# Prospective study to compare the difference in cerebral perfusion in patients undergoing shoulder surgery with the standard beach chair position compared to 30˚ inclination

by

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NDXPET002

*This study is in partial fulfilment of the requirements for the degree*

Master of Medicine in Orthopaedic Surgery

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July 2016

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## Declaration

I, Petrus Hendrik Naude, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever. I further declare the following:

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**Abstract:**

There have been devastating reports of patients suffering permanent neurological damage following surgery in the beach chair position. Recent literature have shown that placing a patient under general anaesthesia in the beach chair position may place patients at risk of complications.

There is no set angle of inclination used by all orthopaedic surgeons. Previous research have used angles of 70˚-90˚. At these angles patients suffered a significant number of cerebral desaturation events that may lead to ischaemic neurological events.
This angle is far more upright than what is used in our practice. We postulated that decreasing the angle of inclination may be protective of cerebral perfusion.

We performed a prospective randomised single blind study. 45 consecutive patients presenting for shoulder surgery were randomised to 2 groups. The control group patients were placed in the normal position used by the surgeon for the procedure and this angle was measured. The patients in the trial group were all placed at 30˚.

Patients with known cerebrovascular disease, younger than 18 years, ASA grade 4 and 5, allergy to local anaesthetic, pre-existing coagulopathies or a failed interscalene block were excluded.
Cerebral oxygenation were measured with the INVOS system along with the other standard observations in theatre. The 2 most important parameters measured were mean arterial pressure and cerebral oxygenation levels.

In both groups there were a large percentage of patients that required intervention for decreases in mean arterial pressure. A total of 69% (72% in control group vs 65% in intervention group) required intervention for decreases in mean arterial pressure.

In our study a total of 7% (9% in control group vs 4% in intervention group) of the patients suffered cerebral desaturation events. This would indicate that decreasing the angle of inclination when using the beach chair position will improve cerebral oxygenation and may therefore protect patients against suffering ischaemic neurological events.

## ACKNOWLEDGEMENTS

To everyone who supported me through this journey. My wife and family have sacrificed a lot during this process.

To the consultants in the department of Orthopaedic Surgery, thank you for all your enthusiastic teaching and mentorship.

To Professor Steve Roche for teaching me how to care for my patients and how to keep on interrogating the literature. He has taught me to be enthusiastic about research and to keep searching for ways to improve patient care.

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**List of abbreviations:**

CDE: Cerebral desaturation events
MAP: Mean arterial pressure
NIBP: Non-invasive blood pressure
LED: Light emitting diode

**Part A: LITERATURE REVIEW**

**Prospective study to compare the difference in cerebral perfusion in patients undergoing shoulder surgery with the standard beach chair position used in our institution compared to 30˚ inclination**

## INTRODUCTION

There have been increasing reports over the last decade of patients suffering devastating neurological complications following shoulder surgery in the beach chair position[1,2,6,11,24]. This has led to an increased interest in the physiological changes experienced by patients undergoing surgery when they are placed in the beach chair position. These changes are not only due to elevating the patient's head above the level of the heart, but also due to suppression of normal cerebral autoregulation by general anaesthesia[17,28].
The current theory is that cerebral hypoperfusion[22] is the cause for these neurological complications. Due to the low incidence of complications, it has not yet been possible to confirm or refute this hypothesis.

There has been clinical research into the factors that influence cerebral perfusion. All of these papers suggest that placing a patient under general anaesthesia in the beach chair position may lead to decreases in cerebral perfusion and therefore place them at risk of developing neurological complications[12,18].
In a 2014 Pant et al performed a systemic review of all the data that was available at the time regarding cerebral oxygenation monitoring of patients in the beach chair position. This review not only shows a strong correlation between CDE's and elevation in the beach chair position, but also suggests that one is able to stratify risk to patients on the basis of age, history of hypertension and stroke, body mass index, diabetes mellitus, obstructive sleep apnoea and height. From the reported data it was clear that there is still a need for more high level studies.
It is this previous research that stimulated our interest to further investigate the risks associated with placing a patient in the beach chair position for surgery. The aim of the study was to investigate how lowering the angle of inclination used in the beach chair position may improve cerebral oxygenation.

