Original article

Reduction in the exposure to being out-of-position among car occupants who used a sleeping device

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ABSTRACT
Background This study assesses the impact on safety of a system designed to enhance sleep in car passengers. The system holds the head posteriorly and limits its rotation in the sagittal and frontal planes, modifying the occupant's head position. This device may have an influence on the interaction between the occupant and the vehicle restraint systems.
Methods It was a randomised, prospective, single-blind, cross-over controlled study in which 41 volunteers were exposed to using the system while riding as car passengers. Whether the device influenced the posture of the occupants and prevented them from adopting out-of-position (OOP) configurations was also analysed. Occupants were videotaped while they were using both the innovative system (cases) and their normal sleeping device (controls), if any.
Results Controls were exposed to OOP situations in 825 occasions (18.4%; 95% CI 17.3% to 19.6%), while cases were exposed in 416 occasions (9.3%; 95% CI 8.4% to 10.2%). The paper also analysed how many cases and controls were exposed at least once to a particular event and how frequent a single participant incurred in an OOP situation. In both cases, the innovative device showed a reduction in exposition. When OOP situations were grouped into severe, moderate and minor events, the innovative device produced a statistically significant reduction in the occurrence of severe and moderate events.
Conclusions A device originally designed to improve comfort and rest in car passengers has been found to reduce the exposure of the occupants to being OOP while resting in the car.
Trial registration number http://www.ClinicalTrials.gov, NCT01062295.

INTRODUCTION
Road transport is the most complex and dangerous system that people deal with on a daily basis.[1] The prevention of road traffic injuries requires the adoption of a systematic approach embracing all contributing events (precrash, crash and postcrash), as well as the interaction between vehicle, occupants and environment.[2] [3] New traffic interventions should be evaluated considering the implications for the safety of the users. Measures to improve mobility or sustainability have been shown to impact the safety of the transport system.[4]

This study evaluates the impact on safety of a prototype product designed to improve sleep quality in car passengers. The system restrains head motion in the sagittal, frontal and transverse planes.

One of Haddon's strategies to prevent harm from road crashes[5] consisted of separating the energy being released in the crash from the occupant. The combination of air bags and seat belts prevents the impact of the occupant's head and torso against the dashboard. Several studies have confirmed the effectiveness of seat belts and air bags in preventing death and severe injuries, but note that deployment of the bag in the absence of belt use or when the occupant is sitting too close to the housing may cause injuries.[6–9] These situations are referred to as being out-of-position (OOP).

A review of the literature shows a variety of injuries attributed to OOP occupants.[7] The National Highway Traffic Safety Administration confirmed 227 air-bag-related deaths as of 1 January 2003.[10] Air-bag-related deaths were associated primarily to craniocervical and chest injuries in a Canadian study.[11] Studies have reported abrasions and contusions to the head,[12] burns of the eye[7] and other ocular injuries (eyeball ruptures, enucleation, hyphema),[13] [14] arterial ruptures,[15] temporomandibular joint and mandibular injuries,[16] basilar skull fractures,[17] maxillofacial fractures[18] and esophageal ruptures.[19] Shorter adult occupants killed by an air bag sustained neck fractures at the atlanto-occipital joint.[20] [21] Severe thoracic injuries caused by air bag deployment to large OOP occupants include multiple rib fractures, flail chest, lung contusions, atrial ruptures and lacerations of the myocardium, pericardium or aorta.[12] [22]

OOP situations are considered in restraint design.[23–26] However, the position that a sleeping occupant adopts in a vehicle may differ from those considered during its design. The goal of this study was to evaluate the potential impact on car occupant's safety of a new device designed to enhance sleep in car passengers. Particularly, this study evaluates whether the use of the device reduces time spent OOP while resting as a passenger.

METHODS
Participants
The sleep study was designed and undertaken by the sleep unit of the Hospital Universitario Txagorritxu (University Hospital Txagorritxu, Vitoria, Spain). Participants were recruited from acquaintances of hospital personnel. A total of 41 volunteers (17 women, 24 men) aged between 30 and 80 years (43.8±10.1 years) enrolled in the study. Exclusion criteria were as follows: acute, chronic or severe disease; musculoskeletal pain after maintaining a posture; being pregnant; and body mass index higher than 40 kg/m². Subjects using psychotropic, stimulant, antidepressant or any

165

illicit substances were also excluded from the study. The protocol was approved by the Human Ethics Committee of Hospital Universitario Txagorritxu. The study was registered with http://www.ClinicalTrials.gov (NCT01062295).[27]

Study design

This was a randomised, prospective, single-blind, cross-over controlled study. Each participant was exposed to two trials on the same night. Both journeys involved an identical itinerary lasting 105 min, with a 15-min break. The itinerary was the same in every case, and it was chosen to allow maintaining a cruise speed between 80 and 110 km/h.

