.com/catalog/342604~hard+cervical+collar+%28+nu+ca01%29~new+delhi</a></td>
<td>Hard Cervical Collar (NU CA01)</td>
</tr>
<tr>
<td><a href="http://www.mnclinic.ru/pics/korset-neck1.jpg">http://www.mnclinic.ru/pics/korset-neck1.jpg</a></td>
<td>Shantz collar</td>
</tr>
<tr>
<td><a href="http://www.remecare.co.uk/acatalog/Neck_Collars.html">http://www.remecare.co.uk/acatalog/Neck_Collars.html</a></td>
<td>Special Protectors® Adjustable Cervical Collar (Rigid)</td>
</tr>
</tbody>
</table>
Appendix 1 Continued.

### B1. High Thoracic Immobilizers

- **ProCare Vista Cervical Collar**
  - ![ProCare Vista Cervical Collar](http://www.sportsbraces.com/product-cart/pc/catalog/images_procare/base/vista.jpg)

- **ProCare Miami J Cervical Collar**
  - ![ProCare Miami J Cervical Collar](http://www.braceshop.com/product-cart/pc/catalog/images_categories/featuredprocaremiamij.jpg)

- **DeRoyal XTW Cervical Collar**
  - ![DeRoyal XTW Cervical Collar](http://jimmedical.com/proddetail.php?prod=XTW)

- **ProCare Vista Cervical Collar**
  - ![ProCare Vista Cervical Collar](https://www.sportsbraces.com/product-cart/pc/catalog/images_procare/base/vistagirl.jpg)

- **ProCare Aspen Cervical Collar**
  - ![ProCare Aspen Cervical Collar](http://media.betterbraces.com/media/catalog/product/cache/1/image/400x400/9df78eab33525d08d6e5fb8d27136e95/pr/procare_aspen_cervical_collar.jpg)

### B2. Low Thoracic Immobilizers

- **Malibu Cervical Collar**
  - ![Malibu Cervical Collar](http://trulife.com/all-products/orthotics/cervical/rigid-collar/malibu-cervical-collar)

- **Ossur Miami JTO® Thoracic Extension with Miami J Collar**

- **Aspen CTO**
  - ![Aspen CTO](http://www.cascadeorthotics.com/html/cto-cervicothoracic-orthosis.html)

- **Trulife S.O.M.I.**
  - ![Trulife S.O.M.I.](http://1.bp.blogspot.com/_ZWqgY-BROGHw/TUsV1HMl8_I/AAAAAAAACLw/k0I8uqVjhvE/s1600/somi37.jpg)

- **Philadelphia Tracheotomy collar with the Philadelphia Stabilizer**
### Appendix 1 Continued.

<table>
<thead>
<tr>
<th>Cranial traction</th>
<th>Description</th>
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<tr>
<td><img src="http://www.ankitscientific.com/products/tractiong10.jpg" alt="Image" /></td>
<td>ANKIT scientific industries Cervical Traction Kit</td>
</tr>
<tr>
<td><img src="http://www.mvmsinc.com/images/products/detail/DU53420140000.jpg" alt="Image" /></td>
<td>Duvo-med Deluxe Overdoor Traction Set</td>
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<tr>
<td><img src="http://www.tradeindia.com/fp1123262/Cervical-Traction-Kit-Sleeping-.html" alt="Image" /></td>
<td>Cervical Traction Kit - sleeping</td>
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<tr>
<td><img src="http://www.bcktherapyequipment.com/traction/saunderscervicaltraction7040.jpg" alt="Image" /></td>
<td>Cervical Traction System</td>
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<td><img src="http://product-image.tradeindia.com/00159484/b/0/Body-Care-Aids-Cervical-Traction-Kit-Sleeping-.jpg" alt="Image" /></td>
<td>Cervical Traction Kit - sleeping</td>
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</table>

### Appendix 1 Continued.

<table>
<thead>
<tr>
<th>D2 board with sandbags</th>
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<td><img src="http://www.ankitscientific.com/products/tractiong10.jpg" alt="Image" /></td>
<td>Photo from our own collection</td>
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<td><img src="http://product-image.tradeindia.com/00159484/b/0/Body-Care-Aids-Cervical-Traction-Kit-Sleeping-.jpg" alt="Image" /></td>
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### Appendix 1 Continued.

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<td><img src="http://www.sellesmedical.co.uk/product_images/0000/5843/FERHI_2.jpg" alt="Image" /></td>
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<td><img src="http://t3.gstatic.com/images?q=tbn:ANd9GcQ3mwNye7E0gQIJUN2vWwq_EfRXw-bvAAz8mGf6V5-96JCdMg&amp;t=1" alt="Image" /></td>
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<td><img src="http://www.feuerwehr-heiligenstadt.de/uploads/pics/Spine_board2.jpg" alt="Image" /></td>
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<tr>
<td><img src="http://i.dailymail.co.uk/i/pix/2010/11/20/article-1331544-0C2858C5000005DC-986_468x329.jpg" alt="Image" /></td>
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<table>
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<th><strong>D² shaped mattress</strong></th>
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<tr>
<td><img src="http://www.pacificrescue.com/Product-Images/EMS%20Immobile-Vac%20mattress.bmp" alt="Image" /> Pacific rescue EMS Immobile-Vac Systems</td>
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<tr>
<td><img src="http://www.spservices.co.uk/item/Brand_SnowsledVacuumMattresswith-Carry8agVacPump_65_0_3296_0.html" alt="Image" /> SPServices Snowsled Vacuum Mattress</td>
</tr>
<tr>
<td><img src="http://www.cupola.be/catalog/images/cat_immob_prod_futur.jpg" alt="Image" /> Cupola VTI Söhngen Vacuummattress</td>
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### Appendix 1  Continued.

**E1 vest without skull pins**

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<tr>
<td><img src="http://farm4.static.flickr.com/3434/3817050967_a98c6a5ec7.jpg" alt="Minerva cast" /></td>
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<tr>
<td><img src="http://trulife.com/images/online-shop/products/large/Orthopaedics/US/Cervical/non_invasive_halo.jpg" alt="Trulife Lerman Non-invasive Halo" /></td>
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**E2 vest with skull pins**

<table>
<thead>
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<th>Image</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="http://www.eastin.eu/en-GB/searches/products/detail/database-rehadat/product-OW_00326" alt="Minerva cast" /></td>
<td></td>
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<td><img src="http://eastmedicalsupply.com/index.php/main_page=product_info&amp;Path=3&amp;products_id=329" alt="Trulife PMT Halo vest orthosis" /></td>
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<tr>
<td><img src="http://www.360oandp.com/Upload-Image/HALO.jpg" alt="360 Orthotics&amp;Prosthetics Halo System NEO-CERV 1233" /></td>
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<tr>
<td><img src="http://www.ortiz.biz/index.php?seccion=1&amp;id_producto=3332" alt="Ortiz halo craneal cervical con chaleco ch 14091403" /></td>
<td></td>
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<tr>
<td><img src="http://shop.goldingsortho.co.za/img/p/250-300-thickbox.jpg" alt="Golding’s Orthopaedic Centre Resolve Halo System" /></td>
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THE ABILITY OF EXTERNAL IMMOBILIZERS TO RESTRICT MOVEMENT OF THE CERVICAL SPINE: A SYSTEMATIC REVIEW

Micha Holla, Joske M.R. Huisman, Nico Verdonschot, Jon Goosen, Allard J.F. Hosman, Gerjon Hannink

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The Ability of External Immobilizers to Restrict Movement of the Cervical Spine: a Systematic Review

Abstract

Purpose: To review the ability of various types of external immobilizers to restrict cervical spine movement.

Methods: With a systematical review of original scientific articles, data on range of motion, type of used external immobilization device and risk of bias were extracted. The described external immobilization devices were grouped and the mean restriction percentage and standard deviation were calculated. Finally, each device was classified to its ability to restrict movement of the cervical spine, according into five levels of immobilization: poor (MIL <20%), fair (MIL 20-40%), moderate (MIL 40-60%), substantial (MIL 60-80%), and nearly complete (MIL ≥80%).

Results: The ability to reduce the range of motion by soft collars was poor in all directions. The ability of cervico-high thoracic devices was moderate to substantial for flexion/extension but poor to moderate for lateral bending and rotation. The ability of cervico-low thoracic devices to restrict flexion/extension and rotation was moderate to substantial, whereas the ability of these devices ability to restrict lateral bending was poor. All cranio-thoracic devices for non-ambulatory patients restricted cervical spine movement substantial to nearly complete in all directions. The ability of vests with non-invasive skull fixation was substantial to nearly complete in all directions. No studies with healthy adults were identified with respect to cranial traction and halo vests, their ability to restrict cervical movement.

Conclusions: Soft collars have a poor ability to reduce mobility of the cervical spine. Cervico-high thoracic devices primarily reduce flexion and extension, but they reduce lateral bending and rotation to a lesser degree. Cervico-low thoracic devices restrict lateral bending to the same extent as cervico-high thoracic devices, but are considerably more effective at restricting flexion, extension, and rotation. Finally, cranio-thoracic devices restrict movement of the cervical spine substantial to nearly complete.

Introduction

Worldwide, hundreds of patients receive external immobilization of the cervical spine each day, and this intervention is believed to have high clinical significance. In the United States alone, each year five million patients receive some form of spinal immobilization.

Several methods to externally immobilize the cervical spine are currently available and are based on immobilizing specific parts of the body. The Advanced Trauma Life Support foundation recommends immobilizing all patients with potential cervical spine injury using a rigid collar, head blocks, and spine board. However, there is currently insufficient evidence to support this guideline.

To date, no properly designed randomized controlled trial has compared the various methods of spinal immobilization with respect to their ability to reduce mortality, prevent neurological disability, increase spinal stability, and minimize adverse effects in trauma patients. Before clinically relevant studies of various treatment strategies can be reported, consensus is needed regarding the definition of currently available immobilizers and their ability to restrict cervical movement.

Previously published systematic reviews of the ability of immobilizing devices to restrict cervical movement specifically addressed individual types of collars and orthotic devices. However, to date, no study has systematically reviewed all available types of devices designed to restrict cervical movement (e.g., cranial traction, spine boards, Minerva casts, halo vests, etc.).

One reason for this lack of systematic reviews may be the historical absence of a validated system for classifying this wide range of external cervical devices. Recently, however, a validated classification system to define and compare various types of external cervical immobilizers was published.

The objective of this study was to systematically review all articles published regarding external cervical immobilizers and to quantify and compare their ability to restrict movement of the cervical spine.

Materials and Methods

Database search

A literature search was performed in accordance with the 2009 Method Guidelines for Systematic Reviews in the Cochrane Back Review Group (CBRG). The electronic databases MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), and the CBRG trials register were searched by one reviewer (author J.H.) in order to identify all studies regarding external immobilizers and their ability to restrict movement of the cervical spine. All databases were searched from their inception through August 1, 2012. References from relevant research articles and systematic reviews were scanned and used to identify additional studies. The search strategy is presented in detail in Appendix 3.1.
Criteria for eligibility and selection of articles
After duplicate articles were removed, all articles identified from the database search were screened for eligibility based on the title and abstract. The eligibility criteria were established by two reviewers (authors J.H. and M.H.), who combined the objective of this study with the CBR guidelines for systematic reviews.8

Only studies that reported the reduction in cervical motion in at least one of three planes (sagittal for flexion and extension, coronal for lateral bending, and axial for rotation) were included. Articles written in English, German, Dutch, and Latin based languages were included. Articles in any other languages were excluded. Studies that only reported the reduction in intervertebral distance in mms were excluded. Only studies performed in healthy adults (and/or human cadavers) with no history of spinal pathology were included, and only studies that reported the reduction in cervical motion compared with that subject’s normal motion were included. Only studies that used a reliable and reproducible measuring method as described by Williams et al. (e.g., electro-magnetic field, 3D optical-electrical devices, digital dual inclinometers, goniometers, or conventional radiography) were included.9 Studies that relied solely on a visual estimation for determining restricted movement were excluded. Finally, studies that reported only the mean reduction in motion rather than individual results were excluded.

Quality assessment of included articles
Full-text versions of all included articles were downloaded and assessed for potential bias by two reviewers (authors M.H. and J.G.), who applied the Quality Assessment Tool for Quantitative Studies (EPHPP).8 Selected studies were rated strong/moderate/weak for the following components: selection bias, study design, confounders, blinding, data collection methods, withdrawals and dropouts. Studies with three or more strong ratings and without any weak rating were considered to be studies of good quality. Studies rated with two or more weak ratings were considered low quality studies. Other studies were rated moderate. Low or moderate quality studies were marked with an asterisk in the tables and figures; these studies were excluded from our conclusions. One of the review authors (M.H.) was also an author on one of the included articles and was excluded from any decision-making regarding this article.

Data extraction
The following data were extracted from the included articles: first author’s surname, year of publication, type and number of participants, name of external immobilizer studied, and mean range of motion with standard deviation and/or 95% confidence interval. If data were not available in the article’s text or tables, the results were extrapolated from the graphs. If standard deviation was not reported, it was calculated from the 95% confidence interval.10 If the percentages of unrestricted motion for lateral bending and/or rotation were reported separately for the right and left sides, the mean and standard deviation were calculated using the mean of the variances.11

All immobilizers described in the selected articles were classified independently by two reviewers (J.H. and M.H.) in accordance with a validated classification system.7 This system is based on the anatomical region (or regions) that the device supports and includes the following five main types (Figure 3.1): A, cervical devices; B, cervico-thoracic devices; C, cranial traction; D, crano-thoracic devices for non-ambulatory patients; and E, cranio-thoracic devices for ambulatory patients.

For all immobilizers analyzed, a mean restriction percentage (MRP) was calculated. First, we obtained the difference in the reported cervical range of motion with and without the immobilizer; this difference was then divided by the cervical range of motion without the immobilizer. In clinical practice, patients with cervical spine injury, a certain safety margin must be applied. Therefore, a minimal immobilization limit (MIL) was introduced. The MIL was calculated by subtracting one standard deviation from the MRP. Finally, to classify the ability of each external immobilizer to restrict cervical mobility, we defined the following five levels of immobilization: poor (MIL <20%), fair (MIL 20-40%), moderate (MIL 40-60%), substantial (MIL 60-80%), and nearly complete (MIL ≥80%).

Results
Database search results and included articles
Our database search yielded 2272 records plus six additional records from the references therein. After removing 99 duplicates, the total number of potentially eligible articles was 2179. After screening the abstracts and titles, 2131 articles were excluded. Three records were excluded due to the language of the text (Hebrew, Russian, and Slovak). Forty-eight full-text articles were retrieved for further analysis, ten of which were subsequently excluded because they did not report standard deviations or 95% confidence intervals.

An additional 25 full-text articles were excluded because the reduction in motion was reported as the mean for the entire cohort, and MRP could be calculated for these studies. Thus, 13 biomechanical studies investigating 23 different cervical immobilization devices in healthy adult volunteers were included in the final analysis. Figure 3.2 provides a flowchart depicting the inclusion and exclusion of articles used in this systematic review.

Quality assessment
The results of quality assessment of all included studies are presented in Table 3.1. Three of the 13 studies were rated as a study of moderate quality. The study by Gavin et al. excluded seven of their 20 subjects because of poor fluoroscopy image quality.12 Their reason for excluding these subjects was related to the shape and movement of the cervical spine and therefore represents a potential bias. Hammacher et al. tested each immobilization device on a small number of participants and found major differences in MRP between left and right rotation for all immobilization devices.13 In some cases, their reported standard deviation was larger than the mean value.14-16
Figure 3.1: Validated classification system for external cervical immobilizing devices based on the anatomical regions in which the devices provide support.7

* This device is composed of materials without any rigid components.
** If the device supports an anatomical border, its category is increased to the higher level.
*** A device that provides any support caudal to the xiphoid process is classified as a type B2 low cervico-thoracic device.

Figure 3.2: Flow diagram of the inclusion and exclusion of articles used in this review.

13272 records identified by electronic database search
2272 records removed by duplicate records
20953 abstracts screened according to inclusion criteria
99 duplicate records removed
20894 records excluded based on screening title and abstract
3 records excluded based on language
48 full text articles assessed for eligibility
10 full text articles assessed for eligibility
25 full text articles excluded for reporting in mean reduction of neck pain
13 full text articles included in qualitative synthesis

48 full text articles identified by electronic database search
99 duplicate records removed
6 records identified by references from other articles
2 records excluded based on duplicate records
2 records excluded based on title and abstract
99 full text articles included in this review.
Johnson et al. tested six different immobilizers. Three immobilizers were applied to each subject without any further clarification. As randomization was not described and age and gender were not evenly distributed in different immobilizers, this study was considered to have potential selection bias and/or confounding. Because these three studies met our inclusion criteria, their results are included in the tables and figures (marked with an asterisk); however their outcomes were excluded from our analysis and final conclusions. Due to the relatively low number of relevant studies and the wide variation in their methods, no meta-analysis was performed.

Types of immobilizers and subjects described in included articles
Table 3.2 summarizes the number of studies that included each immobilization group. No cadaver-based studies were included. Cervico-high thoracic devices (e.g. Aspen brace, CBreeze, Miami J, Necloc, Philadelphia, Stifneck, Vertebrace, Vista, XTW, and Yale models) were well-described in several studies.1, 6, 12-19 None of the studies reported the effect of rigid cervical collars (type A2), cranial traction (type C), or halo vest (type E2) devices on cervical mobility.

The ability to restrict cervical mobility
Table 3.2 and Figure 3.3 summarize MRP and MIL for each device. The ability of soft collars (type A1 devices) to restrict the range of motion in all directions was poor (MIL: 0-22%); no suitable reports for rigid collars (type A2) were available. The ability of cervico-high thoracic devices (type B1) to restrict flexion and extension was moderate to substantial (MIL: 42-78%), poor to moderate for lateral bending (MIL: 13-40%), and poor to moderate for rotation (MIL: 13-40%). Compared to other types of immobilizers, the type B1 devices had relatively high standard deviation (up to 34%) and wide variability among studies that used the same device.

The ability of cervico-low thoracic devices (type B2) to restrict flexion/extension and rotation was moderate to substantial (MIL: 57-88%), whereas the ability of these devices to restrict lateral bending was poor to moderate (MIL: 12-48%). None of the studies evaluated cranial traction devices (type C) with respect to restricting cervical mobility. The ability of cranio-thoracic devices for non-ambulatory patients (type D) to restrict flexion, lateral bending, and rotation was substantial to nearly complete (MIL: 74-92%), and the ability of these devices to restrict extension was moderate to nearly complete (MIL: 41-84%).

The ability of vests with non-invasive skull fixation (type E1) to restrict flexion and extension was substantial to nearly complete (MIL: 68-90%), nearly complete for rotation (MIL: 82-98%), and fair to nearly complete for lateral bending (MIL: 32-94%). With respect to lateral bending, only one study reported a fair MIL (32%, for the Minerva brace);20 the remaining studies reported MIL ≥70% (i.e., substantial MIL or better).21
### Table 3.2A Group A: cervical devices.

<table>
<thead>
<tr>
<th>Group A</th>
<th>Device Name</th>
<th>Author/Year</th>
<th>Subjects</th>
<th>Direction</th>
<th>MRP (%)</th>
<th>SD (%)</th>
<th>MIL (%)</th>
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</thead>
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<tr>
<td></td>
<td>rotation</td>
<td>17</td>
<td>10</td>
<td>7</td>
<td></td>
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<td></td>
<td>Soft collar</td>
<td>Hammacher 1996</td>
<td>N=16 (flexion/extension) total</td>
<td>35</td>
<td>34</td>
<td>2</td>
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<tr>
<td></td>
<td>lateral bending</td>
<td>35</td>
<td>17</td>
<td>18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Soft collar</td>
<td>Bell 2009</td>
<td>N=12 (flexion/extension) total</td>
<td>20</td>
<td>17</td>
<td>3</td>
<td></td>
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<tr>
<td></td>
<td>rotation</td>
<td>33</td>
<td>16</td>
<td>17</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Soft collar</td>
<td>Miller 2010</td>
<td>N=10 (flexion/extension) total</td>
<td>26</td>
<td>5</td>
<td>21</td>
<td></td>
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<td></td>
<td>lateral bending</td>
<td>29</td>
<td>10</td>
<td>19</td>
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<tr>
<td>A2: Rigid cervical collar</td>
<td>No studies available</td>
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### Table 3.2B Group B: cervico-thoracic devices.