## OBJECTIVES OF LITERATURE REVIEW

The literature review investigated the reported neurological risk posed to the patient placed in the beach chair position, and the explanation for this risk with a view to possibly reducing it.

The initial goal was to review the basic science of the physiological changes that occur when a patient is placed in the beach chair position. An assessment of the impact of general anaesthesia on cerebral autoregulation was also undertaken. The changes that occur in cerebral perfusion when a patient's head is elevated relative to their heart and placed under general anaesthesia were assessed. This information will form the basis for understanding the possible clinical implications of positioning a patient in the beach chair position for surgery.

Several studies have been published commenting on the clinical changes that occur in patients placed in the beach chair position. The aim was to review the different aspects that were addressed in these studies and see how they were applicable to this study.

## LITERATURE SEARCH STRATEGY

A literature search was performed using Pubmed and Google Scholar. All articles that were found using these search engines allowed further expansion of the literature search through their references. The search criteria were "cerebral desaturation events" and "beach chair position".

A Pubmed search for "cerebral desaturation events", resulted in 81 articles and Google Scholar cited 572 articles. A Pubmed search for "beach chair position" cited 147 articles and Google Scholar cited 5460 articles.

### Quality of Research

The levels of evidence were assessed by the guide supplied by the Journal of Shoulder and Elbow surgery. There were 7 case reports of complications which were level IV evidence. There were 17 basic science articles looking at the physiological changes experienced by patients in the beach chair position. These articles were level V evidence. Two prospective, non-randomized control trials, which are classified as level II evidence were found.

## LITERATURE REVIEW

*Positioning*

Since the 1970's shoulder arthroscopy has been gaining in popularity. The two positions used for this procedure are the lateral decubitus and the semi-sitting or beach chair position. In 1988 Skyhar et al published their results of arthroscopic shoulder procedures in the beach chair position. They reported no complications and listed the benefits of using this position[26]. The benefits reported for the beach chair position were ease of setup, excellent intra-articular visualization for all arthroscopic procedures, lack of brachial plexus strain, and ease of conversion to an open procedure if needed[26].

The benefit may not be as clear when looking at these perceived advantages more closely. Training and personal experience dictates to a large extent surgeon preference in terms of patient positioning. This preference will undoubtedly create bias in terms of the perceived ease of setup for these two positions. To date there have been no trials to compare the time needed or number of assistants required for the two different positions[14]. Proponents of the beach chair position contend that it allows for easier orientation of the structures in the shoulder. Easier palpation of the external landmarks also allow more accurate portal placement[23,26,29]. However, surgeons that routinely use the lateral decubitus position believe that as long as the glenoid is placed parallel to the floor, it serves as a good reference during shoulder arthroscopy[23]. Li believes that personal preference and experience is likely the biggest determining factor when it comes to ease of orientation during shoulder arthroscopy[14].

Brachial plexus neuropraxia is reported in patients placed in the lateral decubitus position due to excessive traction[10,23,26]. Most of these incidents are reported as transient and recover completely[14]. There are no reports of traction injuries to the brachial plexus when patients are placed in the beach chair position[25]. The low incidence of neuropraxia suffered by patients in the lateral decubitus position and the fact that almost all recover without treatment, makes this perceived advantage of questionable importance. There are no references to how the patient's neck is positioned or on the amount of traction applied to the arm when these complications have been reported.

It is unquestionably easier to convert to an open procedure when a patient is placed in the beach chair position when compared to the lateral decubitus. There is no need to reposition or repeat cleaning and draping of the patient. More experienced surgeons will contend that the need to convert to an open procedure decreases dramatically as your experience level increases[7,23].