Participants were asked to try to sleep during each trial. In one of the trials (control), participants used whatever system they normally used to sleep while being in a car (ie, pillow, just resting the head against the seat headrest, etc). In the other trial (case), participants used the tested sleeping device. Whether the participant was a case or a control in the first trial was randomly assigned and kept blind to the researchers. The passenger seat was placed as far back from the dashboard as possible. The height of the headrest was adjusted to suit the passenger's preferences.

An infrared video camera placed on the dashboard recorded the position of the head during both trials. A rectangle initially centred on a subject's chin marker with nominal dimensions corresponding to 8 cm×4.5 cm was superimposed on the video images to facilitate the assessment of the lateral motion of the head (figure 1).

Sleeping device: head hammock

The Siesta System® prototype 2 consists of a hammock suspended by two elastic cables hanging from two plastic rods that can be attached to the top of the headrest or the back of the seat. The system prevents excessive head flexion in either the sagittal or the frontal plane (lateral flexion) while still providing freedom for small-range motions. The system was originally designed to increase sleep efficiency, reduce the number of awakenings and sleep latency and improve subjective sleep perception. A schema of the Siesta System® prototype 2 is shown in figure 2.

Definition of OOP

Fourteen OOP indicators were defined.[20] [28–30] They were grouped into three categories: severe, moderate and minor indicators, depending on the potential interaction between the occupant and the air bags or intruding vehicle structures in the
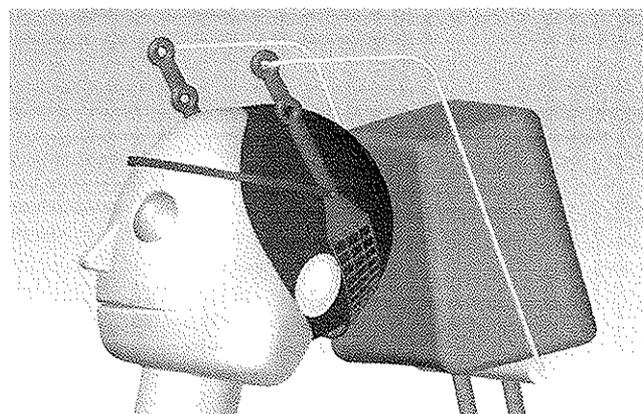
Figure 2 Schematic illustration of the headrest hammock Siesta System® prototype 2.

event of a crash (both frontal and side air bags were considered). The indicators are defined in table 1.

Statistical analysis

Each subject provided 210 min of video recording (105 min as case and 105 min as control). Eight windows of 5 min were randomly selected (ie, per trial, a total of 40 min (38%) was considered). Two observers were trained to collect information from the video recordings. Observers were kept blind to the goal of the study. Each observer analysed a single trial per subject. Video footage was edited so that the observer was blind to the case or control status of a particular trial. The observers recorded values for 14 dichotomous variables (corresponding to the 14 OOP indicators described above) per 5-min window of time per trial. Observation times are presented in table 2.

Repeats of the same OOP event within each time window were not considered to avoid ambiguity and to distinguish between a single long event and several shorter ones. A second randomised selection of time windows was performed and used to replace the first should any issue prevented the observer to assess adequately the position of the occupant.

The main outcome was the number of times that cases and controls were exposed to any OOP event. A secondary outcome was the number of exposures to any OOP event per subject. Statistical analyses consisted of descriptive statistics as well as comparison of proportions using the χ^2 test. In particular, for each indicator, we compared:

Figure 1 Video capture of a participant showing the position using the Siesta System® prototype 2 (left) and without using the system (right).

Table 1 Definition of the 14 events proposed as OOP situations

Severe events	A—Occupant leans on door
	B—Occupant's head rests on lateral window or door
	C—Occupant's shoulder or upper torso leans on door or window
	D—Occupant's head rests on dashboard
	E—Occupant's torso lies on dashboard
	F—Occupant is twisted on seat, with the lateral aspect of the body resting on the seat back
	G—Occupant's chin contacts the chest (neck hyperflexion)
	H—Occupant's face faces roof of the vehicle (neck hyperextension)
Moderate events	A—Chin marker trespasses side vertical line
	B—Chin marker trespasses inferior horizontal line
	C—Occupant's face faces lateral window
	D—Occupant's head lies on shoulder
Minor events	A—Chin marker touches side vertical line for more than 15 s
	B—Chin marker touches inferior horizontal line for more than 15 s

1. the number of cases and controls that were exposed at least once to a specific OOP situation regardless of the time window (N=40);
2. how many times each participant was exposed to a particular OOP situation as a case and as a control (from 0 to 8, corresponding to the eight time windows).