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<th>Group B</th>
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<th>Author/Year</th>
<th>Subjects</th>
<th>Direction</th>
<th>MRP (%)</th>
<th>SD (%)</th>
<th>MIL (%)</th>
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<tr>
<td>B1: Aspen brace</td>
<td>Gavin 2003</td>
<td>N=20 (flexion/extension) total</td>
<td>69/52</td>
<td>10/19</td>
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<tr>
<td></td>
<td>rotation</td>
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<td>-</td>
<td>-</td>
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<td></td>
<td>Hughes 1998</td>
<td>N=15 (flexion/extension) total</td>
<td>52</td>
<td>27</td>
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<td>59</td>
<td>19</td>
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<tr>
<td></td>
<td>rotation</td>
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<tr>
<td></td>
<td>Zhang 2005</td>
<td>N=20 (flexion/extension) total</td>
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<td>12</td>
<td>58</td>
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<tr>
<td></td>
<td>Miami J</td>
<td>Bell 2009</td>
<td>N=12 (flexion/extension) total</td>
<td>87/77</td>
<td>8/13</td>
<td>79/64</td>
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</tr>
<tr>
<td></td>
<td>lateral bending</td>
<td>51</td>
<td>25</td>
<td>26</td>
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<td></td>
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<tr>
<td></td>
<td>rotation</td>
<td>68</td>
<td>18</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Miami J</td>
<td>Gavin 2003</td>
<td>N=20 (flexion/extension) total</td>
<td>60/54</td>
<td>13/15</td>
<td>47/39</td>
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<td>-</td>
<td>-</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>rotation</td>
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<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Miami J</td>
<td>Zhang 2005</td>
<td>N=20 (flexion/extension) total</td>
<td>85/66</td>
<td>14/20</td>
<td>71/46</td>
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<td>lateral bending</td>
<td>38</td>
<td>17</td>
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<td>15</td>
<td>50</td>
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<tr>
<td></td>
<td>Necloc</td>
<td>Hammacher 1996</td>
<td>N=16 (flexion/extension) total</td>
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<td>33/88</td>
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<td></td>
<td>lateral bending</td>
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<td>33</td>
<td>30</td>
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<td></td>
<td>rotation</td>
<td>76</td>
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### Table 3.2B Continued

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<th>Group B</th>
<th>Device Name</th>
<th>Author</th>
<th>Year</th>
<th>Subjects</th>
<th>Direction</th>
<th>MRP (%)</th>
<th>SD (%)</th>
<th>MIL (%)</th>
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</thead>
<tbody>
<tr>
<td>Philadelphia</td>
<td>Johnson&lt;sup&gt;22&lt;/sup&gt;</td>
<td>1977</td>
<td>N=17</td>
<td>(flexion/extension) total</td>
<td>(71/34) -</td>
<td>34</td>
<td>21</td>
<td>13</td>
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<tr>
<td>Stifneck</td>
<td>Chandler&lt;sup&gt;18&lt;/sup&gt;</td>
<td>1992</td>
<td>N=20</td>
<td>(flexion/extension) total</td>
<td>(57)</td>
<td>48</td>
<td>23</td>
<td>25</td>
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<tr>
<td>Stifneck</td>
<td>Chi&lt;sup&gt;3&lt;/sup&gt;</td>
<td>2005</td>
<td>N=18</td>
<td>(flexion/extension) total</td>
<td>(77/77)</td>
<td>73</td>
<td>14</td>
<td>63</td>
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<td>Stifneck</td>
<td>Hammacher&lt;sup&gt;34&lt;/sup&gt;</td>
<td>1996</td>
<td>N=16</td>
<td>(flexion/extension) total</td>
<td>(66/14)</td>
<td>66</td>
<td>14</td>
<td>52</td>
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<tr>
<td>Stifneck</td>
<td>Holla&lt;sup&gt;7&lt;/sup&gt;</td>
<td>2012</td>
<td>N=10</td>
<td>(flexion/extension) total</td>
<td>(48)</td>
<td>66</td>
<td>9</td>
<td>57</td>
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<tr>
<td>Vertebrac</td>
<td>Hammacher&lt;sup&gt;34&lt;/sup&gt;</td>
<td>1996</td>
<td>N=16</td>
<td>(flexion/extension) total</td>
<td>(50/95)</td>
<td>74</td>
<td>11</td>
<td>63</td>
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<tr>
<td>Vista Collar</td>
<td>Miller&lt;sup&gt;19&lt;/sup&gt;</td>
<td>2010</td>
<td>N=10</td>
<td>(flexion/extension) total</td>
<td>(35)</td>
<td>59</td>
<td>5</td>
<td>54</td>
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<tr>
<td>XTW</td>
<td>Zhang&lt;sup&gt;15&lt;/sup&gt;</td>
<td>2005</td>
<td>N=20</td>
<td>(flexion/extension) total</td>
<td>(67/78)</td>
<td>68</td>
<td>14</td>
<td>54</td>
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### Table 3.2B Group B<sub>2</sub>: cervico-low thoracic devices.

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<th>Group B</th>
<th>Device Name</th>
<th>Author</th>
<th>Year</th>
<th>Subjects</th>
<th>Direction</th>
<th>MRP (%)</th>
<th>SD (%)</th>
<th>MIL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B&lt;sub&gt;2&lt;/sub&gt;: cervico-low thoracic devices</td>
<td>Aspen 2-post CTO</td>
<td>Gavin&lt;sup&gt;12&lt;/sup&gt;</td>
<td>2003</td>
<td>N=20</td>
<td>(flexion/extension) total</td>
<td>(94/61)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Aspen 4-post CTO</td>
<td>Gavin&lt;sup&gt;12&lt;/sup&gt;</td>
<td>2003</td>
<td>N=20</td>
<td>(flexion/extension) total</td>
<td>(98/80)</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>cervico-thoracic brace n.a.s.</td>
<td>Johnson&lt;sup&gt;22&lt;/sup&gt;</td>
<td>1977</td>
<td>N=27</td>
<td>(flexion/extension) total</td>
<td>(-/-)</td>
<td>49</td>
<td>18</td>
<td>31</td>
</tr>
<tr>
<td>four poster</td>
<td>Johnson&lt;sup&gt;22&lt;/sup&gt;</td>
<td>1977</td>
<td>N=27</td>
<td>(flexion/extension) total</td>
<td>(-/-)</td>
<td>82</td>
<td>8</td>
<td>74</td>
</tr>
<tr>
<td>Miami J with chest extension</td>
<td>Bell&lt;sup&gt;16&lt;/sup&gt;</td>
<td>2009</td>
<td>N=12</td>
<td>(flexion/extension) total</td>
<td>(90/80)</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>SOMI</td>
<td>Bell&lt;sup&gt;16&lt;/sup&gt;</td>
<td>2009</td>
<td>N=12</td>
<td>(flexion/extension) total</td>
<td>(93/76)</td>
<td>65</td>
<td>17</td>
<td>49</td>
</tr>
<tr>
<td>SOMI</td>
<td>Johnson&lt;sup&gt;22&lt;/sup&gt;</td>
<td>1977</td>
<td>N=22</td>
<td>(flexion/extension) total</td>
<td>(-/-)</td>
<td>66</td>
<td>14</td>
<td>52</td>
</tr>
<tr>
<td>Yale</td>
<td>Johnson&lt;sup&gt;22&lt;/sup&gt;</td>
<td>1978</td>
<td>N=17</td>
<td>(flexion/extension) total</td>
<td>(-/-)</td>
<td>61</td>
<td>22</td>
<td>59</td>
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### Table 3.2C Group C: cranial devices.

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<th>Group C</th>
<th>Device Name</th>
<th>Author</th>
<th>Year</th>
<th>Subjects</th>
<th>Direction</th>
<th>MRP (%)</th>
<th>SD (%)</th>
<th>MIL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1: cranial traction</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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### Table 3.2D Group D: cranio-thoracic devices for non-ambulatory patients.

<table>
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<tr>
<th>Group D</th>
<th>Device Name</th>
<th>Author</th>
<th>Year</th>
<th>Subjects</th>
<th>Direction</th>
<th>MRP (%)</th>
<th>SD (%)</th>
<th>MIL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1: backboard with sandbags and tape</td>
<td>backboard with sandbags</td>
<td>Hamilton</td>
<td>1996</td>
<td>N=26</td>
<td>(flexion/extension) total</td>
<td>(93/72)</td>
<td>(10/2)</td>
<td>(73/41)</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>D2: backboard with head blocks</td>
<td>backboard with head blocks</td>
<td>Holla</td>
<td>2012</td>
<td>N=10</td>
<td>(flexion/extension) total</td>
<td>(-/-) 95</td>
<td>(-/-) 5</td>
<td>(-/-) 90</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D3: shaped mattress</td>
<td>vacuum splint</td>
<td>Hamilton</td>
<td>1996</td>
<td>N=26</td>
<td>(flexion/extension) total</td>
<td>(91/65)</td>
<td>(7/18)</td>
<td>(84/47)</td>
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### Table 3.2E Group E: cranio-thoracic devices for ambulatory patients.

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<tr>
<th>Group E</th>
<th>Device Name</th>
<th>Author</th>
<th>Year</th>
<th>Subjects</th>
<th>Direction</th>
<th>MRP (%)</th>
<th>SD (%)</th>
<th>MIL (%)</th>
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</thead>
<tbody>
<tr>
<td>E1: vest without skull pins</td>
<td>non-invasive halo</td>
<td>Bell</td>
<td>2009</td>
<td>N=12</td>
<td>(flexion/extension) total</td>
<td>(94/80)</td>
<td>(4/10)</td>
<td>(90/70)</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ammerman halo</td>
<td>Chandler</td>
<td>1992</td>
<td>N=20</td>
<td>(flexion/extension) total</td>
<td>(-/-) 81</td>
<td>(-/-) 12</td>
<td>(-/-) 69</td>
<td>lateral bending</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mineva</td>
<td>Sharpe</td>
<td>2005</td>
<td>N=16</td>
<td>(flexion/extension) total</td>
<td>(78/78)</td>
<td>(8/10)</td>
<td>(70/68)</td>
<td>lateral bending</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E2: vest with skull pins</td>
<td>no studies available</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tr>
</tbody>
</table>
Figure 3.3 Mean reduction percentage (MRP) and minimal immobilization limit (MIL) per device.

Figure 3.3A Flexion and extension (mean reduction percentage -1 SD error plot).
Dark gray bars represent flexion, and light gray bars represent extension. If percentages are identical, separate flexion and extension were not mentioned in the original article.
Discussion

We systematically reviewed all published articles regarding all types of external cervical immobilizers and compared their ability to restrict movement of the cervical spine. As predicted by the laws of biomechanics, the level of immobilization generally increases as both the surface area supported and the lever arm increase. Devices that only support the cervical area can restrict the normal range of motion by only 50% (or less), whereas rigid devices that provide support from cranium to the thorax provide nearly complete immobilization. Generally speaking, the classification of an external immobilizer corresponds - at least to a certain degree - to the device’s ability to immobilize the cervical spine. We emphasize that the used classification is not a linear system; type C and type D immobilizers can only be applied in non-ambulatory patients.

As described by both Johnson et al. and Hammacher et al., the reported standard deviation of immobilization for some specific devices (e.g., soft collars, Necloc, Vertebrace, etc.) was quite high, even exceeding the mean values for immobilization\(^{13, 22}\). The relatively small number of participants in these studies cannot explain these large standard deviations, as high variability was reported in other, larger studies as well. In addition, the difference in the ability to immobilize the cervical spine using the same type of device varied by more than 20%. Given that we corrected for differences in the normal range of motion among individuals (i.e., reporting the percentage of immobilization), any differences between individual participants do not likely explain this finding.

One explanation for the differences between studies may be the limited accuracy of the various methods used to measure the range of motion of the cervical spine. Another reason may lie in the different forces generated by the healthy volunteers. Applying larger forces generally results in a wider range of motion, and only experiments using cadavers enable the researcher to control the precise amount of force and correlate this force with the range of motion. However, none of the studies that met our inclusion criteria used cadavers. In addition, the size and application of the device can strongly influence its ability to restrict movement. For example, improperly placing a Stifneck collar can reduce its ability to provide immobilization by \(>20\%\).\(^{16}\) Proper sizing is also a practical issue with many external immobilizers; a cervico-thoracic device that is sized incorrectly by even a few mms can result in many degrees of motion in all directions. To introduce a margin of safety, we therefore developed the MIL; although this method does not entirely solve the problem of severely ill-fitting devices, it covers the usual differences between average individuals.

The ability to restrict flexion and extension was reported using several different methods. For example, some articles reported flexion and extension as separate degrees of freedom. However, this method is not ideal, as the "neutral" position of the cervical spine is unclear. A difference of only ten degrees in the neutral position can result in a mismatch with flexion and extension by twenty degrees. Some articles addressed this
problem by reporting flexion and extension in one single range and one dimension. Although this eliminates the problem of the neutral head position, any separate differences in flexion and/or extension cannot be detected. In our review, both types of reports are included and described. For future research, we advise that authors report flexion and extension as two separate dimensions, and we recommend reporting flexion and extension as one single dimension.

In a 3D motion analysis study by Evans et al., the effectiveness of different cervico-high thoracic immobilizers were compared to their ability to restrict spinal motion through physiological ranges. All tested immobilizers were classified as cervico-high thoracic immobilizers (type B: Vista, Miami-J, Miami-J Advanced and Philadelphia collar). This study was not included since it was published after the performed literature search. However, its results are in line with the results of the studies included in this systematic review; the ability to restrict flexion and extension was substantial (MIL: 61-67%) and fair to moderate for lateral bending (MIL: 21-42%). However, Evans et al. reported the ability to restrict rotation to be moderate to substantial (MIL: 56-66%) while the studies included in this systematic review reported a poor to moderate rotational restriction (MIL: 13-40%).

To the best of our knowledge, this is the first systematic review of cervical immobilization devices based on the anatomical regions in which the devices provide support. However, some potential limitations should be discussed. First, we included only studies that reported the range of motion of healthy cervical spines. The effectiveness of an immobilizing device can potentially differ between healthy individuals and patients with a cervical spine injury. However, because including studies with various types of injuries at various cervical levels would have yielded incompatible results, we excluded such studies. Second, the MIL was used by subtracting one standard deviation from the MIL and assigned into levels of immobilization (poor, fair, moderate, substantial and nearly complete) according to pre-set percentages. These are arbitrary cut off points chosen by the authors to translate immobilization percentages into comprehensible text. However if the mentioned cut-off percentages are increased or decreased by 5% our conclusions do not differ. Furthermore the MRP, MIL and its relation to the cut off points are clearly presented in Figure 3. Third, this review revealed that only the total movement of the entire cervical spine is generally described. It remains unclear whether the different types of immobilizers are restricting movements at the upper or at the lower cervical spine primarily. New studies using validated techniques that can measure intervertebral movement in three dimensions are needed.

One of the most striking findings of our review is that several types of immobilizers that are currently used both widely and on a daily basis (including halo traction, halo vests, head blocks and vacuum splinting) are not described accurately in the literature. Although several reports were available with respect to cervico-thoracic devices, other groups of immobilizers completely lacked any reports or studies. This might be one of the reasons why there is no definitive evidence about the use of orthoses after spinal interventions or in painful conditions of the cervical spine.
Appendix 3.1 Search strategy used to collect articles regarding external immobilization of the cervical spine.

Appendix 3.1a The search terms used, listed by group.

<table>
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<tr>
<th>Therapy group</th>
<th>Anatomy group</th>
<th>Assessment group</th>
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<td>orthotic devices</td>
<td>spine</td>
<td>movement</td>
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<td>cervical spine</td>
<td>range of motion</td>
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<td>orthosis</td>
<td>cervical spine injury</td>
<td>head movement</td>
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<td>immobilisation</td>
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<td>cranio-thoracic</td>
<td>immobilization</td>
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<td>biomechanics</td>
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<td>atlanto-occipital joint</td>
<td>rotation</td>
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<td>rigid collar</td>
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<td>kinetics</td>
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<tr>
<td>braces</td>
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<tr>
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<td>Minerva</td>
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<td></td>
</tr>
<tr>
<td>CTO</td>
<td></td>
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</tr>
<tr>
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<tr>
<td>SOMI</td>
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<tr>
<td>sternal-occipital-mandibular-immobilizer</td>
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<td>halo vest</td>
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<td>halo</td>
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</table>

Appendix 3.1b Search strings used in this article for search in MEDLINE.

The following groups were combined using the string: “A” AND “B” AND “C”

**Therapy (A)**


**Anatomy group (B)**


**Assessment group (C)**

Appendix 3.1c Search strings used in this article for search in EMBASE, CENTRAL and the CBRG trials.

The following groups were combined using the string: "A" AND "B" AND "C"

**Therapy group (A)**
- "orthotic devices" OR "orthotic device" OR "orthoses" OR "orthosis" OR "orthopedic equipment" OR "collar" OR "soft collar" OR "semi-rigid collar" OR "rigid collar" OR "braces" OR "traction" OR "sandbags" OR "head blocks" OR "spine board" OR "backboard" OR "vacuum mattress" OR "surgical casts" OR "cast" OR "minerva" OR "noninvasive halo vest" OR "noninvasive halovest" OR "CTO" OR "cervicothoracic orthoses" OR "SCMI" OR "sternal-occipital-mandibular-immobilizer" OR "halo vest" OR "halovest" OR "halo"

**Anatomy group (B)**
- "spine" OR "cervical vertebrae" OR "cervical spine" OR "cervicothoracic" OR "neck" OR "atlandoaxial joint" OR "atlanto-occipital joint" OR "cervical spine injury" OR "cranio-thoracic"

**Assessment group (C)**
- "movement" OR "range of motion" OR "head movement" OR "immobilisation" OR "immobilisation" OR "biomechanics" OR "kinetics"

References

RESTRICTION OF CERVICAL INTERVERTEBRAL MOVEMENT WITH DIFFERENT TYPES OF EXTERNAL IMMOBILIZERS: A CADAVERIC 3D ANALYSIS STUDY


4
New Perspectives on External Immobilization of the Cervical Spine

Restriction of Cervical Intervertebral Movement With Different Types of External Immobilizers: A Cadaveric 3D Analysis Study

Abstract

Study design: Cadaveric radiostereometric analysis study.

Objective: To quantify the ability of 5 commonly used immobilizers to restrict cervical spine movement, including intervertebral movement, in three directions.

Summary of Background Data: Evidence about the ability of many clinically used cervical immobilizers to restrict cervical movement is limited. Furthermore, their effect on intervertebral movement is unknown.

Methods: Radiographic inert beads were implanted in the cervical vertebral bodies of five fresh-frozen human cadavers. After application of different immobilizers (Stifneck, SOMI, halo-traction, spine board, halo-vest) and controlled flexion-extension, lateral bending and rotation torques, radiostereometric analysis was used to determine the overall and intervertebral 3D movement of each vertebral level. Restriction of cervical movement was described as a mean restriction percentage (MRP) and classified on an arbitrary basis (poor:<20%, fair:20-40%, moderate:40-60%, substantial:60-80%, nearly complete:>80%).

Results: Most of the restriction of flexion/extension was observed at C0-C1 while most rotational restriction was seen at C1-C2. Lateral bending was restricted at C1 to C7. The Stifneck provided the least immobilization with a moderate restriction of flexion-extension (MRP:41%,SD 14%), fair restriction of lateral bending (MRP:29%,SD 13%) and substantial restriction of rotation (MRP:64%,SD 15%). The halo-vest was most the most restrictive immobilizer and reduced movement of the cervical spine substantially for flexion-extension (MRP:70%,SD 11%), substantially for lateral bending (MRP:77%,SD 14%) and nearly complete for rotation (MRP:92%,SD 3%).

Conclusions: The restriction of movement from lowest to highest was: Stifneck, SOMI, halo-traction, head blocks on a spine board, and halo-vest. Notably, the standard deviations of the restrictions were smaller for the cranio-thoracic devices than for the cervico-thoracic devices. With this new knowledge of external immobilizers and their ability to restrict intervertebral cervical movement, their indication and application in clinical practice can be improved for all patients with (suspected) cervical injury.

Introduction

Every day the cervical spine of hundreds of people worldwide is immobilized by several different types of external devices in accordance with the ATLS guidelines. All these immobilizers are meant to restrict, to a greater or lesser extent, movement of the cervical spine to facilitate good recovery from cervical injury, to reduce pain, and to prevent secondary dislocation with spinal cord injury.