*Cerebral oximetry*

In the last decade the use of cerebral oximetry during shoulder surgery has gained in popularity. The realization that decreased cerebral perfusion caused by placing a patient in the beach chair position under general anaesthesia may place patients at risk of developing neurological complications has led to the increased use[1,2,6,11,24]. Despite this, cerebral oximetry is still not compulsory for patients operated in the beach chair position in South Africa. In the private setting, some medical aids require motivation from the anaesthetist to allow for the use of cerebral oximetry. This is due to the high cost of the sensors. Many government institutions do not have access to cerebral oximetry and therefore the use is limited in them. Even at institutions where it is available, it is not always used. The monitor is often reserved for higher risk procedures like cardiac surgery.

In 1977 Jobsis was the first to report that the high degree of transparency of myocardial and brain tissue will allow real-time non-invasive detection of tissue oxygen saturation using transillumination spectroscopy[8]. In 1985 Ferrari et al reported the first study using near-infrared spectroscopy to perform cerebral oximetry[4]. Subsequently in 1993 the United States Food and Drug Administration approved the first commercially available cerebral oximetry device. The INVOS 3100 (Somanetics Corporation, Troy, MI, USA)[16]. There are currently two FDA-cleared cerebral oximeters INVOS 5100 (Somanetics Corporation, Troy, MI) and Foresight (CAS Medical Systems, Branford, CT)[15].

These devices use near-infrared (NIR) spectroscopy to measure cerebral tissue oxygenation. The relative transparency of human tissue, including the skull, in the NIR range allows the measurement of tissue oxygenation by this technique[16].

There is a slight difference in the method employed to achieve this when the INVOS and Foresight systems are compared. The INVOS measures changes in regional oxygenation saturation. The INVOS device achieves this via a proprietary subtraction algorithm. Bi-frontal cortical oxygenation is assessed using a light emitting diode (LED) at 730 nm and 810 nm and differentially spaced receiving optodes[16].

The Foresight measures absolute brain oxygen saturation. LED wavelengths at 690nm, 780nm, 805nm and 850nm is used to assess this[16].

There are however limitations to the use of cerebral oximetry. It can only provide an estimation of cerebral oxygenation directly below the sensor and thereby an estimation of cerebral blood flow. True measurement of cerebral perfusion would require invasive monitoring. Cerebral perfusion pressure is a function of MAP and intracranial pressure. The placement of an invasive temporal arterial line and an epidural sensor, subarachnoid bolt or an intraventricular catheter would be needed to achieve this. For obvious reasons using these invasive methods are not feasible during routine surgery[30].

*Neurological complications*

The beach chair position was considered to be safe[26] until 2005 when case reports of complications following procedures in the beach chair position started to appear. Devastating neurological complications such stroke, blindness, coma and death have been suffered by patients following surgery in the beach chair position[2,6,11]. The incidence of these complications is very low, 0.0291% (8 of 274 255)[6].

These reported complications have led to much interest in the pathophysiology of neurological complications[2,30,31] following procedures in the beach chair position and possible ways to address the risks associated with the beach chair position[12,18]. The exact pathophysiology of neurological complications associated with the beach chair position is still not completely understood. It is postulated that the mechanism responsible for these complications is cerebral hypoperfusion caused by placing patients in a position with their head elevated under general anaesthesia[22,24]. It has not been possible to establish whether this hypothesis is correct[18].

*Basic Science*

Understanding the risks of placing patients in the beach chair position, requires an understanding of the impact of the beach chair position on cerebral perfusion. Various physiological changes occur when an anaesthetized patient is positioned with their head elevated. There is a decrease in mean arterial pressure (MAP), central venous pressure (CVP), cardiac output and partial pressure of oxygen ($PaO_2$). At the same time there is an increase in the alveolar-arterial oxygen gradient ($PAO_2$-$PaO_2$), pulmonary vascular resistance, and total peripheral resistance[2].