Statistical analyses were performed using Stata 9.0.

RESULTS

One of the participants was withdrawn from the study after testing began since he had failed to declare one of the exclusion criteria. The other 40 participants were recorded for a total time of 8400 min (40 participants×2 trials×105 min/trial). Out of these, 3200 min was observed for the study (38%). There were a total of 640 observed 5-min windows (40 participants×2 trials×8 windows). Seven time windows had to be replaced.

One of the participants did not use the seat belt in either trial. A second used the seat belt in one of the trials but not in the other. All other subjects were properly restrained.

There were 4480 potential OOP events (14 events/time window×8 time windows×40 participants). While controls experienced these events on 825 occasions (18.4%; 95% CI 17.3% to 19.6%), cases experienced only 416 episodes (9.3%; 95% CI 8.4% to 10.2%). The decrease in exposure was statistically significant. One of the participants never exposed himself to any OOP situation in either trial. Three additional subjects did not incur in any event when they were using the system.

Per participant, 112 events could occur during one trial (14 events/time window×8 time windows). On average, events occurred in 65 occasions in the control trials (58%; 95% CI 48.3% to 67.3%) and in 54 occasions in the case trials (48.2%; 95% CI 38.7% to 57.9%). Although the CIs overlapped, the device contributed to reducing the participation in potentially OOP situations.

Table 2 Randomised observation windows per case and control

Observation window	Start and end minute (both inclusive)
1	3—7
2	19—23
3	32—36
4	49—53
5	60—64
6	75—79
7	94—98
8	101—105

Table 3 Frequency count of cases and controls exposed to an OOP situation at least once (N=40)

	Controls	Cases	p Value
Any event	39	36	**0.002**
Severe event	26	21	0.370
A—Occupant leans on door	0	0	N/A
B—Occupant's head rests on lateral window or door	1	0	N/A
C—Occupant's shoulder or upper torso leans on door or window	1	0	N/A
D—Occupant's head rests on dashboard	0	0	N/A
E—Occupant's torso lies on dashboard	0	0	N/A
F—Occupant is twisted on seat, with the lateral aspect of the body resting on the seat back	0	0	N/A
G—Occupant's chin contacts the chest (neck hyperflexion)	9	2	0.309
H—Occupant's face faces roof of the vehicle (neck hyperextension)	22	19	0.324
Moderate event	39	36	**0.002**
I—Chin marker trespasses side vertical line	33	29	0.316
J—Chin marker trespasses the inferior horizontal line	35	23	**0.005**
K—Occupant's face faces lateral window	23	3	0.738
L—Occupant's head lies on the shoulder	35	16	0.329
Minor event	35	30	0.053
M—Chin marker touches side vertical line (>15 s)	27	18	0.560
N—Chin marker touches inferior horizontal line (>15 s)	30	28	**0.017**

Significant differences are marked in boldface.

The comparison between the proportions of case and control trials exposed to OOP and between the number of times case and control trials experienced an OOP event were also calculated:
1. Comparison between the number of cases and controls that were exposed at least once to a particular event (N=40).

Table 3 shows the count of case and control periods (N=40) in which the occupant was exposed to each OOP event regardless of the time window. A comparison of exposure to severe, moderate, minor and any OOP situation between cases and controls is also given in table 3.
2. How many times a participant was in a particular OOP situation both as a control and as a case.

Each participant could have been exposed to a particular OOP situation up to eight times. This analysis compared how many times each subject experienced a particular OOP event as a control and as a case. The only event in which a significant

Table 4 Comparison of the number of exposures to event I between cases (rows) and controls (columns)

Exposures (cases)	Exposures (controls)									Total
	0	1	2	3	4	5	6	7	8	
0	3	1	1	1	2	1	2	0	0	11
1	0	0	0	3	5	0	0	1	0	9
2	2	0	0	0	3	0	0	0	1	6
3	1	0	3	2	1	2	0	0	0	9
4	0	0	0	0	0	0	1	0	0	1
5	1	0	0	0	0	0	0	1	2	4
6	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0
Total	7	1	4	6	11	3	3	2	3	40

difference (p=0.019) was found between cases and controls was event I. Table 4 compares the number of exposures to OOP event I between cases and controls. The last column shows the number of cases participating in OOP event I split among the number of exposures (from 0 to 8). Each of the intermediate columns shows the number of exposures when the corresponding people were controls (ie, out of the 11 cases that were never exposed to event I, 3 controls were never exposed, 1 control was exposed one time, 1 control was exposed two times, 2 controls were exposed four times, etc). None of the cases were exposed six times or more. Eleven cases were never exposed and nine cases were exposed only once. The last row in the table shows that exposition was higher among controls.