In a recent study the ability of external immobilizers to restrict the movement of the cervical spine was systematically reviewed. It was shown that some immobilizers were described quite often in the literature, whereas for other commonly used types of immobilizers (including halo-traction, spine board with head blocks and the halo-vest) there was a lack of evidence about their immobilizing capacity. Most studies about external immobilizers of the cervical spine did not report the restricting capacity in all different directions. This is obviously an omission as in reality motion will occur in a complex 3D manner. Flexion and extension were often reported, probably since movement in this plane is relatively easy to measure. Rotation and lateral bending, however, were often not reported, although these are important movements in daily living. In addition, the amount of force (or torque) to generate the spinal motions were frequently not controlled or protocolized.

These aspects make comparisons between different studies and devices virtually impossible. Finally, nearly all publications on the restriction of cervical movement with external immobilizers report on the range of movement of the skull in relation to the torso and do not provide information about the motions at the intervertebral level (relative rotations between two adjacent vertebrae). To our knowledge, only one study has examined the intervertebral cervical movement for flexion and extension with and without a rigid collar. Surprisingly, this study showed that there was an increase of motion at the level of C0 and C1 when a rigid collar was applied. As this study showed a possible counter effect (i.e. an increased motion instead of restriction) of spine immobilizers, it is essential to assess if and how, individual vertebral levels move with different external immobilizers applied. Hence, knowledge of the ability of commonly used types of external immobilizers to restrict movement in all directions on intervertebral levels is important for making good decisions in daily clinical practice.

Therefore, the aim of this study was to quantify the ability of five commonly used external immobilizers to restrict cervical spine movement, including intervertebral movement, in three directions (flexion/extension, rotation and lateral flexion).
Materials and methods

Types and application of external cervical immobilizers

In this cadaveric study five cervical immobilizers frequently used in our institution were selected for testing. These were categorized according to a validated classification system, with five main categories based on the anatomical regions on which the device supports. The following five immobilizers were tested:
- Stifneck Select (cervico high thoracic device - type B, Laerdal NY, USA),
- SOMI brace (cervico low thoracic device - type B, Kingsley Mfg, CA, USA),
- Ferno Milenia Board with head blocks (cranial thoracic for non ambulatory patients - type D, Ferno, West Yorkshire, UK),
- PMT halovest (cranial thoracic for ambulant patients - type E, PMT Corp, MN, USA),
- PMT halotraction system with 5kg calibrated weights (cranial traction - type C, PMT Corp, MN, USA).

All immobilizers were placed and sized according to their user manuals. To determine the normal range of motion of each cadaver, the cervical spine was tested without immobilizer. Next, the immobilizers were tested in the order listed above. Finally, to exclude any structural changes of the cadaver, the cervical motion without any immobilizer was measured again.

Cadaveric specimens

Five fresh-frozen cadavers (three male and two female, mean 81 years (range 77-93)) without any known pathology of the cervical spine and a normal BMI were obtained from our institutional Department of Anatomy. The cadavers were visually inspected to exclude specimens that showed signs of prior surgery. Furthermore, conventional radiographs of the cervical spine showed mild degenerative changes of the cervical spine without any signs of prior fractures, congenital fusion or ankyloses. All cadavers were thawed before use.

Implantation of tantalum beads

The cadavers were placed in supine position. Four lead beads (Ø 3 mm) were placed with a trocar approximately 2-4 mm deep in the skull base (C0) by bilateral percutaneous entry, one centimeter caudal from the mastoid. The bodies of C1 and C2 were accessed through the oro-pharynx. Four tantalum beads (Ø 1 mm) were placed with a trocar inside C1 and C2. A fifth lead bead (Ø 3 mm) was placed inside the center of the second cervical body to facilitate differentiation of C2 from C1 and C3. To access the subaxial vertebrae, a longitudinal incision of the skin, subcutis and platysma muscle was made using a scalpel. With blunt dissection through the anatomical plane medial from the sternocleidomastoid muscle, the anterior side of the vertebral bodies of C3 up to C7 were exposed. Four tantalum beads (Ø 1 mm) were placed with a trocar in cervical bodies of C3 to C7. Cervical muscles and ligaments were left unaffected.

Implantation of the beads was monitored using fluoroscopy. After placement of the beads the subcutis and skin were closed. An overview of bead placement is given in Figure 4.1A-D.

Radiostereometric analysis (RSA)

RSA is a highly accurate method to assess motion of markers fixed inside rigid bodies. RSA involves two X-ray sources aimed at opposing angles which converge on the area of interest (Figure 4.2). Using RSA a translational accuracy of less than 200 μm, with a rotational accuracy (depending on the distance between the beads) of less than one degree can be achieved. Therefore, RSA is extremely useful for measuring very small amounts of motion or migration in various applications ranging from joint replacement surgery to fracture repair surgery to spine surgery. During RSA imaging, the cadavers were placed in supine position above an RSA calibration cage. Two separate images are obtained from an RSA exam. These images were analyzed to determine the relative motion between two adjacent vertebrae. The detailed configuration of the uniplanar RSA setup is depicted in Figure 4.2 (also see ‘Data processing and analysis’). The RSA system was calibrated before use.

Figure 4.1 The configuration of RSA beads on each level of the cervical spine and skull base. Beads were inserted approximately 4 mm deep in the skull base and cervical bodies. Small dots represent 1 mm tantalum beads and the bigger dots 3 mm lead beads.

A-B: AP/lateral view of a C-spine model and 2D over projection of the target spots for the beads. C-D: 30°left/right oblique RSA images of the cervical spine of a cadaver in neutral position with tantalum markers placed in each cervical body.
**Application of external forces**

The cadavers were placed in supine position on a radiolucent table. One threaded central skull pin (Ø 4 mm) was placed at the top of the cranium directing towards the skull base. Two additional pins (Ø 4 mm) were screwed in the skull 3 cm parallel of the central skull pin anterior and posterior to apply rotational forces. The two rotation skull pins and central skull pin were attached to each other with a multi-pin clamp to prevent loosening and movement of the skull pins. A fourth threaded pin was placed in the forehead, perpendicular to the central headpin in the midline at the level of the upper orbital rim, to apply forces for extension. External forces were applied by a balance spring and maintained with a rope, pulleys and 3 kg weights (Figure 4.3A-F).

Flexion of the cervical spine was achieved by the application of 30 N, 2 cm from the skull surface, perpendicular to the central skull pin (Figure 4.3C). Extension of the cervical spine was realized by the application of 30 N, 2 cm from the forehead skin, perpendicular to the forehead pin (Figure 4.3D). Rotation of the cervical spine was achieved by a wheel with a diameter of 10 cm placed perpendicular on the central skull pin and two rotation skull pins. The central skull pin was used as axis.

**Figure 4.2** The uniplanar RSA setup involved two x-ray sources (X-ray A and X-ray B) aimed at opposing angles (60 degrees) which converge on the cervical spine.

During RSA imaging, the cadavers were placed in supine position above an RSA calibration cage (not shown). Two separate images (detector plate) were obtained from an RSA exam. The detector plate was placed below the object table such that all beads placed in C0-C7 were detected. These images were analyzed to determine the relative motion between two adjacent vertebrae.
The wheel with a rope and weights applied a rotational force of 30 N with a lever arm of 5 cm (Figure 4.3F). Lateral bending of the cervical spine was accomplished by traction of 30 N, 2 cm from the skull surface, perpendicular of the central skull pin. During lateral bending the head rested on the radiolucent table. Rotation of the head during lateral bending was not corrected by additional external forces (Figure 4.3E). The movement of the cervical spine cadaver was tested in all cadavers in the following order: flexion, extension, right / left lateral bending, right / left rotation.

### Results

The ability of different types of external immobilizers of the cervical spine in all directions are described in Table 4.1A-C and depicted in Figure 4.4A-C.

Flexion in cadavers 1 and 4 could not be calculated for each intervertebral level due to over projection of the skull/non-visible markers and were excluded from the analyses for these individual intervertebral levels.

The RSA analysis without immobilizers demonstrated that most of the normal intervertebral cervical flexion-extension is generated from level C0-C1, while lateral bending and rotation is mainly generated from level C1-C2. All immobilizers restricted cervical flexion-extension, most at the level C0-C1 and rotation and lateral bending at the level of C1-C2. Less absolute restriction of movement in degrees was seen at the levels C3-C7 although the crano-thoracic immobilizers (type D/E) also restricted intervertebral motion at C3 to C7 nearly complete (Table 4.1). The mean intervertebral movement was nearly always reduced with all tested immobilizers. Nevertheless, occasionally an increased intervertebral movement was measured in some cadavers with different types of immobilizers and at different cervical levels.

The Stifneck (type B1), resulted in a mean flexion-extension restriction of 27° (range 18°-35°) to the normal flexion-extension values, the Stifneck induced moderate restriction with an MRP of 41% (SD 14%). The mean lateral bending restriction was 24° (range 5°-42°). The Stifneck restricted lateral bending fairly with an MRP of 29% (SD 13%). Rotation was restricted substantially with an MRP of 64% (SD 15%).

The SOMI orthosis (type B2) restricted cervical motion in all directions. A substantial restriction of flexion-extension with an MRP of 76% (SD 8%), a moderate restriction of lateral bending with an MRP of 55% (SD 15%) and a substantial restriction of rotation with an MRP of 79% (SD 12%) was achieved.

The halo-ring traction (type C) resulted in a substantial restriction of cervical movement for flexion-extension with an MRP of 70% (SD 3%), a nearly complete restriction of lateral bending with an MRP of 88% (SD 4%) and a substantial immobilization for rotation with an MRP of 64% (SD 20%).

The head blocks with spine board (type D2) restricted flexion-extension substantially with an MRP of 73% (SD 9%). Furthermore, a nearly complete restriction of lateral bending with an MRP of 85% (SD 7%) and nearly complete restriction of rotation with an MRP of 94% (SD 4%) was achieved.

The halo-vest (category E1) reduced movement of the cervical spine substantially for flexion-extension with an MRP of 70% (SD 11%) and lateral bending nearly complete with an MRP 90% (SD 5%). A nearly complete immobilization for rotation with an MRP of 92% (SD 3%) was achieved with the halo-vest.

### Data processing and analysis

Tantalum markers were marked with computer software and manually checked. The position of each cervical body was determined to a 3D coordinate system. The local coordinate system was created using a square calibration box containing markers. By identifying the markers inside this box, a transformation from 2D coordinates (X-ray photos) to 3D coordinates can be calculated, as the positions of these calibration markers relative to each other are known. The calibration box was placed in such a way that the local coordinate system aligns with the (expected) anatomical axes.

The RSA calculation results are presented as Euler angles. Markers were inserted in the vertebrae, from which the rigid body transformations (i.e. rotations and translations) were calculated. One vertebra was used as a reference, relative to which the transformation of the adjacent vertebra was calculated (and so on). Angulation around the x,y,z-axis represented lateral bending, flexion-extension and rotation, respectively (Figures 4.3A-F left above). Using this coordinate system the angulation of each vertebral body in relation to its adjacent level was determined. This angulation was reported in absolute numbers (with range) in degrees of movement.

Furthermore, the total angulation/rotation between the skull base (C0) and C7 was calculated relative to the neutral pre-test position (i.e. without immobilizer) of each specific cadaver. The percentage restriction of an immobilizer was calculated by dividing the measured absolute movement (C0 vs C7) in degrees with immobilizer by the measured absolute movement (C0 vs C7) in degrees without the immobilizer in that specific cadaver. A mean restriction percentage (MRP) was calculated to quantify this restriction of the immobilizers and categorized according to an arbitrary description of level of immobilization (poor: <20%, fair: 20-40%, moderate: 40-60%, substantial 60-80%, nearly complete: >80%).

The intervertebral movement was nearly always reduced with all tested immobilizers. Nevertheless, occasionally an increased intervertebral movement was measured in some cadavers with different types of immobilizers and at different cervical levels.

The Stifneck (type B1), resulted in a mean flexion-extension restriction of 27° (range 18°-35°) to the normal flexion-extension values, the Stifneck induced moderate restriction with an MRP of 41% (SD 14%). The mean lateral bending restriction was 24° (range 5°-42°). The Stifneck restricted lateral bending fairly with an MRP of 29% (SD 13%). Rotation was restricted substantially with an MRP of 64% (SD 15%).

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The halo-ring traction (type C) resulted in a substantial restriction of cervical movement for flexion-extension with an MRP of 70% (SD 3%), a nearly complete restriction of lateral bending with an MRP of 88% (SD 4%) and a substantial immobilization for rotation with an MRP of 64% (SD 20%).

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The halo-vest (category E1) reduced movement of the cervical spine substantially for flexion-extension with an MRP of 70% (SD 11%) and lateral bending nearly complete with an MRP 90% (SD 5%). A nearly complete immobilization for rotation with an MRP of 92% (SD 3%) was achieved with the halo-vest.
Table 4.1 The intervertebral angulation/rotation with and without different external cervical immobilizers was calculated as the difference between the measured absolute intervertebral movement in degrees with immobilizer and the measured absolute intervertebral movement in degrees without the immobilizer in that specific cadaver. Intervertebral angulation/rotation presented as mean restriction (range). The percentage restriction was calculated by dividing the measured absolute movement (C0 vs C7) in degrees with immobilizer by the measured absolute movement (C0 vs C7) in degrees without the immobilizer in that specific cadaver. Total angulation/rotation between the skull base (C0) and C7 are presented as mean restriction (range) and percentage restriction (SD). Calculations were performed relative to the neutral pre-test position (i.e. without immobilizer) of each specific cadaver.

Table 4.1A Flexion-extension (mean [minimal / maximal]).

<table>
<thead>
<tr>
<th>no immobilizer</th>
<th>post test</th>
<th>Stifneck</th>
<th>SOMI</th>
<th>Halo traction</th>
<th>Spine board</th>
<th>Halo-vest</th>
</tr>
</thead>
<tbody>
<tr>
<td>C0-C1</td>
<td>17° (12/24)</td>
<td>14° (9/19)</td>
<td>-9° (-15/4)</td>
<td>-12° (-20/6)</td>
<td>-11° (-15/4)</td>
<td>-13° (-19/10)</td>
</tr>
<tr>
<td>C1-C2</td>
<td>12° (8/13)</td>
<td>15° (6/9)</td>
<td>-3° (-10/5)</td>
<td>-9° (-13/-1)</td>
<td>-6° (-13/1)</td>
<td>-8° (-10/6)</td>
</tr>
<tr>
<td>C2-C3</td>
<td>5° (1/3)</td>
<td>3° (2/3)</td>
<td>2° (-5/3)</td>
<td>-3° (-8/1)</td>
<td>-3° (-8/1)</td>
<td>-5° (-8/-3)</td>
</tr>
<tr>
<td>C3-C4</td>
<td>4° (2/5)</td>
<td>6° (4/7)</td>
<td>1° (-1/2)</td>
<td>-3° (-6/-1)</td>
<td>-3° (-7/0)</td>
<td>-3° (-7/-1)</td>
</tr>
<tr>
<td>C4-C5</td>
<td>7° (2/1)</td>
<td>3° (3/4)</td>
<td>6° (-11/-2)</td>
<td>-5° (-11/0)</td>
<td>-5° (-15/-1)</td>
<td>6° (-14/-1)</td>
</tr>
<tr>
<td>C5-C6</td>
<td>9° (4/12)</td>
<td>5° (2/3)</td>
<td>4° (-5/-3)</td>
<td>-7° (-11/-2)</td>
<td>-6° (-9/-2)</td>
<td>-7° (-11/-1)</td>
</tr>
<tr>
<td>C6-C7</td>
<td>8° (7/9)</td>
<td>2° (3/4)</td>
<td>4° (-8/1)</td>
<td>-5° (-7/-2)</td>
<td>-6° (-9/-2)</td>
<td>-6° (-7/-5)</td>
</tr>
<tr>
<td>C0-C7</td>
<td>64° (60/71)</td>
<td>1,4</td>
<td>-27° (-35/-18)</td>
<td>-46° (-49/-41)</td>
<td>-45° (-50/-41)</td>
<td>-44° (-54/-30)</td>
</tr>
</tbody>
</table>

Numbers in subscript represent cadaver numbers that were excluded from the analyses. Due to non-visible markers flexion-extension could not be calculated.

*Insufficient data available to determine a post-test mean and range of the angulation between C0 and C7, due to over projection of the skull.

Table 4.1B Lateral bending.

<table>
<thead>
<tr>
<th>no immobilizer</th>
<th>post test</th>
<th>Stifneck</th>
<th>SOMI</th>
<th>Halo traction</th>
<th>Spine board</th>
<th>Halo-vest</th>
</tr>
</thead>
<tbody>
<tr>
<td>C0-C1</td>
<td>9° (2/16)</td>
<td>5° (0/12)</td>
<td>-2° (-9/3)</td>
<td>-3° (-14/3)</td>
<td>-6° (-16/-1)</td>
<td>-6° (-15/0)</td>
</tr>
<tr>
<td>C1-C2</td>
<td>24° (7/37)</td>
<td>22° (11/29)</td>
<td>-1° (-27/2)</td>
<td>-2° (-30/2)</td>
<td>-2° (-37/-6)</td>
<td>-2° (-37/3)</td>
</tr>
<tr>
<td>C2-C3</td>
<td>13° (4/23)</td>
<td>11° (4/17)</td>
<td>-2° (-11/4)</td>
<td>-6° (-13/-1)</td>
<td>-11° (-20/-3)</td>
<td>-8° (-17/-3)</td>
</tr>
<tr>
<td>C3-C4</td>
<td>10° (1/18)</td>
<td>13° (4/18)</td>
<td>-2° (-5/4)</td>
<td>-7° (-11/0)</td>
<td>-11° (-17/-2)</td>
<td>-9° (-15/-1)</td>
</tr>
<tr>
<td>C4-C5</td>
<td>10° (0/7)</td>
<td>10° (0/18)</td>
<td>-2° (-5/2)</td>
<td>-6° (-9/-1)</td>
<td>-9° (-14/-0)</td>
<td>-10° (-16/-0)</td>
</tr>
<tr>
<td>C5-C6</td>
<td>5° (1/10)</td>
<td>8° (0/13)</td>
<td>1° (-1/4)</td>
<td>-2° (-5/-3)</td>
<td>-5° (-8/1)</td>
<td>-5° (-10/1)</td>
</tr>
<tr>
<td>C6-C7</td>
<td>6° (3/11)</td>
<td>8° (5/10)</td>
<td>0° (-2/3)</td>
<td>-4° (-7/-2)</td>
<td>-5° (-8/-3)</td>
<td>-7° (-11/-3)</td>
</tr>
<tr>
<td>C0-C7</td>
<td>78° (31-95)</td>
<td>76° (36/102)</td>
<td>-2° (-42/-5)</td>
<td>-46° (-64/-9)</td>
<td>-69° (-86/-28)</td>
<td>-88° (-86/-23)</td>
</tr>
<tr>
<td>C0-C7</td>
<td>100%</td>
<td>*</td>
<td>-2° (-9/0)</td>
<td>-55° (-15)</td>
<td>-88% (9)</td>
<td>-85% (7)</td>
</tr>
</tbody>
</table>

Table 4.1C Rotation (full range of both left and right rotation).

<table>
<thead>
<tr>
<th>no immobilizer</th>
<th>post test</th>
<th>Stifneck</th>
<th>SOMI</th>
<th>Halo traction</th>
<th>Spine board</th>
<th>Halo-vest</th>
</tr>
</thead>
<tbody>
<tr>
<td>C0-C1</td>
<td>3° (1/9)</td>
<td>4° (0/9)</td>
<td>-2° (-8/2)</td>
<td>-2° (-9/2)</td>
<td>-2° (-3/-0)</td>
<td>-3° (-8/0)</td>
</tr>
<tr>
<td>C1-C2</td>
<td>46° (20/67)</td>
<td>48° (16/69)</td>
<td>-3° (-47/-15)</td>
<td>-39° (-62/-15)</td>
<td>-31° (-52/-19)</td>
<td>-46° (-69/-29)</td>
</tr>
<tr>
<td>C2-C3</td>
<td>10° (0/4)</td>
<td>10° (0)</td>
<td>-1° (-3/0)</td>
<td>0° (-3/-2)</td>
<td>0° (-2/1)</td>
<td>-1° (-3/-0)</td>
</tr>
<tr>
<td>C3-C4</td>
<td>4° (1/10)</td>
<td>5° (0/10)</td>
<td>-3° (-8/2)</td>
<td>-3° (-9/0)</td>
<td>-3° (-9/0)</td>
<td>-4° (-9/-1)</td>
</tr>
<tr>
<td>C4-C5</td>
<td>6° (0/14)</td>
<td>8° (1/14)</td>
<td>-5° (-11/-1)</td>
<td>-5° (-12/0)</td>
<td>-4° (-9/-0)</td>
<td>-6° (-14/-0)</td>
</tr>
<tr>
<td>C5-C6</td>
<td>1° (0/3)</td>
<td>3° (0/8)</td>
<td>-1° (-3/0)</td>
<td>-1° (-3/-3)</td>
<td>-1° (-3/-1)</td>
<td>-1° (-3/-1)</td>
</tr>
<tr>
<td>C6-C7</td>
<td>2° (0/4)</td>
<td>3° (0/4)</td>
<td>-1° (-3/0)</td>
<td>-2° (-4/0)</td>
<td>-2° (-3/-0)</td>
<td>-2° (-4/-1)</td>
</tr>
<tr>
<td>C0-C7</td>
<td>65° (42/103)</td>
<td>70° (25/111)</td>
<td>-4° (-7/-5)</td>
<td>-53° (-94/-3)</td>
<td>-42° (-77/-21)</td>
<td>-67° (-101/-41)</td>
</tr>
<tr>
<td>C0-C7</td>
<td>100%</td>
<td>*</td>
<td>-6° (-4/-0)</td>
<td>-79% (-12)</td>
<td>-64% (20)</td>
<td>94% (4)</td>
</tr>
</tbody>
</table>

Numbers in subscript represent cadaver numbers that were excluded from the analyses. Due to non-visible markers flexion-extension could not be calculated.