In the awake patient, an increase in systemic vascular resistance compensates for these changes. These compensatory mechanisms are blunted by the vasodilatory effects of anaesthetic agents and loss of autoregulation experienced under general anaesthesia. This in turn leads to decreased cerebral perfusion pressure (CPP)[5,27,33].

The MAP of the brain when placed in the beach chair position is not the same as that measured by the blood pressure cuff placed on the arm. The difference in blood pressure between the brain and the arm is equal to the hydrostatic pressure gradient. The hydrostatic gradient is 0.77mmHg for every centimeter change in height. This pressure gradient is often overlooked when patients undergo procedures in the beach chair position[2].

In general the distance between the blood pressure cuff and the external auditory meatus is used to correct for cerebral perfusion. The external auditory meatus is used as a surrogate for the base of the brain. This does not take into account the upper most part of the cerebral cortex which is another 10-12cm higher than the base of the brain and represents an extra pressure gradient of around 9mmHg. These areas with watershed perfusion are thought to be affected by decreases in cerebral perfusion[2].

Recent literature have investigated the clinical significance of this phenomenon. Traditionally the belief was that cerebral autoregulation could maintain cerebral perfusion when the MAP was maintained between 50 and 150mmHg[2,9]. Currently the belief is that a higher minimum MAP of 80mmHg should be aimed for to prevent cerebral hypoperfusion due to loss of cerebral autoregulation[9,13,19,21,22].

Triplet et al looked at the changes in temporal artery MAP (eTMAP) relative to non-invasive brachial blood pressure (NIBP) when a patient is placed in the beach chair position. They compared the readings with the patient supine, at 30˚ and at 70˚ inclination. They showed a statistically significant decrease in NIBP and eTMAP when a patient's position is changed from supine into beach chair position. These decreases occurred in a defined ratio as the amount of inclination is increased[31].

Following the results from this study, the same group performed a further study to see whether there is a correlation between the decreases seen in eTMAP and NIBP and cerebral desaturation events (CDE's) experienced by the patients in the beach chair position. This study showed that there was no correlation between changes in eTMAP and NIBP at the time when patients experienced CDE's. This underlined the importance of using cerebral oximetry when a performing surgery in the beach chair position. They believe that eTMAP, NIBP and cerebral oximetry should be used together to estimate cerebral perfusion[30].

Apart from all the physiological changes that occur during surgery in the beach chair position, there are also patient factors that must be considered. In 2013 Salazar published results from a study that looked at how CDE's may alter neurocognitive function. The study also looked at which risk factors may place patients at risk of developing CDE's. Of all the variables that were assessed, increased BMI was the only patient risk factor that lead to a statistically significant increased risk of developing a CDE during surgery.

*Clinical Research*

In 2010 Murphy et al published their results when they looked at the number of cerebral desaturation events (CDE's) suffered by patients when operated in the beach chair position compared to patients operated in the lateral decubitus position. They showed that 8o% of patients operated in the beach chair position, under general anaesthesia suffered CDE's compared to no patients placed in the lateral decubitus position. The patients in their study was placed at 80-90˚ inclination[18]. In this study it was reported that there was no diffirence in MAP between the two groups. There was however no reference made to the number of interventions done for decreases in MAP.

This study confirmed the hypothesis that placing a patient in a position with their head elevated relative to their heart, leads to decreases in cerebral perfusion pressure and therefore places patients at risk of suffering CDE's[18].

The decrease in cerebral perfusion pressure caused by placing a patient in the beach chair position is further compounded by the impact of general anaesthesia on cerebral autoregulation. Koh et al investigated the impact of general anaesthesia on cerebral perfusion[12].