DISCUSSION

This study analysed the impact on safety of a device intended to facilitate and improve the quality of sleep in car passengers, particularly in terms of exposure to being OOP while resting as a passenger. Analysis of video captures from 40 volunteers showed that the device tended to keep the occupants' head and torso in a more favourable position in case of a crash. Volunteers experienced significantly fewer OOP situations when they were using the device.

Although there is no literature relating occupant sleep and being OOP, sleeping passengers are likely more susceptible incurring in OOP situations due to associated muscular relaxation and tendency to seek a comfortable posture. Several of the participants were OOP during the experiments with their head and upper torso resting on the lateral structure of the car. The study found that, even if passengers using the system slept longer and deeper, their position on the seat was better than that of passengers who were not using the system.

The OOP indicators were chosen based on published literature.[20 28–30] We augmented the number of OOP indicators by adding situations that would not imply a great risk of resulting injury per se but that could suggest that the occupant was leaving a normal seating position. These indicators constitute the moderate and minor event categories in table 1. We acknowledge that other researchers could have proposed a different set of indicators.

The existence of repeated events during a given observation period was disregarded on purpose. This methodology is conservative: counting all the events per time window would have caused the differences between cases and controls to increase, but never to decrease.

Despite the limited size of the sample, we found significant differences. We report the results using parametric tests, assuming a normal distribution of the data. Due to the sample size, results of normality tests are not reliable. Thus, in case the data were not drawn from a normally distributed population, analyses were repeated using non-parametric methods. The non-parametric tests confirmed the results obtained before and also found significant differences for events K, L and M. As mentioned before, the design of the experimental study was made after a pilot study to estimate the sample size needed to obtain significant differences in quality of sleep.[27]

Although it may seem counter-intuitive that some point differences in table 3 failed to reach statistical significance, the p values are derived from χ^2 tests comparing the proportion of observed versus expected OOP counts in our sample. Thus, differences were reached within two major categories (moderate and minor), whereas they were not reached in some particular instances, such as in K events.

What is already known on the subject?

▶ Out-of-position occupants are exposed to the risk of sustaining injuries caused by the incorrect use of seat belts or by being too close to the air bag housing.
▶ Sleeping occupants are more likely to adopt arbitrary seating positions that may lead to out-of-position configurations.

What this study adds

▶ This study evaluates the safety performance of a system designed to enhance sleep in car passengers.
▶ A system partially restraining the head from moving contributes to improve the initial head and torso position of car occupants in a crash so that the restraints can act more effectively.

There were some limitations to the study, including camera positioning. Because the camera was not orthogonal to the occupant's sagittal plane, we could not perform any numerical estimation of the lateral displacement of the head.

The device tested limits the motion of the head in the sagittal and frontal anatomical planes and therefore prevents the occupant from leaning against the dashboard or the door panel or pillar of the vehicle.[20 28 30] The study found a statistically significant reduction in occupant exposure to moderate (event J, p=0.005) or minor OOP events (event N, p-value=0.017) and in the number of times exposed to a single moderate event (event I, p-value=0.019). Though the number of exposures to severe OOP events was smaller in the case group, the differences did not reach statistical significance.

The system exhibited a potential for preventing OOP that might also be applicable to children in child restraint systems. Given the large proportion of head injuries among children, especially when the impact is not pure frontal and the lateral component forces the head out of the restraint system,[31 32] a device that limits the motion of the head should be studied. Future evaluations of the system should incorporate orthogonal views of the subject. A lateral camera capturing the motion of the subject in the sagittal plane in combination with a pure frontal camera tracking the motion in the frontal plane is recommended.

CONCLUSIONS

A new device designed to facilitate and improve sleep in car occupants has been found to reduce the exposure of the occupants to being OOP while resting in the car. The device holds the head posteriorly and limits the rotation in the sagittal and frontal planes. A number of conditions considered as OOP or potentially leading OOP situations were defined. The analysis of the video captures of volunteers participating in a cross-over controlled study showed that when the participants used the system, they were exposed to less different dangerous situations and were exposed less frequently.

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An ironic injury

An elderly woman in New Zealand on her way to a Falls Prevention Course was knocked off her bike when she was hit by the course instructor pulling out of a driveway. This prompted questions about the reduced visibility caused by four-wheel-drive vehicles and campervans.

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