*Insufficient data available to determine a post-test mean and range of the angulation between C0 and C7, due to over projection of the skull.
**Figure 4.4** Restriction of angulation from C0 and C7 in percentages, compared to unrestricted angulation per cadaver.

- Cadaver 1
- Cadaver 2
- Cadaver 3
- Cadaver 4
- Cadaver 5

**Figure 4.4A** Restriction of flexion-extension with different immobilizers. Cadaver 1 and 4 are not depicted due to incomplete data by over projection of the skull in flexion.

**Figure 4.4B** Restriction of lateral bending with different immobilizers.

**Figure 4.4C** Restriction of rotation with different immobilizers.
Discussion

Knowledge on the ability of commonly used types of external immobilizers to restrict movement of the cervical spine is essential to guide decision-making in daily clinical practice. In this study, the ability of five commonly used immobilizers to restrict cervical spine movement was investigated using RSA. The restriction of movement from least to most was as follows, Stifneck (type B1), SOMI (type B2), halotraction (type C) (excluding rotation), head blocks on a spine board (type D2) and halovest (type E2).

The Stifneck restricted cervical movement fair to substantial. Several in-vivo studies with similar cervico-high thoracic devices showed comparable results, allowing 30 to 60% of the normal range of motion in all directions.8-12 Cervico-high thoracic immobilizers restrict movement indirectly, i.e. by support on the shoulder girdles and mandible, mobile in relation to the skull base and cervical spine. Absolute restriction cannot be achieved by this principle. Cervico-high thoracic immobilizers might be helpful in patients with spinal injury to prevent secondary dislocation by restriction of extreme cervical movement.

The Somi orthosis restricted cervical movement moderate to substantial. Similar results for cervico-low thoracic immobilizers were reported by others.8,10,12 The higher restriction of cervico-low thoracic immobilizers, when compared to cervico-high thoracic, can be explained by the longer lever arm connecting the support areas and direct support on the thorax/thoracic spine areas.

To the best of our knowledge, our study is the first to evaluate restriction by halo-traction. Halo-traction restricted flexion-extension and lateral bending more than the Stifneck and Somi. A substantial rotational restriction (MRP 64%) was achieved using cranial traction, probably caused by traction over the ligaments of the oblique-oriented cervical facet joints. In the present study, 5kg of longitudinal traction over the halo-traction system was used. However, in clinical practice variable weights are applied. Higher longitudinal traction forces are likely to result in even more restriction. Halo-traction might be useful for axial instable fractures and facet dislocation fractures. Using head blocks strapped to a spine board, flexion and extension were substantially restricted and lateral bending and rotation were nearly completely restricted. The only other study to report on restriction of head blocks strapped to a spine board showed similar results.13 These results can be explained by the fact that head blocks strapped to a spine board make a direct rigid connection between the skull and thorax with a long lever arm. The spine board with head blocks is easy and fast to apply, and provide the highest level of immobilization of the noninvasive orthosis. However, it is only suitable for pre-hospital and emergency room use due to potential occurrence of pressure ulcers. The use of padded spine boards might however reduce the development of pressure ulcers.14

Finally, the halo-vest restricted cervical lateral bending and rotation nearly complete. However, some flexion/extension remained possible. This might be caused by inevitable movement of the vest in relation to the thorax. The halo-vest can be used in patients with mechanical highly instable cervical injury. From our study it appears that complete restriction of the cervical spine movement cannot be accomplished with external immobilizers only. However, it is questionable if complete restriction of the cervical spine is truly necessary in all cases.15

Some potential limitations have to be discussed. Cervical movement was measured in cadavers of relative high age. It is known that the cervical spine movement decreases with age and results might have been different in younger patients.16 Furthermore, spinal movement might be different due to the lack of muscle activity. In addition, movement of the uninjured cervical spine was examined as it is unethical to perform several cervical restriction tests in patients with spinal injury.

With the findings of this study, the choice for a specific type of immobilizer can be facilitated for clinical practice. It can be hypothesized that mechanically relatively stable fractures can be treated with cervicothoracic devices while more mechanically instable fractures can be stabilized effectively in the pre-hospital and ER setting with head blocks on a spine board, and in the hospital or ambulatory setting with a halo-vest. However, before implementation in clinical practice well designed clinical studies to support these hypotheses are essential.

In conclusion, this is the first study that described intervertebral cervical movement with and without external immobilizers of the cervical spine using RSA. With this new knowledge of external immobilizers and their ability to restrict intervertebral cervical movement, their indication and application in clinical practice can be improved for all patients with (suspected) cervical injury.
References

THE VALUE OF A RIGID COLLAR IN ADDITION TO HEAD BLOCKS: A PROOF OF PRINCIPLE STUDY

Micha Holla

Published in Emerg Med J. 2012;29(2):104-7
The Value of a Rigid Collar in Addition to Head Blocks: a Proof of Principle Study

Abstract

Background: All trauma patients with a cervical spinal column injury or with a mechanism of injury with the potential to cause cervical spinal injury should be immobilized until a spinal injury is excluded. Immobilization of the entire patient with a rigid cervical collar, backboard, head blocks with tape or straps is recommended by the Advanced Trauma Life Support guidelines. However there is insufficient evidence to support these guidelines.

Objective: To analyze the effects on the range of motion of the addition of a rigid collar to head blocks strapped on a backboard.

Method: The active range of motion of the cervical spine was determined by computerized digital dual inclinometry, in ten healthy volunteers with a rigid collar, head blocks strapped on a padded spine board and a combination of both. Maximal opening of the mouth with all types of immobilizer in place was also measured.

Results: The addition of a rigid collar to head blocks strapped on a spine board did not result in extra immobilization of the cervical spine. Opening of the mouth was significantly reduced in patients with a rigid collar.

Conclusion: Based on this proof of principle study and other previous evidence of adverse effects of rigid collars, the addition of a rigid collar to head blocks is considered unnecessary and potentially dangerous. Therefore the use of this combination of cervical spine immobilizers must be reconsidered.

Introduction

All trauma patients with a cervical spinal column injury or with a mechanism of injury having the potential to cause cervical spinal injury should be immobilized at the scene, during transport and in hospital, until a spinal injury is excluded. Immobilization of the entire spine with a rigid cervical collar, head immobilization, backboard, tape and straps is recommended in the Advance Trauma Life Support guidelines by the American College of Surgeons. More than five million patients require spinal immobilization each year. From a trial in 1983 it was concluded that the combination of a rigid collar with sandbags and tape was most effective in immobilization of the cervical spine. In the 1990s, the sandbags and tape were replaced by foam head blocks strapped to padded backboards. The combination of a rigid collar with foam head blocks strapped on a backboard is now commonly used worldwide. The rationale for this technique is that two different immobilizers probably result in better immobilization and are therefore safer. However, there is insufficient evidence to support these guidelines. No scientific reports have been published about this method of double immobilization. In this study the effects on the range of motion of the addition of a rigid collar to head blocks strapped on a backboard were analyzed.

Materials and Methods

For the rigid collar we used the Stifneck Select collar (Laerdal Medical Corp, Wappingers Falls, New York, USA), which is made of a hard polyethylene shell that can be closed with a Velcro ban. It is padded with a 2 mm layer of soft foam. The collar immobilizes the cervical spine by bridging the sternum, clavicles, trapezoidal muscles and upper back to the occipital bone and mandible. The collar was used according to the manufacturer’s instructions. Sof-Loc head blocks (#35993 Iron Duck, Chicopee, Massachusetts, USA) were used. These two vinyl-dipped foam blocks were strapped with two Velcro straps on both sides of the head to a padded spine board (Traumatras, Almelo, the Netherlands). The skull and head blocks were fixed directly to the spine board, which in turn was connected to the thorax with straps. Ten healthy subjects with different body types, as described in Table 5.1, were selected to test the rigid collar, the head blocks strapped on the backboard and the combination of both. The volunteers were asked to flex, extend, laterally bend and rotate their head as much as possible with the different immobilizers on, as shown in Figure 5.1. The range of motion was measured with a computerized digital inclinometer (EDI 320 CYBEX, Ronkonkoma, New York USA) as described by the American Medical Association. The range of motion without an immobilizer was considered 100% of the normal range of motion. The same volunteers were asked to open their mouth as far as possible with and without application of the immobilizers. The distance from the lower border of the upper incisors and the upper border of the lower incisors was measured.
three times with a ruler as described by Chin et al, and the average calculated. The mean active range of motion and SD was determined for each immobilizing technique. A two-tailed paired Student t test and 95% confidence interval was calculated using SPSS 16.

### Results

The range of motion of the cervical spine with and without cervical immobilization is presented in Figure 5.2 and Table 5.2. With the rigid collar on, the mean range of motion in all directions was limited to at least 34% of the normal range of motion. With the head blocks alone the mean range of motion was reduced to at least 12% of the normal range of motion. The range of motion in all directions was not reduced with the addition of a rigid collar to head blocks. As described in Table 5.3, the difference in the range of motion was significant reduced (p<0.005) by the collar compared with no immobilization. A second significant decrease (p<0.005) in the range of motion in all directions was seen when the head blocks were compared with the rigid collar. No significant decrease (p>0.05) in the range of motion was observed when the collar was added to the head blocks. The mean mouth opening was significant reduced (p<0.01) from 47 mm (SD 9 mm) without a collar to 34 mm (SD 11 mm) with a collar.

### Figure 5.2

The mean range of motion of the cervical spine with a rigid collar, head blocks and a combination of both in ten healthy subjects. The inserted lines represent the smallest detectable differences measured with the Cybex EDI-320 as reported by Hoving.10

### Table 5.1

The body characteristics and chosen Stifneck collar size of ten healthy volunteers.

<table>
<thead>
<tr>
<th>volunteer number</th>
<th>gender</th>
<th>age (years)</th>
<th>body length (cm)</th>
<th>body weight (kg)</th>
<th>BMI (kg/m²)</th>
<th>distance mandibular corner – C5 joint (cm)</th>
<th>minimal neck diameter (cm)</th>
<th>StifneckSelect collar size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>male</td>
<td>31</td>
<td>185</td>
<td>85</td>
<td>25</td>
<td>14</td>
<td>39</td>
<td>regular</td>
</tr>
<tr>
<td>2</td>
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<td>43</td>
<td>190</td>
<td>101</td>
<td>28</td>
<td>13</td>
<td>45</td>
<td>short</td>
</tr>
<tr>
<td>3</td>
<td>male</td>
<td>34</td>
<td>185</td>
<td>63</td>
<td>18</td>
<td>16</td>
<td>37</td>
<td>regular</td>
</tr>
<tr>
<td>4</td>
<td>male</td>
<td>31</td>
<td>198</td>
<td>101</td>
<td>26</td>
<td>15</td>
<td>41</td>
<td>tall</td>
</tr>
<tr>
<td>5</td>
<td>female</td>
<td>36</td>
<td>170</td>
<td>65</td>
<td>22</td>
<td>14</td>
<td>36</td>
<td>regular</td>
</tr>
<tr>
<td>6</td>
<td>male</td>
<td>26</td>
<td>191</td>
<td>78</td>
<td>21</td>
<td>15</td>
<td>37</td>
<td>tall</td>
</tr>
<tr>
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<td>23</td>
<td>168</td>
<td>53</td>
<td>19</td>
<td>11</td>
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<td>18</td>
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<td>tall</td>
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<tr>
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<td>167</td>
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<td>65</td>
<td>20</td>
<td>18</td>
<td>32</td>
<td>tall</td>
</tr>
</tbody>
</table>

### Figure 5.1

The range of motion of the cervical spine of a healthy subject with a rigid collar, head blocks on a spine board and a combination of both.
New Perspectives on External Immobilization of the Cervical Spine

Table 5.2 Mean range of motion (with standard deviation) and percentage of range of motion (with standard deviation) of the cervical spine with different cervical spine immobilizers.

<table>
<thead>
<tr>
<th>type of immobilizer</th>
<th>lateral bending</th>
<th>flexion-extension</th>
<th>rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td>77° (15%)</td>
<td>114° (5°)</td>
<td>151° (25%)</td>
</tr>
<tr>
<td>collar</td>
<td>40° (10%)</td>
<td>55° (14%)</td>
<td>53° (20%)</td>
</tr>
<tr>
<td>head blocks</td>
<td>10° (10%)</td>
<td>6° (6°)</td>
<td>8° (5°)</td>
</tr>
<tr>
<td>collar and head blocks</td>
<td>12° (9%)</td>
<td>4° (5°)</td>
<td>6° (5°)</td>
</tr>
</tbody>
</table>

Table 5.3 Mean differences and 95% confidence intervals for difference between the range of motion of the cervical spine possible with different immobilization methods.

<table>
<thead>
<tr>
<th></th>
<th>lateral bending</th>
<th>flexion-extension</th>
<th>rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>none - collar</td>
<td>-42°*** (34°; 49°)</td>
<td>58*** (51°; 65°)</td>
<td>99*** (89°; 101°)</td>
</tr>
<tr>
<td>collar - head blocks</td>
<td>32°*** (26°; 38°)</td>
<td>48*** (42°; 55°)</td>
<td>47*** (37°; 58°)</td>
</tr>
<tr>
<td>head blocks - collar and head blocks</td>
<td>-1° (-6°; 4°)</td>
<td>2° (-1°; 6°)</td>
<td>-4° (-7°; 0°)</td>
</tr>
</tbody>
</table>

* p<0.05, ** p<0.001, *** p<0.005

Figure 5.3 An overview of adverse effects of rigid collars.1,3,6,12,13,15-26,28,29

difficulty to obtain an odontoid peg radiograph
upward pressure on mandible closing the mouth
plastics decreasing the quality of radiographs
pressure on fractured ribs and clavicle
increasing pain when fractured

elevated pressure on jugular veins
increasing intra cranial pressures
increased pressure on skin causing pressure sores
increasing motion of the high cervical spine when mouth is opened
discomfort in neck causing misinterpretation as pain from cervical injury
incomplete stabilisation due to mobile shoulder girdles misleading full immobilisation

Discussion

This proof of principle study demonstrates that the application of a rigid collar in addition to head blocks does not provide extra immobilization of the cervical spine. No previous reports showing benefit of this combination of immobilization are available. Nonetheless, this combination has been used worldwide on millions of patients.1 It is well known that most commonly used collars do not fully immobilise the cervical spine. At least 19° of flexion-extension, 46° of axial rotation, or 45° of lateral bending is possible with different collars. Other rigid collars like the Aspen, Ambu and Miami J-collar function in a similar manner. The use of sandbags and tape was more effective in immobilization of the cervical spine than any collar. The addition of a Philadelphia collar to sandbags reduced the extension from 15° to 7°. Although the range of motion was measured with a handheld goniometer and no significance analysis was reported in that study, the combination of a collar and sandbags with tape was previously advised. However, the modern foam head blocks strapped to a spine board, as used in this study, limit all cervical motions, including extension to less than 15°. Therefore it is clear that the semi-constraining rigid collars do not add extra immobilization to full-constraining head blocks. The assumption that a combination of two different immobilizers results in the best immobilization is not true. The number of subjects in this study is limited. After evaluation of a pilot study of ten subjects, however, it became obvious that the best cervical immobilizer determines the range of motion of the cervical spine. Therefore it is not likely that increasing the number of healthy volunteers in this proof of principle, will affect the outcome of this study. However, a larger prospective trial with injured patients is needed.

No extremely obese, short or injured subjects were included in this study. It is unknown if, and how, the range of motion is affected by external immobilizers in these groups of patients. Further prospective clinical trials are needed to answer these questions. Although the reliability for the range of motion for inclinometry is rated good, with an intraobserver and interobserver intraclass correlation coefficient of 0.85, 0.70, respectively, the smallest detectable differences with the Cybex EDI-320 go up to 10° for flexion-extension, 7° for lateral flexion and 14° for rotation. However, despite the 95% CIs of this study, these measurement errors will not affect the clinical message of the study: a rigid collar does not provide additional immobilization when used in combination with head blocks.

In agreement with other studies we found that the use of a rigid collar significantly reduces mouth opening.11,12 All rigid collars immobilise the cervical spine by compression of the mandible. This forces the mandible upwards to close the mouth. If less pressure is applied the mandible to increase the mouth opening more movement is possible in the cervical spine. Limited mouth opening will make removal of blood, broken teeth or artificial dentures and placing a tracheal tube more difficult. Some tubes cannot be placed when a rigid collar is in place.13 Apart from a lack of additional immobilization and a limitation of the opening of the mouth a number of adverse side effects of rigid collars are described in the literature, as discussed in the following sections.2
**Increased motion in the high cervical spine**

The pressure of the collar on the mandible forces the skull to tilt backwards when the mouth is opened. A fluoroscopic study with chewing healthy people showed an increased motion at the higher levels of the cervical spine when wearing a rigid collar. As upper cervical spine fractures occur relatively frequently, complete immobilization of the total cervical spine is needed in patients with possible instability of the spine.

**Pressure sores of the skin**

With rigid collars like the Stifneck, local pressures on the skin go up to 80 mmHg. This can cause collar-related decubitus ulcerations. Pressure sores can complicate later surgery and make later immobilization with an orthosis impossible.

**Increased intracranial pressure**

A rigid collar can act like a cervical tourniquet, since it compresses the jugular veins with interface pressures of >10 mmHg. Several studies describe an increase of intracranial pressure due to rigid collars. Because trauma patients, especially those with cervical injuries, often have intracranial contusions, it is clinically relevant to keep the intracranial pressure as low as possible.

**Increased pain and discomfort**

As rigid collars rests upon the clavicles, sternum and upper ribs, fractures in this area will cause additional pain. Furthermore, a rigid collar can cause pain in an otherwise healthy subject.

The examining doctor can misinterpret this as pain from a cervical spinal injury.

**Difficulty in obtaining adequate radiographs**

It is not possible to make an odontoid peg radiograph with a rigid collar on because the mouth cannot be fully opened. Temporary removal of the collar leads to extra manipulations and is time consuming. Furthermore, rigid collars are not completely radiolucent. The contrast of the image will decrease, and misleading distortions can occur at the edges of the collar.

**False sense of full Immobilization**

Complete immobilization by a rigid collar is impossible because it rests on the mobile shoulder girdles and mobile mandible. A false sense of security that the cervical spine is fully immobilized with a rigid collar can be created. Manual support of the head by an experienced person is always needed when a patient is log rolled with only a rigid cervical collar on. The adverse effects of rigid collars are summarised in Figure 5.3.

One might argue that a rigid collar may work as a reminder to the trauma team that the cervical spine is not cleared for instability. The head blocks, however, can work as a similar reminder. The rigid collar can be useful in temporary immobilization of the neck at extrication of patients in a sitting position in cars. However, based on the results of this study, the rigid collar should be removed when the head blocks are placed.