In a prospective study, Koh compared patients undergoing surgery in the beach chair position under general anaesthesia with patients undergoing surgery under conscious sedation and a regional block. 57% of patients in the asleep group suffered CDE's compared to 0% of the patients in the awake group. These results highlighted the impact of general anaesthesia on cerebral autoregulation. From this study it is clear that patients under general anaesthesia cannot compensate for decreased cerebral perfusion caused by elevating their head during surgery. During this study a 70˚ angle of inclination was used when patients were placed in the beach chair position[12].

Both these studies used fairly high angles of inclination when positioning their patients in the beach chair position. Apart from the angle of inclination, there are other factors that influences the pressure gradient between the heart and the brain. The patient's height and build will also influence this difference. It would have been interesting to see what the difference in height is between the subject's heart and brain, and how this may impact the risk for patients to develop a CDE's.

Pohl et al showed in their case series, that prolonged periods of hypotension is a significant risk factor for the development of severe ischaemic neurological complications. It is therefore of utmost importance to perform close monitoring of patients' blood pressure and to treat hypotension promptly when surgery is performed with the patient in the beach chair position. The improvement in pump technology used in arthroscopic surgery have decreased the need for hypotension to improve visualization.

In none of the previous studies any of the patients developed any neurological complications. This is probably due to very low incidence of these complications[12,18,30,31]. During these studies the cerebral oxygenation levels is monitored closely and there is prompt interventions performed for any observed decreases in cerebral oxygenation. It is not clear how this in itself may protect patients against developing neurological complications.

**FURTHER LITERATURE**

The ongoing information regarding cerebral oxygenation provided by cerebral oximetry has allowed the anaesthetists to improve the care provided to the patients undergoing surgery in the beach chair position. It allows for immediate intervention when patients suffer decreases in cerebral oximetry[3,32]. I believe that in time cerebral oximetry will become compulsory when surgery is performed with a patient in the beach chair position.

The only information provided in the literature regarding the positioning of the patients in the study is the angle of inclination used. There are however other aspects of the positioning that may impact on the haemodynamic changes that a patient is exposed to in the beach chair position. When positioning the patient, attention must be paid to the position of the patient's legs during surgery. After elevating the back of the operating table to elevate the patient's head, the table should be placed in the Trendellenburg position. This elevates the legs relative to the rest of the body. The table should also be broken at the knees or a pillow placed under the knees. This takes tension of the vessels in the lower limbs. Pneumatic calf compressors can also be utilized. All of these aspects of the positioning will improve the venous return from the lower limbs and thereby improve the preload of the heart. This in turn will improve stroke volume and mean arterial pressure. In this study all patients were positioned using this technique.

Previous studies only refer to the angle of inclination used and not on any of these aspects. More information regarding all aspects of the positioning of patients in previous literature would allow more complete assessment of factors that may influence the number of CDE's recorded.

The other aspect that is not addressed in this or previous studies is the height difference between the patient's head and heart. This is not only influenced by the angle of inclination used, but also by the patient's height and build. In future studies these differences in height should also be measured to assess its impact on cerebral oxygenation.

There is an obvious need for further research into the safety of using the beach chair position. There isn't consensus in the literature regarding the safety of this practice. Many studies highlight the potential risks posed by elevating a patients head while under general anaesthesia. The actual risk has not been quantified in the literature with respect to patients placed in the beach chair position.

All literature is based on the presumption that cerebral hypoperfusion is the mechanism that lead to the neurological complications seen in these patients. To date there is no information that refutes this assumption, but ongoing research is needed to confirm this. Due to the very low incidence of these complications, it is very difficult to show what degree of cerebral hypoperfusion is needed for a patient to develop neurological complications. All research to date have focused on the number of cerebral desaturation events experienced by patients in the beach chair position. The impact of prolonged exposure to decreased levels of cerebral oxygenation have not been studied. It would not be ethical to leave patients exposed to prolonged periods of cerebral hypoperfusion for the sake of research.

It is clear that there are still much research needed for us to completely understand all the aspects involved with the complications that patients are exposed to when undergoing surgery in the beach chair position. Wide spread collaborative research will be needed to look at all aspects of these complications and make definitive suggestions regarding the management of these patients.