**Conclusions**

The results of this proof of principle study demonstrate that the addition of a rigid collar to head blocks does not provide any extra immobilization of the cervical spine and is therefore considered unnecessary. Furthermore, this study showed that a rigid collar reduces the ability to open the mouth and clear the airway. In view of this and other known adverse effects of a rigid collar (increased motion at the level of the high cervical spine, increased intracranial pressures, pressure sores of the skin, increased pain and discomfort, poor quality of radiographs and a false sense of immobilization), the combination of a rigid collar and head blocks should be reconsidered.
References

COMPARISON OF VACUUM MATTRESSES AND PADDED SPINE BOARDS WITH HEAD BLOCKS

Micha Holla, Willem-Jan Sieverink, Allard Hosman, Nico Verdonschot, Gerjon Hannink

Submitted to European Journal of Trauma and Emergency Surgery.
Comparison of Vacuum Mattresses and Padded Spine Boards with Head Blocks

Abstract

Objective: To compare the characteristics of two vacuum mattresses (Germa EasyFix and the RedVac VM7000) and two padded spine boards with head blocks (Arpemat and Comfort Board) with regard to dimensions and weight, usability, restriction of spinal movement, time needed to apply and remove the immobilizer, absorption of X-ray beams, and skin contact pressure.

Methods: Emergency service workers applied one or more of the four immobilization devices to healthy volunteers and subsequently completed a questionnaire rating the devices on a five-point scale: cleanability, expected durability, ability to roll the patient, ability to lift the patient, accessibility of the thorax and abdomen, and the restriction of spinal movement. The times needed to apply and remove the immobilizer were recorded. Absorption of X-ray beams was measured using a DIADOS Diagnostic Dosemeter and R/F/D detector. Skin contact pressure measurements were performed on ten healthy volunteers using Tekscan pressure sensors.

Results: A total of 51 emergency service workers completed the questionnaire. The Arpemat scored significantly higher for cleanability compared to the Comfort Board. For durability, the Arpemat scored significantly higher compared to the other immobilizers. No differences between the four immobilizers were found regarding the ability to roll the patient, the ability to lift the patient, and the accessibility of the thorax and abdomen. The Arpemat and Comfort Board scored significantly higher for cervical spine restriction compared to the RedVac VM7000. The total time needed to apply the immobilizer including log roll or scoop-stretcher procedure was significantly shorter for the Comfort Board compared to the RedVac 7000VM. At the scapular level, the Arpemat showed significantly lower peak pressures compared to the Comfort Board. In contrast, at the sacral level, the Arpemat showed significantly higher peak pressures compared to the other immobilizers. The Germa EasyFix showed the highest absorption of X-rays (> 40%) in both anterior-posterior and lateral direction.

Conclusion: Although the users of pre-hospital immobilizers must weigh the importance of different items and costs, the results of this study suggest that the use of padded spine boards with head blocks is most advisable when immobilizing trauma patients in the pre-hospital setting.

Introduction

Each year, at least five million trauma victims are immobilized in a pre-hospital setting in the United States, with an incidence of 10,000 cases of spinal cord injury. Since the 1960s, the spine board has been the gold standard for pre-hospital transfer and transport of trauma victims. The spine boards are used to transfer patients with possible spinal injury from the scene of the accident to an ambulance stretcher and to the hospital. The patient is secured to the board with straps, enabling in-line rolling of the patient in case of vomiting. Most spine boards are made from one component and are therefore easy to clean and durable. Known problems of spine boards are the increased risk of skin problems due to high skin contact pressures, and the increased stress levels of the immobilized due to low comfort. Despite the known disadvantages of the spine board, guidelines for spinal cord and vertebral injury such as the Advanced Trauma Life Support (ATLS) still recommend using this immobilization technique.

The introduction of the vacuum mattress and padded spine boards for pre-hospital immobilization has offered emergency services workers alternative solutions. This new generation of products reduces issues of skin contact pressures and increases comfort for the immobilized. Both padded spine boards and vacuum mattresses are increasingly used in pre-hospital practice, however there are regional variations in use of one or the other. Several studies have compared vacuum mattresses or padded spine boards with unpadded spine boards or vacuum mattresses reporting on the level of spinal immobilization, time needed to apply, skin contact pressures and comfort.

When deciding on the most appropriate spinal-immobilizer for pre-hospital use, other important items such as cleanability, durability, and the ability to lift and roll the patient have to be considered, although these factors have not been reported on. To our knowledge, only two studies directly compare vacuum mattresses with padded spine boards, testing only one type of spine board with one type vacuum mattress. In this study, we compare the characteristics of two vacuum mattresses and two padded spine boards with regard to dimensions and weight, usability, restriction of spinal movement, time needed to apply and remove the immobilizer, absorption of X-ray beams, and skin contact pressure.

Materials and Methods

Immobilizers

We selected two padded spine boards, the Arpemat (Arpemat, Druten, the Netherlands) and the Comfort Board (Technovas, Meerssen, the Netherlands), and two vacuum mattresses, the Germa EasyFix (AB Germa, Kristianstad, Sweden) and the RedVac VM7000 (Kohlbrat&Brunz, Radstadt, Austria) for comparison.
The Arpemat is a foam mattress with a plastic cover that is shaped to fit on a spine board, and has an integrated baseplate for head blocks. We used the Arpemat together with a Ferno Millennia spine board (Ferno, Wilmington, OH, USA). The Comfort Board is a spine board with an embedded replaceable polyester inlay. In this study, both the Arpemat and Comfort Board were combined with Ferno head blocks and a Ferno Fastrap (Ferno). As the Comfort Board does not have an integrated base plate to fix the headblocks, we used a Ferno baseplate.

Both the Germa EasyFix and RedVac VM7000 are body-shaped vacuum mattresses filled with granules and equipped with model-specific straps (Table 6.1).

We tested these immobilizers on six items; 1) dimensions and weight, 2) usability, 3) restriction of spinal movement, 4) time needed to apply and remove the immobilizer, 5) contact pressure, and 6) the absorption of X-ray beams. In all cases, immobilization was performed following the manufacturers’ instructions.

**Dimensions and weight**
The dimensions and weight of the four immobilizers were measured using a digital floor scale (Seca 877, Birmingham, UK). Dimensions of the vacuum mattresses were measured in unfolded and folded state. The box volume was calculated using the length, width and height of the immobilizer in folded (not vacuum) state.

**Usability**
During ten days of testing, a total of 51 emergency service workers (15 ambulance drivers, 13 paramedics, 20 firefighters, and 3 trauma helicopter physicians; mean age 43.4 (SD 8.9) years) of the region Gelderland-Zuid (VRGZ), the Netherlands, applied one or more of the four immobilization devices to healthy volunteers. A team of two emergency workers applied the immobilizer on one volunteer. None of the healthy volunteers had a history of neck or back pain prior to the test, and all gave their informed consent. Following the test, the emergency service workers independently completed a questionnaire, scoring the ability to clean the immobilizer, its expected durability, the ability to roll the patient, the ability to lift the patient, and the accessibility of the thorax and abdomen. Items were scored on a five-point scale (1: “poor”, 2: “fair”, 3: “good”, 4: “very good”, 5: “excellent”).

**Restriction of the spinal movement**
Once the healthy volunteers were immobilized, they were instructed to perform rotation, flexion-extension and lateral bending movements. The restriction of spinal movement (cervical spine and thoracolumbar spine) by the immobilizers was scored independently on a five-point scale by the emergency service workers, as described above.
**Time needed to apply and remove the immobilizer**

The time needed to apply and remove the immobilizer was recorded using a stopwatch. The time was stopped when the emergency service workers indicated that the volunteer was completely immobilized on an ambulance stretcher (Stryker M-1 Roll-in 6100) and ready for transport. Interval times were marked at the beginning and end of the log roll or scoop-stretcher procedure. A log roll procedure was performed on the ground if the volunteer was placed on the padded spine board. A scoop-stretcher (Ferno EXL) was used to lift the patient from the ground on the vacuum mattress.

**Skin contact pressure**

Peak contact pressures were measured with ten healthy subjects (medical students; 7 males and 3 females; BMI range 19.6 to 27.1) using a CONFORMat Model 5330 pressure sensor (Tekscan, South Boston, MA). The pressure sensor was calibrated prior to use following the manufacturer’s instructions. The sensor was placed between the volunteer and the immobilization device. Contact pressure measurements for all four immobilizers were obtained from all volunteers. The contact pressures at the scapular and sacral level were measured twice with an interval of five minutes and averaged. The Ferno Millennia spine board (without the Arpemat) was also included in the contact pressure measurements.

**Absorption of X-ray beams**

X-rays were created with a Varian X-ray system (120 µGy in 70kV/12.5mA) and absorption was measured with a DIADOS Diagnostic Dosimeter and R/F/D detector (PTW, Freiburg, Germany). The absorption of X-ray beams by the immobilizers was tested at the cervical, thoracic, lumbar and sacral levels in anterior-posterior and lateral directions. The Ferno Millennia spine board (without the Arpemat), Ferno head blocks, and Ferno baseplate without Arpemat, were also included.

**Statistical analyses**

Descriptive statistics were used to summarize the data. Unless otherwise indicated, the data were summarized as median with range. Differences in medians for usability, restriction of spinal movement, and time to apply/remove data were tested using Kruskal-Wallis tests followed by Wilcoxon rank sum tests for pairwise comparisons. Friedman’s one-way repeated measures analysis of variance by ranks was used to test for differences in mean and peak pressures measurements between the vacuum mattresses and padded spine boards, followed by Wilcoxon signed-rank tests for pairwise comparisons. The Benjamin-Hochberg procedure was used to control the probability of Type I errors due to multiple comparisons. Statistical analyses were performed using R version 3.4.0 (R Foundation, Vienna, Austria). P-values < 0.05 were considered statistically significant.

**Results**

**Dimensions and weight**

Table 6.1 gives an overview of the dimensions and weight of the tested immobilizers. The Arpemat with Ferno spine board, Comfort Board, Germafix, and RedVac weighed 6.7, 8.0, 8.2, and 8.3 kg respectively. The dimensions of the folded Germa EasyFix was smallest; this immobilizer can be reduced to 60x60x30 cm. The box volume of the padded spine boards was smaller than the box volume of the vacuum mattresses: Arpemat with Ferno spine board (71.6 dm³) and Comfort Board (66.6 dm³) versus Germa EasyFix (108.0 dm³) and RedVac VM7000 (121.0 dm³).

**Usability**

The questionnaire scores for usability are given in Figure 6.1. The Arpemat scored significantly higher for cleanability (median 4, range 2-5) compared to the Comfort Board (median 3, range 1-4; p = 0.04). For durability, the Arpemat scored significantly higher (median 4, range 3-4) compared to the Comfort Board (median 2, range 1-4; p = 0.007). Germa EasyFix (median 3, range 2-4; p = 0.004), and RedVac VM7000 (median 3, range 2-4; p = 0.03).

No significant differences between the four immobilizers were found regarding ability to roll the patient (Kruskal-Wallis test, χ² = 1.18, df = 3, p-value = 0.76), the ability to lift the patient (Kruskal-Wallis test, χ² = 0.49, df = 3, p = 0.92), and the accessibility of the thorax and abdomen (Kruskal-Wallis test, χ² = 7.48, df = 3, p = 0.06).

**Restriction of the spinal movement**

The scores for restriction of spinal movement are shown in Figure 6.2. The Arpemat (median 4, range 2-4) and Comfort Board (median 4, range 2-4) scored significantly higher for restriction of the cervical spine compared to the RedVac VM7000 (median 3, range 1-4; p = 0.02 and p = 0.01, respectively). No significant differences between the four immobilizers were found regarding the ability to restrict the movement of the thoracolumbar spine (Kruskal-Wallis test, χ² = 0.63, df = 3, p = 0.89).

**Time needed for application and removal of immobilizer**

The total time needed to apply the immobilizer including log roll or scoop-stretcher procedure was significantly shorter for the Comfort Board (2’54” (2’01”-3’49’)) compared to the RedVac VM7000/M (5’46” (4’45”-8’06’); p = 0.04). No significant differences in total time needed to apply and to remove the immobilizer were found between any of the other immobilizers (Table 6.2).
Comparison of Vacuum Mattresses and Padded Spine Boards with Head Blocks

Contact pressure

The peak contact pressures of the tested immobilizers are shown in Figure 6.3. At the scapular level, the Arpemat (78 mmHg (65.5-106)) showed significantly lower peak pressures compared to the Comfort Board (102.5 mmHg (79-134); p = 0.02). The Arpemat (166.5 mmHg (115-203)) showed significantly higher peak pressures at the sacral level compared to the Comfort Board (119.8 mmHg (96.5-144); p = 0.005), Germa EasyFix (110 mmHg (67.5-159); p = 0.003), and RedVac VM7000 (125.5 mmHg (73.5-158); p = 0.04) (Table 6.3).
Absorption of X-ray beams
All immobilizers absorbed a part of the X-ray beams in the anterior-posterior direction. At the level of the spine, thorax and abdomen, both padded spine boards had no absorption of X-rays in the lateral direction. The Germa EasyFix showed the highest absorption of X-rays (>40%) in both anterior-posterior and lateral direction on all levels (Table 6.4).

Table 6.3 Peak pressures at scapular and sacral levels. Values represent median (range).

<table>
<thead>
<tr>
<th></th>
<th>Scapular pressure (mmHg)</th>
<th>Sacral pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unpadded board</td>
<td>Ferno Millennia</td>
<td>158 (100-198)</td>
</tr>
<tr>
<td>Padded board</td>
<td>Arpemat + Ferno Millennia</td>
<td>78 (66-106)</td>
</tr>
<tr>
<td></td>
<td>Comfort Board</td>
<td>103 (79-134)</td>
</tr>
<tr>
<td>Vacuum mattress</td>
<td>Germa EasyFix</td>
<td>90 (65-140)</td>
</tr>
<tr>
<td></td>
<td>RedVac VM7000</td>
<td>100 (58-148)</td>
</tr>
</tbody>
</table>

Table 6.4 Absorption in % µGy of the vacuum mattresses and (padded) spine boards.

<table>
<thead>
<tr>
<th></th>
<th>Anterior-posterior</th>
<th>Lateral</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C2</td>
<td>Th6</td>
</tr>
<tr>
<td>Ferno Baseplate (only)</td>
<td>17%</td>
<td>0%</td>
</tr>
<tr>
<td>Ferno Head blocks (only)</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Arpemat + Ferno Millennia</td>
<td>20%</td>
<td>19%</td>
</tr>
<tr>
<td>Arpemat (padding only)</td>
<td>16%</td>
<td>14%</td>
</tr>
<tr>
<td>Ferno Millennia (spine board only)</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>Comfort Board + Ferno baseplate</td>
<td>29%</td>
<td>14%</td>
</tr>
<tr>
<td>Comfort Board (spine board only)</td>
<td>14%</td>
<td>14%</td>
</tr>
<tr>
<td>Germa EasyFix</td>
<td>43%</td>
<td>47%</td>
</tr>
<tr>
<td>RedVac VM7000</td>
<td>16%</td>
<td>21%</td>
</tr>
</tbody>
</table>

* p=0.02; ** p=0.01; *** p=0.001
Discussion

We compared the characteristics of two vacuum mattresses and two padded spine boards with regard to dimensions and weight, usability, restriction of spinal movement, time needed to apply and remove the immobilizer, absorption of X-ray beams, and skin contact pressure. Our results show that the Arpemat padded spine board was rated best by the emergency service workers for cleanability, when compared with the Comfort Board, and rated best for durability when compared to Comfort Board and vacuum mattresses. The emergency service workers reported that padded spine boards with head blocks provided better cervical immobilization than the RedVac VM7000 vacuum splint. In addition, they were quicker to apply and had less X-ray absorption compared to vacuum mattresses.

The padded spine boards were less voluminous and lighter than the vacuum mattresses. The dimensions of the immobilizer can be important for ambulances with limited space for storage as some ambulances have limited space for an unfoldable spine board, while others have little space for storing a voluminous vacuum mattress. When discussing effective use of ambulance space, it is necessary to keep in mind that for an inline transfer to a vacuum mattress, an additional scoop stretcher is needed.

The padded spine boards weighed just under two kilograms less than the vacuum mattresses. This weight is relative to normal body weights, only a fraction of the total weight that emergency service workers have to lift during a transfer.

The Arpemat scored best on cleanliness: it can easily be detached from the spine board, has a smooth surface, and the straps can be washed separately. In contrast, the Comfort Board has an inlay that is difficult to remove from the board, thus allowing dirt and fluids to enter between the ridges of inlay and board.

The emergency service workers scored the durability of the Arpemat higher than that of the Comfort Board and vacuum mattresses. This may be due to the perceived vulnerability of the soft exterior of the inlay of the Comfort Board and vacuum mattresses. For the latter type, this may cause a loss of vacuum and stability. There were no significant differences between the padded spine board and vacuum mattresses with respect to the ability to roll and lift patients.

Quick access to the thorax and abdomen for acute thoracic drains or manual cardiac resuscitation is considered to be of vital importance. Due to the shape of the vacuum mattress, which is nearly completely wrapped around the patient, we would expect less accessibility than in the more open design of the spine board with wraps. Surprisingly, no significant difference was found regarding the accessibility to thorax and abdomen between the padded spine boards and vacuum mattresses (p=0.06). However, the number of observations was low and a greater number of observations may have yielded statistical significance.
translucent padded spine board immediately on arrival, so these findings may not be clinically relevant.

We note a number of limitations. First, the data for usability and immobilization were collected using a questionnaire and therefore based on the perceptions of experienced emergency service workers. The restriction of spinal movement should preferably be measured by digital 3D motion trackers. Second, due to limited time available to the observers for testing, they were not all able to rate all the immobilizers. Ideally, all usability scores would be obtained after a prolonged time of application by the observers in real practice, for all types of immobilizers. This would increase the validity of the usability scores. Third, for the skin contact pressure tests, all volunteers were adults with normal body mass indexes. No children or extreme elderly, skinny or obese people were included in this study. Inclusion of these groups of patients could provide different results. Finally, we only tested healthy volunteers. It is likely that studying trauma victims as done by Mahshidfar et al. would provide a more realistic outcome, however, there are ethical concerns about instructing trauma patients to move.

In this study the Arpemat padded spine board, as scored by independent emergency service workers, was more usable in terms of ability to clean when compared to the Comfort Board and more durable than the Comfort Board and tested vacuum mattresses. Finally, the padded spine boards with head blocks were given better scores for the immobilization of the cervical spine by the emergency workers, than the vacuum mattresses. In addition, the padded spine boards with head blocks could be applied more quickly and provided less X-ray absorption when compared with vacuum mattresses. All tested immobilizers had significantly lower mean peak pressures when compared with an unpadded spine board.

**Conclusion**

Although the users of pre-hospital immobilizers must weigh the importance of many different items and costs, our results suggest that the use of padded spine boards with head blocks is most advisable when immobilizing trauma patients in the pre-hospital setting.

Ideally, our results should be confirmed in large prospective pre-hospital studies with randomized patient populations testing both padded spine boards and vacuum mattresses, also recording the relevant consequences of the two types of immobilizers.

**Acknowledgement**

We would like to thank the following distributors for supply of the equipment tested in this study:
- Vandeputte Medical, Nieuwegein, the Netherlands for the Germa EasyFix vacuum mattress and Ferno equipment;
- Innoventa BV, Bunnik, the Netherlands for the RedVac VM7000 vacuum mattress;
- Arno Peters, Druten, the Netherlands for the Arpemat (padding) and Ferno spine board;
- Technovas, Meerssen, the Netherlands for the Comfort Board;
- Veiligheidsregio Gelderland-Zuid, Nijmegen, the Netherlands for the Stryker Ambulance Stretcher and Ferno Fastrap.
New Perspectives on External Immobilization of the Cervical Spine

Comparison of Vacuum Mattresses and Padded Spine Boards with Head Blocks

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4. ATLS. Advanced Trauma Life Support for Doctors (Student Course Manual); Edition 1, editor: Amer College of Surgeons; 2008.
A NEW CRANIO-THORACIC MATTRESS FOR IMMOBILIZATION OF THE CERVICAL SPINE IN CRITICAL CARE PATIENTS


Published in the Journal of Trauma Nursing 2017;24(4):261-269.
A New Cranio-Thoracic Mattress for Immobilization of the Cervical Spine in Critical Care Patients

Abstract

Background: 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.

Purpose: In this study a newly developed cranio-thoracic 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 head blocks strapped to a spine board.

Methods: Cervical movement was measured by radiostereometric analysis in five fresh frozen cadavers. Peak-interface and discomfort pressures were measured in ten healthy volunteers. Radiographic absorption was calculated by measuring the total emission radiation with and without immobilizer.

Results: 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 head blocks strapped to a spine board and the Pharaoh mattress. The mean peak pressures on the Pharaoh mattress were significantly lower compared to the spine board. Healthy volunteers gave significantly lower numeric discomfort scores on the Pharaoh mattress when compared to the spine board. The Pharaoh mattress absorbed more X-rays than the spine board.

Conclusions: The Pharaoh mattress provides similar restriction of cervical movement compared to head blocks strapped to a spine board, 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 unstable spinal fractures.

Introduction

Cervical spine injury occurs in 6.1% of the patients after blunt trauma. More than one third of these patients are critically ill and have moderate to severe head injury with lowered consciousness and are nursed on the intensive care unit. Immobilization of the spine in a proven mechanically unstable fracture of the cervical spine fracture is necessary to prevent secondary dislocation of the spine and to avoid iatrogenic spinal cord injury, although every current cervical immobilization technique has considerable risks for complications. Cervical collars and cervico-thoracic immobilizers cause a venous outflow obstruction and are a nociceptive stimulus. This can cause significantly elevated intracranial pressures, which are a potential risk to patients with head injury. Furthermore, collars do not fully restrict cervical movement, can cause peak skin pressures resulting in skin ulcers, and limit access to neck and airway. Vacuum mattresses reduce cervical movement and can prevent peak skin pressures, nonetheless the access to the thorax and head is rather limited. The halo vest and halo traction are invasive to the skin, relatively expensive, do not allow access to the thorax, are contraindicated when certain skull fractures are present, and can lead to higher morbidity and mortality in the elderly due to pulmonary problems. Head blocks or sandbags fixed to the mattress are often used and effectively reduce cervical movement. However, turning is impossible and proper nursing care of the patient difficult. The disadvantages of the currently used immobilizers result in problems with immobilization of cervical spine, especially in the critical care patients.

A new cranio-thoracic cervical immobilizer has been developed with the goal to restrict cervical movement, to allow access to vital areas of the head, neck and chest, and to allow turning and care of the patient with limited risks of complications.

Purpose

The goal of this study was to test the newly developed mattress and compare it with head blocks strapped to a spine board, regarding restriction of cervical range of movement, peak pressure at the skin-interface, discomfort and radiographic absorption.

Methods

Design of the new immobilizer

After evaluation of the principles of cervical immobilization an anatomically pre-shaped mattress, connecting head and thorax was chosen as a model. The so called Pharaoh mattress is made of three parts, i.e. a head component, a torso component, and a dorsal connecting board (Figure 7.1A). The distance between head and torso components are adjustable, so it can fit patients with short and long necks. The head component applies
A New Cranio Thoracic Mattress

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Figure 7.1 The Pharaoh mattress: an anatomically pre-shaped cranio-thoracic immobilizer. A: presented with patient and features. B: technical drawing for use with Creative commons “attribution-share alike 4.0.”

The Pharaoh mattress (Aquarius, the Netherlands) was compared with head blocks strapped to a Millennia Spine board (Ferno, West Yorkshire, England).

Cervical spine movement was measured in human cadavers using radiostereometric analysis (RSA): a highly accurate method to assess motion of markers fixed inside rigid bodies.15 Five fresh-frozen cadavers (three male and two female, mean 81 years (range 77- 93)) without any known pathology of the cervical spine and a normal BMI were obtained from our institutional Department of Anatomy. The cadavers were visually inspected to exclude specimens that showed signs of prior surgery. All cadavers were thawed before use and placed in supine position. Radiological beads were placed with a regular anatomical approach inside the occipital condyles (C0) and the cervical bodies of C1 to C7. The configuration of the bead placement is given in Figure 7.2. The configuration of the RSA setup is depicted in Figure 7.3. External forces to the skull were created by weights on a rope, conducted with pulleys, to pins placed in the skull ( Figure 7.4A/B). Flexion of the cervical spine was achieved by the application of 30 N, 2 cm from the skull surface, perpendicular to the central skull pin ( Figure 7.4C). Extension of the cervical spine was realized by the application of 30 N, 2 cm from the forehead skin, perpendicular to the fore head pin ( Figure 7.4D). Rotation of the cervical spine was achieved by a wheel with a

pressure on the occiput and temporal areas, leaving the parietal skull, face and neck free, essential for possible mouth opening, endotracheal tubes, tracheostomy and/or cranial pressure sensors for measurement of intra cranial pressures. The torso component applies pressure on the dorsum and posterior-lateral thorax/abdomen. The ventral and lateral parts of the chest and abdomen are accessible for thoracic drains, 12 lead ECGs and possible mechanical resuscitation. The lower end of the torso component leaves space for defecation, catheters and cleaning of the urogenital area. Both the edges of the head and torso components are curved with the same radius to facilitate turning of the patients. To reduce peak skin pressures the inlay of the head component is made from viscoelastic memory foam (Tempur Original, Tempur Benelux, Veenendaal, Netherlands). The supporting head and torso component are made of polyurethane foam with a density of 80kg/m.14 The stiff connection board is made from Lexan with Velcro strips. The head and torso straps are made of a polyurethane sling with braided Velcro strips. Non-ferromagnetic and radiolucent materials are used to enable additional MRI and radiography. The intention of the authors is non-commercial and Creative commons “attribution-share alike 4.0” do apply (https://creativecommons.org/licenses/by-sa/4.0/). This means that all technical details and drawings of the mattress are free and can be downloaded (Figure 7B). Others are free to use the design (commercial or non-commercial) if credits are given. In case of design changes, this has to be described.

Restriction of cervical spine movement

The Pharaoh mattress (Aquarius, the Netherlands) was compared with head blocks strapped to a Millennia Spine board (Ferno, West Yorkshire, England).

Cervical spine movement was measured in human cadavers using radiostereometric analysis (RSA): a highly accurate method to assess motion of markers fixed inside rigid bodies.15 Five fresh-frozen cadavers (three male and two female, mean 81 years (range 77- 93)) without any known pathology of the cervical spine and a normal BMI were obtained from our institutional Department of Anatomy. The cadavers were visually inspected to exclude specimens that showed signs of prior surgery. All cadavers were thawed before use and placed in supine position. Radiological beads were placed with a regular anatomical approach inside the occipital condyles (C0) and the cervical bodies of C1 to C7. The configuration of the bead placement is given in Figure 7.2. The configuration of the RSA setup is depicted in Figure 7.3. External forces to the skull were created by weights on a rope, conducted with pulleys, to pins placed in the skull ( Figure 7.4A/B). Flexion of the cervical spine was achieved by the application of 30 N, 2 cm from the skull surface, perpendicular to the central skull pin ( Figure 7.4C). Extension of the cervical spine was realized by the application of 30 N, 2 cm from the forehead skin, perpendicular to the fore head pin ( Figure 7.4D). Rotation of the cervical spine was achieved by a wheel with a
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Figure 7.2 The configuration of tantalum beads on each level of the cervical spine and skull base.

Small dots represent 1 mm tantalum beads and the bigger dots 3 mm lead beads. A: AP / lateral view of a C-spine model and the target spots for the beads. C: 30° left / right oblique RSA images of the cervical spine of a cadaver in neutral position with tantalum markers placed in each cervical body.

A diameter of 10 cm placed perpendicular on the central skull pin and two rotation skull pins. The wheel with a rope and weights applied a rotational force of 30 N with a lever arm of 5 cm (Figure 7.4F). Lateral bending of the cervical spine was accomplished by traction of 30 N, 2 cm from the skull surface, perpendicular of the central skull pin. During lateral bending the head rested on the radiolucent table. Rotation of the head during lateral bending was not corrected by additional external forces (Figure 7.4E). Tantalum markers were marked with computer software and manually checked. The position of each cervical body was determined to a 3D coordinate system. Angulation around the x,y,z-axis represented lateral bending, flexion-extension and rotation, respectively (left upper corners of Figure 7.4). With this coordinate system the angulation of each vertebral body in relation to its adjacent level was determined.

Furthermore, the total angulation/rotation between the skull base (C0) and C7 was calculated relative to the neutral position of each specific cadaver. The restriction of the immobilizer was determined in absolute degrees as well as in percentage of restriction per cadaver (when compared to the movement without immobilizer of that specific cadaver). A mean restriction percentage (MRP) was calculated to quantify this restriction of the immobilizers.

Figure 7.3 Radiostereometric analysis setup.

Peak interface pressure and discomfort

To measure the peak pressure at the interface of the immobilizers and skin, and to test comfort, ten healthy volunteers (four men and six women, with an average age of 24 years (range 20-28 years)) were recruited. The average body mass index (BMI) of the subjects was 22.9 kg/m² (range 20.3-27.6). The study protocol was approved by our institutional review board (CMO Arnhem-Nijmegen; CMO2014/103). Written informed consent was obtained from all healthy volunteers. Volunteers were successively assigned to either start with the head blocks strapped to a spine board or the Pharaoh mattress. Calibrated pressure sensors (CONFORMat® CER1 Tekscan, Inc., Boston, US) were placed between the immobilizers and the volunteers. Directly after full immobilization, the peak interface pressures (PIP) were measured in the occipital, scapular and sacral regions.

The level of discomfort in the occipital, scapular, and sacral regions, were scored directly after application of the immobilizer, and at 10, 20 and 30 minutes thereafter. The volunteers used a numeric rating score; a score of 0 represented no discomfort, whereas a score of 10 represented maximum discomfort.

Radiographic absorption

The regular settings for conventional roentgen imaging of the cervical spine from our radiology department were used (75kV with 16 mA). The emission of the X-ray beam in a dose area product (DAP) was measured by a dosimeter (DiaVolt-Multi in combination with...
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DiaControl expert, PTW Freiburg, Germany). The baseline DAP, the emission without any immobilizers in line of the beam, as generated with these settings) was 2.3 mGy·cm².

The radiographic absorption percentage of the Pharaoh mattress and spine board was determined in AP and lateral direction approximately at the level of C2, C7 and T12. The radiographic absorption percentage was calculated by dividing the DAP without immobilizer by the DAP with immobilizer.

Statistical analyses
Linear mixed models for repeated measures were used to compare the restriction, mean peak pressure measurements and discomfort scores between spine board with head blocks and the Pharaoh mattress at the different time points (for discomfort scores), adjusting for age, gender, and BMI. P values <0.05 were considered statistically significant. Statistical analysis was performed using R 3.3.1 (R Foundation, Vienna, Austria).

Results

The absolute and relative restriction of cervical spine movement per vertebrae and of C0 in relation to C7 with the Pharaoh mattress and head blocks strapped to spine board, are described in Table 7.1.

Both head blocks strapped to a spine board and Pharaoh mattress restricted cervical movement significantly in all directions. No significant differences in restriction were found between head blocks strapped to a spine board and the new Pharaoh mattress for flexion-extension (-8.0° (95%CI -29.4° - 13.4°); p = 0.5), lateral bending (-5.4° (95%CI -22.0° - 11.2°); p = 0.5), and rotation (-0.8° (95%CI -17.4° - 15.8°); p = 0.9).

The Pharaoh mattress and head blocks with spine board provided a mean restriction of flexion-extension (C0 vs C7) of 59% (SD 15%) and 73% (SD 9%) respectively. Most of the restriction of flexion and extension was achieved in C0-C1. Furthermore, the Pharaoh mattress and the head blocks with spine board provided 77% (SD 14%) and 85% (SD 7%) restriction of lateral bending respectively. Most of the lateral bending restriction was achieved in C1-C2.

Finally, the Pharaoh mattress and the head blocks with spine board provided 93% (SD 3%) and 94% (SD 4%) restriction of rotation, respectively. Most of the rotational restriction was achieved in C1-C2.

The highest peak interface pressures were found in the midline of the occiput, both scapular spines and the sacrum (Figure 7.5). On the spine board the mean peak pressures were 153.3 (SD 34.5) mmHg at the occiput, 109.6 (SD 14.6) mmHg at the scapulae and 186.1 (SD 30.3) mmHg at the sacrum. The mean of peak pressures on the Pharaoh mattress was significantly lower with pressures of 41.6 (SD 11.9) mmHg at the occiput (p < 0.001), 46.6 (SD 16.5) mmHg at the scapulae (p < 0.001), and 81.8 (SD 26.2) mmHg at the sacrum (p < 0.001).
Table 7.1 Restriction of intervertebral movement with the Pharaoh mattress and head blocks strapped to a spine board. (mean restriction in degrees (minimal/maximal) and angulation of C0 in relation to C7 (mean restriction in degrees (minimal/maximal) and percentage (SD)).

Table 7.1A Flexion-extension.

<table>
<thead>
<tr>
<th></th>
<th>no immobilizer</th>
<th>head blocks &amp; spine board</th>
<th>Pharaoh</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pre test</td>
<td>post test</td>
<td></td>
</tr>
<tr>
<td>CD-C1</td>
<td>17° (12/24)</td>
<td>-13° (-19°/-10)</td>
<td>-7° (10°/-2)</td>
</tr>
<tr>
<td>C1-C2</td>
<td>12° (9/15)</td>
<td>-8° (-16°/-4)</td>
<td>-6° (10°/-1)</td>
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<tr>
<td>C2-C3</td>
<td>5° (1/10)</td>
<td>-5° (-8°/-3)</td>
<td>-3° (8°/-1)</td>
</tr>
<tr>
<td>C3-C4</td>
<td>4° (2/8)</td>
<td>-3° (-7°/-1)</td>
<td>-1° (8°/-3)</td>
</tr>
<tr>
<td>C4-C5</td>
<td>7° (2/15)</td>
<td>-6° (-14°/-1)</td>
<td>-6° (-15°/-1)</td>
</tr>
<tr>
<td>C5-C6</td>
<td>9° (4/12)</td>
<td>-7° (11°/-1)</td>
<td>-8° (12°/-4)</td>
</tr>
<tr>
<td>C6-C7</td>
<td>8° (7/9)</td>
<td>-6° (-7°/-5)</td>
<td>-6° (-6°/-5)</td>
</tr>
<tr>
<td>CD-C7</td>
<td>64° (60°/71)</td>
<td>-44° (-51°/-40)</td>
<td>-36° (-48°/-26)</td>
</tr>
<tr>
<td>CD-C7</td>
<td>100%</td>
<td>-73% (9)</td>
<td>-59% (15)</td>
</tr>
</tbody>
</table>

Numbers in subscript represent cadaver numbers that were excluded from the analyses. Due to non-visible markers flexion-extension could not be calculated.

* Insufficient data available to determine a post-test mean and range of the angulation between C0 and C7, due to over projection of the skull.

Table 7.1B Lateral bending.

<table>
<thead>
<tr>
<th></th>
<th>no immobilizer</th>
<th>head blocks &amp; spine board</th>
<th>Pharaoh</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pre test</td>
<td>post test</td>
<td></td>
</tr>
<tr>
<td>CD-C1</td>
<td>9° (2/16)</td>
<td>-6° (-16°/-1)</td>
<td>-5° (-15°/0)</td>
</tr>
<tr>
<td>C1-C2</td>
<td>24° (7/37)</td>
<td>-23° (-37°/-3)</td>
<td>-22° (-35°/-3)</td>
</tr>
<tr>
<td>C2-C3</td>
<td>13° (4/23)</td>
<td>-8° (-17°/-3)</td>
<td>-9° (-17°/-3)</td>
</tr>
<tr>
<td>C3-C4</td>
<td>10° (1/18)</td>
<td>-9° (-13°/-1)</td>
<td>-10° (-17°/1)</td>
</tr>
<tr>
<td>C4-C5</td>
<td>10° (0/17)</td>
<td>-10° (-16°/0)</td>
<td>-9° (-14°/0)</td>
</tr>
<tr>
<td>C5-C6</td>
<td>5° (1/10)</td>
<td>-5° (-10°/-1)</td>
<td>-5° (-10°/0)</td>
</tr>
<tr>
<td>C6-C7</td>
<td>6° (3/11)</td>
<td>-7° (-11°/-3)</td>
<td>-6° (-10°/-2)</td>
</tr>
<tr>
<td>CD-C7</td>
<td>78° (31-95)</td>
<td>-68° (-86°/-23)</td>
<td>-62° (-77°/-17)</td>
</tr>
<tr>
<td>CD-C7</td>
<td>100%</td>
<td>-85% (7)</td>
<td>-77% (14)</td>
</tr>
</tbody>
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Table 7.1C Rotation.

<table>
<thead>
<tr>
<th></th>
<th>no immobilizer</th>
<th>head blocks &amp; spine board</th>
<th>Pharaoh</th>
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</thead>
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<tr>
<td></td>
<td>pre test</td>
<td>post test</td>
<td></td>
</tr>
<tr>
<td>CD-C1</td>
<td>3° (1/9)</td>
<td>4° (0/9)</td>
<td>-3° (-8°/-1)</td>
</tr>
<tr>
<td>C1-C2</td>
<td>48° (39/67)</td>
<td>48° (16/69)</td>
<td>-46° (-65°/-28)</td>
</tr>
<tr>
<td>C2-C3</td>
<td>1° (0/3)</td>
<td>1° (0/2)</td>
<td>-1° (-3°/-1)</td>
</tr>
<tr>
<td>C3-C4</td>
<td>4° (1/10)</td>
<td>5° (0/10)</td>
<td>-4° (-9°/-1)</td>
</tr>
<tr>
<td>C4-C5</td>
<td>6° (0/14)</td>
<td>8° (1/14)</td>
<td>-6° (-14°/-6)</td>
</tr>
<tr>
<td>C5-C6</td>
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<td>3° (0/8)</td>
<td>-1° (-3°/-1)</td>
</tr>
<tr>
<td>C6-C7</td>
<td>2° (0/4)</td>
<td>3° (0/4)</td>
<td>-2° (-4°/-1)</td>
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<tr>
<td>CD-C7</td>
<td>65° (42/103)</td>
<td>70° (25/111)</td>
<td>-61° (-101/-41)</td>
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</tbody>
</table>

Figure 7.5 The mean peak interface pressure and standard deviation per body region on the spine board and the Pharaoh mattress.

Discomfort scores increased over time in all body regions (Figure 7.7). At baseline, at the level of occipital region the mean discomfort scores were 1.9 (SD 1.3) for the Pharaoh mattress and 3.1 (SD 2.5) for the spine board strapped to head blocks, at the scapular region 2.5 (SD 1.0) and 2.6 (SD 1.7), and at the sacral region 2.7 (SD 1.6) and 4.1 (SD 2.5), respectively. After 30 min, mean discomfort scores increased to 3.0 (SD 1.3) and 6.1 (SD 2.8) at the occipital region, 2.8 (SD 1.0) and 5.2 (SD 2.8) at the scapular region, and 4.9 (SD 2.1) and 6.1 (SD 2.7) at the sacrum, for the Pharaoh mattress and the spine board with head...
New Perspectives on External Immobilization of the Cervical Spine

Figure 7.6 Map of pressure interfaces five minutes after application of head blocks strapped to a spine board, and the Pharaoh mattress (center). Cross-sections at the level of occiput, scapulae and sacrum (lateral). Black lines represent the positions of the Tekscan sensors. Note peak pressures >100 mmHg at the occiput, scapulae and sacrum in the spine board.

Figure 7.7 The average numeric rating score for comfort per body region and time spent on external immobilizer.

Table 7.2 Radiographic absorption percentage of Dose Area Product (DAP) caused by head blocks with a spine board and the Pharaoh mattress, at different levels in different directions.

<table>
<thead>
<tr>
<th>Level</th>
<th>AP</th>
<th>lateral</th>
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</thead>
<tbody>
<tr>
<td>C2</td>
<td>45%</td>
<td>80%</td>
</tr>
<tr>
<td>C7</td>
<td>45%</td>
<td>80%</td>
</tr>
<tr>
<td>Th12</td>
<td>35%</td>
<td>0%</td>
</tr>
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</table>

Discussion

In the cadaveric part of this study, the new Pharaoh mattress resulted in a mean restriction of 59% of normal flexion-extension, 77% of normal lateral bending and 93% of normal rotation of the cervical spine. No significant differences in restriction of cervical movement were seen between head blocks strapped to a spine board and the new Pharaoh mattress. These results can be explained by the fact that the same principle of immobilization is used: support of the device on temporal and occipital areas, connected with a rigid board and thoracic straps. Rotation and lateral bending are nearly completely restricted with this principle. However, in this study some flexion-extension was possible with both the head blocks with spine board and the Pharaoh mattress. This was earlier reported in other studies when a dual digital inclinometer was used. A possible explanation for this difference can be an underestimation of flexion-extension when a dual digital inclinometer was used.
is used compared with RSA. Furthermore, in the earlier studies healthy volunteers were actively flexing and extending their cervical spine. In this study a controlled passive torque, possibly higher than generated with active muscle-induced forces, was applied.