## Aims and objectives of research

Previous research have shown that surgery in the beach chair position places patients at risk of developing serious neurological complications. All aspects of positioning patients must be researched to find ways to decrease the risk to patients.

The goal of the study was to assess the impact of decreasing the angle of inclination used during surgery in the beach chair position on the number of CDE's suffered by patients. The main objectives are to record the number of patients that suffer CDE's and the number of interventions performed for decreases in MAP. Absolute readings of cerebral oxygenation of below 55% will also be recorded.

Previous studies performed surgery in the beach chair position at an angle of inclination of 70˚-90˚. These angles are higher than what is used in general in our unit. The study will assess how lowering the angle of inclination to 30˚ will affect the number of CDE's suffered by patients. This will be compared to patients operated at the normal angle used by the surgeon involved. These angles will be measured and recorded.

The decision not to use the higher angles used in previous studies as the control group in this study is because it would be unethical to expose patients to increased risk for the sake of the study.

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**PART B: MANUSCRIPT IN ARTICLE FORMAT**

**Prospective study to compare the difference in cerebral perfusion in patients undergoing shoulder surgery with the standard beach chair position used in our institution compared to 30˚ inclination**

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**Background:** The increasing number of case reports of patients suffering devastating neurological complications following surgery in the beach chair position have highlighted the risks of this practice. We hypothesized that decreasing the angle of inclination used in beach chair position may be protective of cerebral oxygenation.

**Methods:** Forty five consecutive patients underwent elective shoulder surgery in the beach chair position under general anaesthesia. 22 patients were placed in the normal position used in our unit and the angle of inclination was measured. The remaining 23 patients were placed at 30˚ inclination. Cerebral oxygen saturation ($Scto_2$) and mean arterial pressure (MAP) was measured at baseline and during surgery. Cerebral desaturation events (CDE's), where the $Scto_2$ drops below 20% of the baseline where documented and treated. Decreases in the MAP were also documented and treated.

**Results:** The average angle of inclination used in the control group was 38.7˚. A total of 69% of patients had decreases in MAP that required intervention (72% in control vs 65% in intervention group). 7% of all patients suffered CDE's (9% in control vs 4% in intervention group).

**Conclusion:** Placing patients at a lower angle of inclination during procedures in the beach chair position leads to fewer CDE's when compared to previous studies where higher angles of inclination were utilised.

**Level of evidence:** Level II, Randomized control trial (low statistical power), Treatment study.

**Key words:** Beach chair, cerebral oxygenation, shoulder surgery

Institutional Review Board approval: Departmental Research Committee, University of Cape Town, project number 179/2014

There have been an increase in the number of case reports of patients suffering devastating neurological complications following surgery in the beach chair position[1,4,7,20].

Complications such as blindness[2], cranial nerve neuropraxia[3], pituitary apoplexy[9], cardiovascular collapse[24] and even death[4] have been reported.

The focus of most of the literature have been on the changes in cerebral perfusion caused by elevating a patient's head while under general anaesthesia[11,13,22,24,28]. The term cerebral desaturation events (CDE'S) have been coined to describe the periodic decreases in cerebral oxygenation experienced by patients in the beach chair position. It is CDE's that is hypothesized to place patients at risk of developing ischaemic neurological complications[19,20].

Various changes occur when a patient is placed under general anaesthesia and elevated into a seated position. There is a decrease in mean arterial pressure (MAP), central venous pressure (CVP) and cardiac output[7,19,20]. In the awake patient an increase in systemic vascular resistance compensates for these changes. These compensatory mechanisms are blunted by the vasodilatory effects of anaesthetic agents and loss of autoregulation experienced under general anaesthesia. This in turn leads to decreased cerebral perfusion pressure (CPP) [15,22,28].