The interface pressure between skin and immobilizer with the Pharaoh mattress were all below 100mmHg and significantly lower when compared to head blocks and spine board. The spine board produced peak pressures well above 100 mmHg at the level of occiput, scapulae and sacrum. Bronneberg et al, showed in an in vitro study that the first signs of tissue damage can be found after applying pressures as low as 50mmHg for 24 hours. It is already known that prolonged stay of more than 30 minutes on a spine board can lead to serious pressure ulcers. Spine boards padded with a thin layer of flexible materials, similar to the Pharaoh mattress can effectively reduce these peak pressures at the level of the occiput and scapula below 50mmHg. However, the peak pressure at the level of the sacrum in the Pharaoh mattress was 82 mmHg, a possible risk area for pressure ulcers. In this version of the Pharaoh mattress the support at the level of the sacrum is made from 4 cm thick poly urethane. In a next version a thicker layer and/or softer polyurethane or viscoelastic memory foam might be used at the level of the sacrum.

The level of discomfort was at all times significantly lower when the Pharaoh mattress was compared with head blocks and spine board. It is known that an unpaded spine board is not comfortable and that a padded spine board will reduce pain and stress. Although the comatose patient will not complain about discomfort, it can be rationalized that reduction of unpleasant stimuli is desirable. Pain and discomfort are physiological warnings for the development of pressure ulcers.

The absorption of radiographic energy of the Pharaoh mattress was at some specific levels higher when compared with a spine board with head blocks. This is the consequence of the use of more materials (polyurethane and viscoelastic memory-foam) to reduce peak interface pressures. The higher absorption can result in radiography with lowered quality. Moreover abrupt changes of absorption levels by materials can cause difficulties in the setting of contrast and brightness. To examine the true effect on radiographic imaging conventional en CT images in clinical patients should be made.

Limitations
In this study the Pharaoh mattress was tested with cadavers and healthy volunteers only. It remains unclear how this new cranio-thoracic immobilizer will function in clinical practice. Nonetheless, this study is relevant to assess its safety before testing and applying it in clinical practice.

Furthermore, this study compared the Pharaoh mattress only with the head blocks strapped to a spine board. The immobilization by a spine board with head blocks is mostly used in the pre-hospital and emergency room setting and can restrict cervical movement nearly completely. Although the spine board is not routinely used in the intensive care unit, it was nonetheless used as a golden standard for comparison with the Pharaoh mattress. No cervical collars or cervico-thoracic devices were tested in this study. As there are many publications on the limited level of immobilization achieved with collars and the known dangers of collars and cervico-thoracic devices, including increased intracranial pressures, pressure ulcers, pain and discomfort, decreased access to the oropharynx, these were not considered a viable option to use in the clinic. Furthermore no halo-vest or halo-traction were included in this study, because we consider placement of these invasive instruments in healthy subjects for scoring comfort and pain, unethical. In a setting with real patients with a halo-vest or halo-traction, pain and comfort scores could be obtained, nonetheless it would be also unethical to compare different type of immobilizers on the same patient. In this study we therefore compared the Pharaoh mattress with a spine board with head blocks.

Moreover, the peak pressures, comfort and radiolucency were not tested with halo-traction and halo vests in this study. This would certainly produce interesting data but is unethical to test on health volunteers.

It should be stated that the Pharaoh mattress is only suitable for non-ambulatory patients in a hospital setting. It was not made for pre-hospital extrication or transfers and certainly not suitable for mobile patients. However, this Pharaoh mattress can solve problems for the comatose patients with proven mechanically unstable cervical fractures, waiting for surgical internal fixation, final immobilization with a halo-vest, or death. The Pharaoh mattress can restrict cervical movement comparable with a head blocks strapped to a spine board, with lowered chances for the development of pressure ulcers and increased comfort when compared with head blocks strapped to a spine board.

The current version of the Pharaoh mattress was designed for patients with a normal cervical lordosis/thoracic kyphosis and tested in people without any former spinal problems. In the elderly, patients with Scheuermann or Bechterew an increased thoracic kyphosis and cervical lordosis results in a relative ventral position of the skull in relation to the torso. For these patients it might be necessary to develop a special head component with an elevated occipital support. Furthermore, the current version of the Pharaoh mattress is not coated with a special material to prevent soiling. A good material for a cleanable interface between patient and mattress is needed.

Finally, it must be stated that in this study the focus was on the cervical spine. In contrary to immobilization with collars, cervico-thoracic devices, halo-ring, and halo vest, the Pharaoh mattress can facilitate in-line turning and immobilization of the complete spinal column. At this point, further research is necessary to analyze the immobilizing effects on the thoracic and lumbar spine.

New Perspectives on External Immobilization of the Cervical Spine
a New Cranio Thoracic Mattress
Conclusions

With the results of this study, further clinical research with the Pharaoh mattress in critical care patients with mechanically unstable vertebral injuries can be initiated. Allowing others to copy and improve the design of the mattress, according to the rules of Creative commons (attribution-share alike), we encourage colleagues to test and improve the Pharaoh mattress, leading to a better care for the critically ill patients.

Disclaimer

Aquarius (Wijk bij Duurstede, the Netherlands) a producer of custom made mattresses, helped with the production of the tested mattress. No funds or grants were received in support of this work. No benefits in any way have been received from a commercial party related directly or indirectly to the subject of this article. Creative commons “attribution-share alike” license apply, design of mattress may be used and reproduced by third parties.

References

DISCUSSION AND FUTURE PERSPECTIVES OF EXTERNAL IMMOBILIZATION OF THE CERVICAL SPINE
Discussion and Future Perspectives of External Immobilization of the Cervical Spine

There are a number of reasons for immobilizing the cervical spine, including safeguarding the position of the head in patients with neuromuscular problems, reduction of pain in degenerative pathology, and post-operative care allowing structures to heal. However, the most common indication for cervical immobilizers is preventing additional spinal cord injury in patients with (suspected) cervical column injury. By restricting movement of the cervical spine, the vulnerable spinal cord is at rest and thereby protected from mechanically instable structures of the cervical spine.

The main topic of discussion on external cervical immobilizers is whether they actually achieve their primary goal. To answer this question, it is essential to understand the biomechanical way in which external immobilizers restrict cervical movement.

In this thesis, we examined frequently used and newly developed cervical immobilizers with respect to their ability to restrict cervical movement.

We firstly constructed a clear and reproducible classification of the different types of cervical immobilizers; there are many different immobilizers with many different names. Some of the brand names refer to the city where the immobilizer was invented, e.g. the Boston brace, Aspen brace, Philadelphia Brace, Miami J brace, while other brand names refer to the shape of the immobilizer, e.g. halo-traction and halo vest. No clear definition or classification for cervical immobilizers is available, making it difficult to compare different external mobilizers. This is most likely a reason for the scarce availability of evidence based guidelines for the use of specific immobilizers in daily practice. Therefore, we developed a new classification system for external immobilizers and validated it (chapter 2).

This new classification is based on the areas which are supported by the immobilizers, so we have been able to assign all currently available cervical external immobilizers to reproducible groups. In addition to the value of classification for scientific research purposes, the classification can also be helpful in clinical practice, as the prescriber no longer needs to remember specific brand names, but can use the generic name from the classification system (chapter 2). The description of the specific type of immobilizer (e.g. cervico-high thoracic device) should be sufficient for the prescribing medical specialist. The medical technician can then choose a specific type of immobilizer based on patient specific parameters and costs.

As always in classification systems, discussions occur at the crossing point of (sub)groups; what if an immobilizer ends at the border of two anatomical regions? To solve this problem, we provided clear decision rules to the classification figures as subheadings (Figure 2.1, chapter 2 of this thesis). A possible issue with (new) classification systems is that users might not memorize the exact rules needed for proper classification. As with any
new classification system, it takes time for the new users to get acquainted to these rules and many years might be needed before it is used routinely in clinical practice.

After creating and validating the classification system for cervical immobilizers, as described in chapter 2, we were able to group different types of immobilizers and to perform a systematic review to test the ability of different immobilizers to restrict cervical movement. From the systematic review (chapter 3), it became clear that soft collars (type A1: cervical immobilizer) do not adequately restrict cervical movement: all published studies with healthy volunteers showed that more than half of normal cervical movement was possible.2–4 Although these were not studies with patients, it appears that soft collars are not advisable for patients with mechanically unstable cervical fractures.

In contrast, all the cervico-thoracic immobilizers (type B1, B2) we reviewed were able to restrict cervical movement, with a wide restriction range of 20% to 80% of normal movement in all directions. Lateral bending of the cervical spine was less restricted than flexion and extension. The cervico-thoracic immobilizers can best be used in conscious patients with cervical fractures where mechanical instability is only expected at the extremes of cervical movement. Caution is needed for use in comatose patients as they can rapidly cause skin ulcerations5–9 (Figures 8.1 and 8.2), pressure on the trachea (Figure 8.3) and elevated intracranial pressures10–13. These complications can have serious consequences for the possibilities of surgery and neurological outcome.14

**Figure 8.1** Patient with a lowered consciousness and a rigid collar (left above). Note the beginning of pressure ulcers after one hour (left below) and advanced deep mandibular ulcers after two days of a Stifneck (right).

**Figure 8.2** Patient with halo-vest (type E2) on the intensive care unit. Note the limited access to the thorax (left) and skin ulcerations cause by the vest (right).

**Figure 8.3** PA patient with lowered consciousness and a Sterno Occipital Mandibular Immobilizer (type B2). Note the pressure on the trachea (right above) and the beginning of skin pressure ulcers (right below).
The reported restriction by cranio-thoracic immobilizers (type C) was more than 60% of normal cervical movement (chapters 3, 4). These immobilizers can be valuable in cases of patients with suspected or proven mechanical instable cervical injury. However, with these devices, as for the cervico-thoracic immobilizers, extra care needs to be taken when handling comatose patients. Despite anti-decubital materials, pressure ulcers can still develop with cranio-thoracic immobilizers, and the thorax is not easily accessible for ECGs, radiography, thoracotomy and mechanical resuscitation (Figure 8.2).

In addition to these findings, it appeared that some types of immobilizers e.g. the cervico-high thoracic immobilizers (type B) have often been investigated and described in the literature, while limited reports are available regarding cranial traction (type C) and cranio-thoracic immobilizers (type D and E) (chapter 3). It is worth noting that cranio-thoracic immobilizers such as halo traction, halo-vest and head blocks strapped to a spine board, are used all around the world on a daily basis for hundreds of trauma patients, with only a limited scientific background of their ability to restrict cervical movement; the lack of knowledge regarding their biomechanical restrictive effects is surprising.

With the results of the systematic review (chapter 3) it has become clear that new studies investigating the ability to restrict cervical movement of different types of frequently used cervical immobilizers with precise measurements are necessary. Furthermore, it was striking that most studies only measured the movement of the skull base (C0) in relation to C7, thus it remains unknown what happens at intervertebral levels of the cervical spine: what levels are restricted most and/or least? Or possibly, as described in another study, does the movement at certain vertebral levels increase instead of decrease when a cervical immobilizer is applied? Therefore, we performed an RSA study with 3D intervertebral movement analysis, with controlled forces and lever arms in cadaveric specimens. We confirmed that most of the normal movement of the unrestricted spine was contributed by the upper levels C0, C1 and C2. It was thus not surprising that most of the restriction of movement caused by the tested cervical immobilizers also occurred at these high levels of the cervical column. Chin et al. noticed an increase of cervical movement at specific levels after applying a rigid collar.

The results of our RSA cadaver study, combined with those from the systematic review enabled us to confirm the hypothesis described in chapter 1: the level of restriction in all directions, by cervical immobilizers increased as the distance of supporting areas increased. An increase of restriction of cervical movement was seen according to the classification system A to E. Clinical experience and patient comfort studies, show that comfort for the patient decreases and complexity of the device increases as the level of immobilization increases (Table 8.1). These findings can be applied when determining the choice of a specific type of cervical immobilizer. For example, in bio-

<table>
<thead>
<tr>
<th>type of immobilizer</th>
<th>flexion-extension</th>
<th>lateral bending</th>
<th>rotation</th>
<th>complexity</th>
<th>comfort</th>
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<tr>
<td>A: cervical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B: cervico-thoracic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C: cranial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D: cranio-thoracic non-ambulatory</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E: cranio-thoracic ambulatory</td>
<td></td>
<td></td>
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</tbody>
</table>

mean restriction percentage: 0-25% 25-50% 50-75% 75-100%
collar with head blocks strapped to a spine board\textsuperscript{20}, although there is little to none scientific evidence to support this frequently used technique.\textsuperscript{21} Therefore, we conducted a proof of principle study in ten healthy subjects. In this study, (chapter 5) we showed that the addition of a rigid collar to head blocks offers no additional restriction of the cervical spine. From a mechanical point of view these findings were predictable: the most restrictive immobilizer determines the definitive range of motion. To visualize this principle, the use of a rigid collar in addition to head blocks can be compared with the use of an umbrella in addition to a parachute (Figure 8.6). A jump out of an airplane with an umbrella alone, will obviously lower the falling speed; however, not to a safe level. In comparison, a rigid collar can significantly restrict cervical movement, though some normal cervical movement (20\% - 80\%) is still possible (chapters 3 and 4). However, with a descent with a parachute alone, the vertical speed will be reduced so much that a safe landing is possible.\textsuperscript{22} In comparison, head blocks strapped to a spine board will provide a nearly complete restriction, with less than 20\% of normal cervical movement possible (chapters 4 and 5). The current ATLS cervical immobilization protocol advocating the use of a rigid collar with head blocks can thus be compared to jumping out of a plane with both a parachute and an umbrella. Each time we land safely, we praise the current protocol.

It is, however, questionable whether the combination of techniques is actually safer than the use of a single technique. Holding the umbrella requires an extra hand from the parachutist, and the umbrella could tangle the lines of the parachute. In comparison, the addition of a rigid collar to head blocks is not without risks. In chapter 5 we describe a limited opening of the mouth when using a rigid collar; this obstruction of the airway makes the quick insertion of a normal tube either difficult or even impossible.\textsuperscript{23} Furthermore, as mentioned above, rigid collars cause pain and discomfort\textsuperscript{16, 17} and can result in pressure ulcers.\textsuperscript{5-9} Less well known, but no less important, is that collars put pressure on the jugular veins\textsuperscript{14} and cause significantly increased intra-cranial pressures.\textsuperscript{10-13} A significant and potentially preventable contribution to the overall morbidity arises from secondary brain swelling and raised intracranial pressures. It prevents adequate cerebral perfusion with well-oxygenated blood. This is relevant, as many patients with cervical injury have significant head injuries\textsuperscript{24} and thus can be crucial for the morbidity and mortality of the patient.

With the evolution of new scientific insights and medical equipment, protocols have to be adapted accordingly. After the publication of this article (chapter 5), the protocol for pre-hospital immobilization in the Netherlands (LPA-9) was changed: the use of a rigid
collar is no longer advocated in the Dutch pre-hospital setting. Nonetheless, the ATLS still advocates the use of a rigid collar in combination with head blocks. With the findings of the studies described in this thesis and the internationally growing evidence and awareness that the combination of a rigid collar in addition to head blocks can have serious risks, the American Association of Neurological Surgeons and ATLS organization should reconsider their advice on the addition of a rigid collar to head blocks. In this perspective it is good to rephrase a quote from Dr Styner, founder of the ATLS principles, “If there is something wrong with the system, the system has to be changed”.

From the results of the studies described in chapters 3, 4 and 5, we can conclude now that head blocks strapped to a spine board restrict cervical movement nearly completely (>90%). However, the unpadded spine board, like with rigid collars, comes with some serious disadvantages including pain, discomfort, and pressure ulcers. Therefore, in the last decennia, new pre-hospital spine immobilizers have been developed and are now commercially available: the padded spine board (type D2) and the vacuum mattress (type D3). Both techniques have proven to reduce pain, discomfort and pressure ulcers, although no comparative studies have been conducted, making a choice for one of the techniques difficult.

We performed a study comparing the usability and safety of the vacuum mattress and padded spine board (chapter 6). In this study emergency services workers reported that the padded spine board was lighter, less voluminous and more applicable in daily practice. Furthermore, the padded spine boards resulted in greater restriction of spinal movement, quicker application, and less X-ray absorption compared with vacuum mattresses. These outcomes provide valuable input into the decision-making process of emergency services management and workers regarding the choice of immobilizer.

Following pre-hospital immobilization of the spine, in most cases cervical injury is usually prevented and the immobilizers can be removed. However, in a small group of patients there is significant injury of the cervical column and immobilization remains necessary until internal fixation can take place. In these, often comatose, patients cervical, cranio-thoracic and thoracic immobilizers can cause serious complications (Figures 8.2, 8.3 and 8.4), while it is feared that the omission of any immobilizers in patients with mechanically significant instable injury can result in iatrogenic spinal cord injury during care on the intensive care unit. To solve this problem, we created a new anatomically shaped mattress, the Pharaoh mattress. In chapter 7, we tested this new cranio-thoracic immobilizer (type D3) designed for critical care patients with cervical injury, on its restriction of cervical movement with RSA in five cadavers and for radiolucency. We also measured peak interface pressures and comfort, and compared these with head blocks strapped to a spine board. No significant differences in restriction of cervical movement was observed when the Pharaoh mattress was compared with the head blocks strapped to a spine board, but the mean of peak pressures was significantly lower compared with the spine board. Furthermore, the volunteers scored the Pharaoh mattress significantly lower on discomfort compared to the unpadded spine board. A negative aspect of the Pharaoh mattress was that it absorbed more X-rays than the head blocks with spine board (chapter 7). Further research is needed to see if this results in a need for higher X-ray dosage or artefacts during conventional radiography and CT. As the Pharaoh mattress does not contain metal, it is MRI compatible.

One of the remaining design issues regarding the Pharaoh mattress is its coating. The interface has to be hydrophilic to absorb body fluids and allow airflow to the skin, to prevent moisture skin lesions. A prototype with new skin-mattress interface is currently made in conjunction with a producer of shaped mattresses for patients with scoliosis. This prototype is expected to be ready for testing at the end of 2017. The Pharaoh mattress can be helpful for large spine centers and small trauma hospitals, as it can stabilize the injured cervical spine in the hospital setting while the patient is awaiting surgery or transfer to another hospital. Please note that the Pharaoh mattress has not been designed for making transfers from street to stretcher, and it is therefore not suitable for pre-hospital use.
Current problems and future perspectives

In this thesis, we investigated the ability of frequently used and newly developed cervical immobilizers to restrict cervical movement. However, the main issue with regard to whether pre-hospital cervical immobilization can achieve its primary goal, the prevention of (additional) iatrogenic spinal cord injury, has not yet been answered. In this section, the main reasons for this are described, and possible directions for future research are indicated.

Low incidence of spinal cord injury

Although the impact of spinal cord injury on the individual patient is high, its incidence is relatively low with less than four people in a population of 100,000 per year.33 A study in Norway showed an even lower annual rate of iatrogenic spinal cord injury, at approximately 2.3 people in a population of 100,000.34 Most of these iatrogenic spinal cord injuries were caused by intervention for cervical spinal stenosis, operations on the aorta and spine, and not by manipulation after acute spinal column injury.34 Due to this low incidence, studies with large numbers are needed. Only with large multi-center studies or long-lasting national registries, recording the type of immobilizer, additional interventions and the development of spinal cord injury in time, it will become possible to generate the data required to investigate differences between different types of immobilizers. Help is needed from international spine surgeon and trauma communities to set up a networks to achieve such a registry.

Limited knowledge on non-iatrogenic development of spinal cord injury signs

It is difficult to predict how symptoms of spinal cord injury will develop after the primary trauma.35 In some patients, the loss of sensory and motor functions improves spontaneously within minutes or hours; but in other patients it can take days to months. In other patients, without any movement of the cervical spine, spinal cord injury symptoms can increase in a matter of minutes or hours as a result of secondary changes, including swelling and/or ischemia of the spinal cord.36 Due to these unpredictable secondary responses, it is hard to determine whether spinal cord injury is influenced by movement of the cervical spine or by the primary injury itself. It is possible that the progression of spinal cord injury is more dependent on decompression of increased intra-spinal pressures and vascularization by realignment, than on the prevention of minimal cervical movement.

By using new imaging techniques, including functional MRI and MR Angiography, we may be able to better understand these processes in the future. In addition, the use of biomarkers in the spinal fluid and blood can aid in the assessment of spinal cord injury and its prognosis.37

Fear of iatrogenic spinal cord injury

Since the impact of spinal cord injury is high, health care workers (emergency medical services workers, doctors, nurses) are very cautious to cause additional spinal cord injury. In many medical emergency courses, the relevance of the cervical spine injury and risk of spinal cord injury is emphasized. The Hippocrates adagio “Primum non nocere”, interpreted by the ATLS foundation to do no further harm, has probably saved many lives worldwide. This has also had the effect that some care workers have developed a fear that even small movements of the cervical spine will have disastrous consequences for the patient. Since the forces on the spinal cord needed to establish significant injury to the cervical spine are a multitude of those generated from a small amount of cervical movement, it is unlikely that small movements have a significant impact on the outcome of spinal cord injury.38

In the past, roofs were ripped off cars as part of time-consuming procedures to extricate patients with possible cervical injury with extrication collars (Figure 8.8). Recent 3D-motion analysis studies have shown that with controlled self-extrication, the cervical movement was less than compared with conventional extrication techniques.39 Nevertheless, the fear of causing iatrogenic spinal cord injury and its impact is so high, that complex and time-consuming extrications still occur daily.40-41 To analyze the real effects of immobilization, a large prospective study is needed with groups of people that are extricated and transported with, and without cervical immobilizers. However there are many ethical concerns related to this type of study due to the fear of complications.

Absence of validated tool assessment of spinal cord injury in the pre-hospital setting

The assessment of spinal injury is complex and time-consuming. For a good examination of possible spinal cord injury, according to the American Spinal Injury Association (ASIA) Impairment Scale, the patient needs to be awake and alert.42 Furthermore, a full neurological
physical examination takes more than 15 minutes to perform. In the pre-hospital setting, there is often no time and/or facilities to perform a neurological examination according to the ASIA guidelines. In most cases, when a patient is brought into the hospital by emergency services workers, it is unclear if there are signs of spinal cord injury and if these have worsened during extrication, transport and transfers. A validated quick neurological examination for detection of spinal cord injury is needed.

**Limited knowledge of cervical intervertebral movement in living people with cervical immobilizers**

In the studies, described in this thesis, we described the cervical intervertebral movement of cadavers. However, it would be interesting to analyze intervertebral movement with different immobilizers on, in the in-vivo situation. The movement of the cervical spine with normal tension of the cervical muscles and ligaments in living people might be different than in cadavers. The use of open MRI-scanners is a promising technique for gathering data on intervertebral movement of the cervical spine with and without immobilizing devices.

**Other directions for the future**

Apart from the future headings, mentioned above, similar studies could be started to enhance our understanding of thoraco-lumbar immobilizers. We expect that a similar classification system for thoraco-lumbar immobilizers, based on the same principles of immobilizing devices.

**References**

SUMMARY OF THIS THESIS
SAMENVATTING VAN DIT PROEFSCHRIFT
Summary of this Thesis

The cervical spine is frequently immobilized by several different invasive and non-invasive techniques.

The relevance of external immobilization of the cervical spine is described in chapter 1, where we also summarize the biomechanical principles of the cervical spine and the goals of external immobilization. External immobilization is in frequent use all around the globe, however we note a number of issues with the current procedures: a lack of a classification system of different external cervical immobilizers, an absence of a systematic review of cervical immobilizers and their ability to restrict cervical movement, limited knowledge of frequently used groups of immobilizers and their effects on intervertebral movement, a lack of rationale for the use of a rigid collar in addition to head blocks, problems with external cervical immobilization in the critical care patient and, a lack of information regarding new pre-hospital immobilizing techniques.

Chapter 2, presents a new classification for different external immobilizers based on anatomical support areas: Type A: cervical (A1: soft collar, A2: rigid collar), Type B: cervico-thoracic (B1: cervico-high thoracic, B2: cervico-low thoracic), Type C: cranial, Type D: cranio-thoracic for non-ambulatory patients (D1: board with sandbags, D2: board with head blocks, D3: anatomical mattress) type E: cranio-thoracic for ambulatory patients (E1: vest without skull pins, E2: vest with skull pins). The inter-observer and intra-observer agreement of the classification was established by 28 independent observers who classified fifty photographs of different devices. The mean interobserver and intraobserver agreements were excellent, with a Fleiss’ kappa of 0.88 and 0.91 respectively. Furthermore, the participants considered the proposed classification to be clear and applicable in clinical practice.

A systematic review of external immobilizers is presented in chapter 3. To review the ability of the different types of external immobilizers to restrict cervical spine movement, original articles with reliable and complete data on the restriction of cervical movement were selected. Of the 2272 articles identified using an electronic database search, 13 studies were included for qualitative synthesis. Each device was classified as to its ability to restrict movement of the cervical spine using five levels of immobilization: poor (MIL <20%), fair (MIL 20-40%), moderate (MIL 40-60%), substantial (MIL 60-80%), and nearly complete (MIL ≥80%). The ability of soft collars (type A1) to reduce the range of motion was poor in all directions. The ability of cervico-high thoracic devices (type B1) was moderate to substantial for flexion/extension, but poor to moderate for lateral bending and rotation. Cervico-low thoracic device (type B2) restriction of flexion/extension and rotation was moderate to substantial, whereas the ability of these devices to restrict lateral bending was poor to moderate. All cranio-thoracic devices for non-ambulatory patients (type D) restricted cervical spine movement substantial to nearly complete in all directions. The ability of vests with non-invasive skull fixation (type E1) was substantial to nearly complete in all directions.
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directions. We could not find any studies with healthy adults with respect to cranial traction (type C) or halo vests with skull pins (type E) and their ability to restrict cervical movement.

In chapter 4, a cadaveric radiostereometric analysis study is described that reports on the ability of five commonly used immobilizers to restrict cervical spine movement, including intervertebral movement, in three directions. Radiographic inert beads were implanted in the cervical vertebral bodies of five fresh-frozen human cadavers. After the application of different immobilizers (Stifneck, SOMI, halo-traction, spine board, halo-vest) and controlled flexion-extension, lateral bending and rotation torques, we used radiostereometric analysis to determine the overall and intervertebral 3D movement. Most of the restriction of flexion/extension was observed at CO-C1, while most rotational restriction was seen at C1-C2. Lateral bending was restricted at C1 to C7. The restriction of movement from lowest to highest was: Stifneck (type B), SOMI (type B), halo-traction (type C), head blocks on a spine board (type E), and halo-vest (type E). Notably, the crano-thoracic immobilizers (type D/E) had less variance in their ability to restrict cervical movement, than the cervico thoracic immobilizers (type B).

In chapter 5, the value of a rigid cervical collar in addition to head blocks strapped to a spine board, as recommended by the Advanced Trauma Life Support (ATLS) and American Association of Neurological Surgeons (AANS) guidelines, was investigated. The active range of motion of the cervical spine was determined by digital dual inclinometry in ten healthy volunteers with a Stifneck collar (type B), head blocks strapped on a spine board (type E), and a combination of both. We also measured the maximal opening of the mouth with all types of immobilizer in place. The addition of a rigid collar to head blocks strapped on a spine board did not result in extra immobilization of the cervical spine. Opening of the mouth was significantly reduced in patients with a rigid collar. Based on this proof of principle study and previous evidence of adverse effects of rigid collars, the addition of a rigid collar to head blocks is considered unnecessary, and even potentially dangerous.

In chapter 6, two types of vacuum mattresses (Germa EasyFix and the RedVac VM7000) were compared with two types of padded spine boards with head blocks (Arpemat and Comfort Board). In this controlled experimental study, emergency services workers immobilized different healthy volunteers using the four different immobilization devices. The emergency service workers scored the Arpemat significantly higher for cleanability compared to the Comfort Board. For durability, the Arpemat scored significantly higher compared to the other immobilizers. No differences between the four immobilizers were found regarding the ability to roll the patient, the ability to lift the patient, and the accessibility of the thorax and abdomen. The Arpemat and Comfort Board scored significantly higher for cervical spine restriction compared to the RedVac VM7000. The total time needed to apply the immobilizer including log rol or scoop-stretcher procedure was significantly shorter for the Comfort Board compared to the RadVac 7000VM. At the scapular level, the Arpemat showed significantly lower peak pressures compared to the Comfort Board. In contrast, at the sacral level the Arpemat showed significantly higher peak pressures compared to the other immobilizers. The Germa EasyFix showed the highest absorption of X-rays. Although the users of pre-hospital immobilizers must weigh the importance of these different items and costs, the results of this study suggest that the use of padded spine boards with head blocks is most advisable when immobilizing trauma patients in the pre-hospital setting.

In chapter 7, we tested a new crano-thoracic immobilizer (Pharaoh mattress (type D)) designed for critical care patients with cervical injury, for its ability to restrict cervical movement with radiostereometric analysis in five cadavers. Furthermore, radiolucency, skin contact peak pressures and comfort were compared with head blocks strapped to a spine board. We found no significant differences in restriction of cervical movement with the Pharaoh mattress compared to the head blocks strapped to a spine board. The mean of peak pressures on the Pharaoh mattress was significantly lower compared to that of the spine board. The volunteers gave significantly lower numeric discomfort scores for the Pharaoh mattress compared to the unpadded spine board. However, the Pharaoh mattress absorbed more X-rays than the head blocks, strapped to a spine board did. We conclude that this new mattress is applicable for the immobilization of the spine in critical care patients with mechanically instable cervical spine injury.

The impact of the findings of the previous chapters on healthcare is discussed in chapter 8. Based on our findings, we are still unable to answer the question whether pre-hospital immobilization is useful. Nonetheless, with the new perspective, we can advise on the best technique for pre-hospital spinal immobilization. Our results show that the addition of a rigid collar to head blocks, as recommended by ATLS and AANS, has no value in restricting cervical movement, and that negative side effects are well known. Furthermore, there is evidence that the head blocks strapped to padded spine board are faster to apply and are more useable than vacuum mattresses in the pre-hospital setting.

In this thesis, we demonstrate the lack of evidence for application of external immobilization and set goals for evaluation of currently used techniques and practices. We present a validated classification for different external immobilizers and their ability to restrict cervical movement. This improved understanding will enable us and others to gather better scientific evidence on common medical interventions, and improve care for patients with suspected or proven cervical spine injury.
**Samenvatting van dit proefschrift**

Immobilisatie van de cervicale wervelkolom kan met behulp van veel verschillende invasieve en niet-invasieve technieken worden gerealiseerd. In hoofdstuk 1 van dit proefschrift worden de doelen en biomechanische principes van externe immobilisatie van de cervicale wervelkolom beschreven en wordt geschetst welke problemen zich daarbij voordoen.

Terwijl wereldwijd, iedere dag bij vele mensen de cervicale wervelkolom extern geïmmobiliseerd wordt, bestaan er nog meerdere hiaten in de kennis van de huidige immobilisatiemethoden: 1) er ontbreekt een classificatiesysteem voor de verschillende externe cervicale immobilisatiemiddelen, 2) er is geen systematisch overzicht van cervicale immobilisatiemiddelen en de mate waarin deze middelende cervicale wervelkolom immobili- sieren, 3) er is beperkte kennis van veel gebruikte immobilisatietechnieken en hun effect op intervertebrale beweeglijkheid, 4) er ontbreekt een onderbouwing voor het gebruik van een harde halskraag naast een wervelplank met hoofdsteunen, 5) er is zeer beperkte informatie over nieuwe pre-hospitale immobilisatietechnieken en 6) er zijn problemen bij externe immobilisatie van de wervelkolom bij zwaar gewonde en/of comateuze patiënten.


In hoofdstuk 3 wordt een systematisch literatuuroverzicht van externe immobilisatiemiddelen gepresenteerd. Om de verschillende immobilisatiemiddelen en de mate waarin deze middelen de cervicale beweeglijkheid beperken te beschrijven, werden alle beschikbare wetenschappelijke artikelen met betrouwbaar complete gegevens over de beperking van beweeglijkheid van de cervicale wervelkolom geïncludeerd. Met behulp van een literatuuroeplapdrecht werden 2272 artikelen geidentificeerd, waarvan uiteindelijk 13 artikelen geïdentificeerd werden. Voor ieder immobilisatiemiddel werd een gemiddelde immobilisatiegrens (mean immobilization limit (MIL)) bepaald. Ieder immobilisatiemiddel werd ingedeeld naar de mate van beperking van de beweeglijkheid van de cervicale wervelkolom, gebruikmakend van vijf niveaus van immobilisatie (slecht (MIL <20%), matig (MIL 20-40%), redelijk (MIL 40-60%), substantieel (MIL 60-80%) en bijna volledig (MIL ≥80%).
De mate waarin de beweeglijkheid van de cervicale wervelkolom wordt beperkt door zachte halskragen (type A) was slecht in alle richtingen (flexie/extensie, latero-flexie en rotatie). Voor de cervico-hoog thoracale middelen (type B) was deze redelijk tot substantieel voor flexie/extensie, maar slecht tot matig voor latero-flexie en rotatie. Bij de cervico-laag thoracale middelen (type B2) was de beperking van flexie/extensie en rotatie redelijk tot substantieel, terwijl hun vermogen om latero-flexie te beperken slechts tot redelijk was. Alle cranio-thoracale middelen voor niet mobiele patiënten (type D) beperkten de cervicale beweegelijkheid substantieel tot bijna volledig in alle richtingen. Vesten zonder invasieve schedelpennen (type E) beperkten de cervicale beweeglijkheid substantieel tot bijna volledig in alle richtingen. Er werden geen studies gevonden waarin de mate van beperking van de cervicale beweeglijkheid bij gebruik van craniale tractie (type C) of halo vesten met schedelpennen (type E2) werd onderzocht.

In hoofdstuk 4 wordt beschreven in welke mate verschillende immobialisatiemiddelen de cervicale beweeglijkheid beperken, inclusief de intervertebrale beweeglijkheid. In de cervicale wervels van vijf humane kadavers, werden niet-röntgendoorlaatbare kogeltjes geïmplant. Na de toepassing van verschillende immobialisatiemiddelen (Stifneck, SOMI, halo-tractie, hoofdsteenen op een wervelplank, halo-vest) en het aanbrengen van een gecontroleerd moment voor flexie/extensie, latero-flexie en rotatie, werd een radio-stereometrische analyse uitgevoerd om de totale en intervertebrale beweeglijkheid in drie richtingen te bepalen. De meeste beperking van flexie/extensie werd gezien op het niveau van C0-C1, terwijl de meeste beperking van rotatie gezien werd op het niveau van C1-C2. Latero-flexie werd beperkt op het niveau van C1 tot en met C7. De mate van beperking van beweeglijkheid, van het minst tot het meest, werd achtereenvolgens bereikt door de Stifneck (type B1), SOMI (type B2), halo-tractie (type C), wervelplank met hoofdsteenen (type E1) en het halo-vest (type E2). Opmerkelijk hierbij was dat de cranio-thoracale middelen (type D) minder variatie hadden in de mate van beperking van de beweeglijkheid dan de cervico-thoracale immobialisatiemiddelen (type B).

In hoofdstuk 5 wordt een studie beschreven naar de waarde van een harde halskraag. De resultaten die hebben laten zien dat de toevoeging van een harde halskraag naast hoofdsteunen op een wervelplank, zoals geadviseerd door de ATLS en AANS, geen toegevoegde waarde heeft aan de Cyrus. De Arpemat scoorde ten opzichte van de andere immobialisatiemiddelen significant hoger voor duurzaamheid. De Halo-tractor scoorde significant hoger voor comfort en beperking van beweging dan de Comfort Board. De Comfort Board scoorde significant hoger voor beweging dan de Halo-tractor.

In hoofdstuk 6, worden twee typen vacuümmatrassen (Germa EasyFix en de RedVac VM7000) vergeleken met twee typen wervelplanken met zachte bedekking (Arpemat en het Comfort Board). In deze gecontroleerde experimentele studie immobaliseerden 31 prehospitaliere hulpverleners vrijwilligers met behulp van de vier verschillende immobilisatiemiddelen. De prehospitaliere hulpverleners oordeelden dat de Arpemat beter schoon te maken was dan de Comfort Board. De Arpemat scoorde ten opzichte van de andere immobialisatiemiddelen significant hoger voor duurzaamheid. Er was geen significant verschil tussen de vier immobilisatiemiddelen ten aanzien van het gemak waarmee de patiënt te rollen en op te tillen is en wat betreft de toegankelijkheid tot borstkas en buik. De Arpemat en het Comfort Board scoorden significant hoger voor beperking van de cervicale beweeglijkheid dan de RedVac 7000VM. In het gebied van de schouderbladen, resulteerde het gebruik van de Arpemat in significante lagere huidcontactdrukken in vergelijking met het Comfort Board. Echter, in vergelijking met de andere immobialisatiemiddelen resulteerde gebruik van de Arpemat in significant hogere contactdrukken ter hoogte van de sacrum.

In hoofdstuk 7 wordt een studie beschreven over een nieuw cranio-thoracaal immobilisatie middel: de Farao-matras (type D3), ontworpen voor ernstig gewonde/comateuze patiënten met cervicaal letsel. Met radio-stereometrische analyse in vijf kadavers werd het vermogen om beweeglijkheid te beperken bepaald. Verder werden de röntgendoorlaatbaarheid en huidcontactdrukken vergeleken met hoofdsteenen, bevestigd op een wervelplank. Er was geen significante verschil aantoonbaar voor de mate van cervicale beperking tussen het Farao-matras en de Comfort Board. De Arpemat en het Comfort Board scoorden significant hoger voor comfort en duurzaamheid. Er was geen significant verschil aantoonbaar voor de mate van cervicale beperking tussen het Farao-matras en de Comfort Board. De Arpemat scoorde significant hoger voor comfort en duurzaamheid.

In hoofdstuk 8 wordt bediscussieerd over de maximale mondopening bij het gebruik van helmsteunen en wervelplank. Het Farao-matras in vergelijking met de hoofdsteunen heeft significante lagere huidcontactdrukken in vergelijking met de hoofdsteunen en wervelplank. De Comfort Board scoorde significant hoger voor duurzaamheid. De Comfort Board scoorde significant hoger voor comfort en beperking van beweging dan de Arpemat.

In hoofdstuk 9 wordt bediscussieerd over de beste technieken voor prehospitaliere immobilisatie van trauma-patiënten. Het beschrijven van de bevindingen van de eerdere hoofdstukken op de gezondheidszorg wordt bediscussieerd in hoofdstuk 8. Helaas, zijn we echter nog steeds niet in staat om de vraag te beantwoorden of prehospitaliere immobilisatie daadwerkelijk zinnig is. Echter, met de in dit proefschrift verkregen nieuwe inzichten kunnen adviezen worden gegeven over de beste technieken voor prehospitaliere immobilisatie. Onze resultaten suggereren dat het gebruik van wervelplanken met zachte bedekking bij bedrijfsteunen met hoofdsteenen op een wervelplank, zoals geadviseerd door de ATLS en AANS, geen toegevoegde waarde heeft aan de Cyrus. De Arpemat scoorde significant hoger voor comfort en beperking van beweging dan de Comfort Board. De Comfort Board scoorde significant hoger voor comfort en duurzaamheid.

De impact van de bevindingen van de eerdere hoofdstukken op de gezondheidszorg wordt bediscussieerd in hoofdstuk 8. Helaas, zijn we echter nog steeds niet in staat om de vraag te beantwoorden of prehospitaliere immobilisatie daadwerkelijk zinnig is. Echter, met de in dit proefschrift verkregen nieuwe inzichten kunnen adviezen worden gegeven over de beste technieken voor prehospitaliere immobilisatie. Onze resultaten suggereren dat het gebruik van wervelplanken met zachte bedekking bij bedrijfsteunen met hoofdsteenen en wervelplank, zoals geadviseerd door de ATLS en AANS, geen toegevoegde waarde heeft aan de Cyrus. De Arpemat scoorde significant hoger voor comfort en beperking van beweging dan de Comfort Board.
leggen zijn en in de praktijk bruikbaarder zijn dan vacuümmatrassen. In dit proefschrift tonen we aan dat er een gebrek is aan bewijs voor de toepassing van externe immobilisatie en bepalen we de doelen voor de evaluatie van hedendaags gebruikte technieken en toepassingen. We presenteren een gevalideerd classificatiesysteem voor verschillende externe immobilisatiemiddelen en de mate waarin deze de cervicale beweeglijkheid beperken. Dit verbeterde begrip stelt ons en anderen in staat om beter bewijs te verzamelen over deze veel toegepaste medische handeling. Daarnaast kan het de zorg voor patiënten met een verdenking op, of bewezen cervicale wervelkolomletsel verbeteren.
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presenteren: “arm~been en de Wijze van Verandering”.
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