Previous research from Murphy et al in 2010[15] and from Koh et al[10] in 2012 looked at number of CDE's suffered by patients during shoulder surgery. Murphy et al showed significantly more CDE's in patients in the beach chair position when compared to patients placed in the lateral decubitus position (80% vs 0%)[15]. Koh et al showed that patients undergoing surgery in the beach chair position showed fewer CDE's when placed under conscious sedation when compared to patients placed under general anaesthesia[10] (57% vs 0%).

In the study by Murphy the patients were placed in the beach chair position at an angle of 80°[15]. In the study by Koh patients were placed at 70°[10]. This led the hypothesis that decreasing the angle of inclination used when a patient is placed in the beach chair position may decrease the number of CDE's observed.

## Materials and methods

We performed a prospective, single blind, randomised control trial to evaluate the impact of lowering the angle of inclination used in the beach chair position on cerebral perfusion. Patients that had elective shoulder surgery in the beach chair position were enrolled in the study.

After obtaining approval for the study from the Departmental Research Committee and Human Research Ethics Committee of the University of Cape Town, patients were approached to be enrolled in the study. Patients that had elective surgery planned in the beach chair position were asked to participate.

45 patients were enrolled in the study. 22 patients had their surgery at the "normal" angle of inclination used by the surgeon for their procedure. 23 patients were randomised to having their surgery at an angle of inclination of 30˚. There was an even spread arthroscopic and open procedures performed between the two groups.

The exclusion criteria were: known cerebrovascular disease, known orthostatic hypotension, American Society of Anesthesiologists (ASA) grade 4 & 5, coagulopathy, allergy to local anaesthetic, failed interscalene block, age under 18 years and inability to give informed consent. Patients that had elective surgery planned in the beach chair position were reviewed by the surgeon and anaesthesiologist for any possible factors that may exclude them from participation in the study.

***Table I Patient variables***

| | | Normal (n=22) | 30˚ (n=23) | Difference |
|---|---|---|---|---|
| Age | | 55.8±16.4 | 52±15.6 | 3.8 |
| Gender | | | | |
| | Male | 8 (36%) | 5 (22%) | |
| | Female | 14 (64%) | 18 (78%) | |
| Surgery | | | | |
| | Open | 13 (59%) | 14 (64%) | -5% |
| | Arthroscopic | 9 (41%) | 8 (36%) | 5% |
| Anaesthetic time (min) | | 118.2 ±31.4 | 117.8 ±37.9 | 0.4 |
| Blood loss | | 116.8 ±127.3 | 120.4 ±124.7 | 3.6 |
| ASA | | 2 (1-3) | 2 (1-3) | - |

*ASA American Society of Anaesthesiologists*

*Continues data is given as mean ±standard deviation or median (range) and categorical data as number of patients (%).*

### Procedure

The day before surgery all patients enrolled in the study were reviewed in the ward and examined to ensure that they were undergoing the correct surgical intervention for an appropriate indication. Consent for the procedure and for inclusion in the study were obtained at this time. The limb was then marked for surgery.

Prior to surgery an interscalene block under ultrasound guidance was performed using bupivacaine. Baseline observations were obtained prior to induction of general anaesthesia. Non-invasive brachial blood pressure (NIBP), pulse oximetry, electrocardiography (ECG) and temperature monitoring were performed on all patients. Anaesthesia induction was performed using Propofol and muscle relaxation achieved with Rocuronium. Anaesthesia was maintained with Isoflurane.

## Cerebral monitoring

Cerebral monitoring was performed with an INVOS 5100 monitor from Covidien. Electroencephalograph pads were placed on the frontotemporal area to measure regional cerebral oxygen saturation.

Baseline levels were measured prior to induction of anaesthesia and used as a reference throughout the procedure. Monitoring of the cerebral oxygenation were continued for the length of the procedure.

## Positioning

The group that the subject was randomised to, was revealed to the operating surgeon when the anaesthetist was satisfied that positioning can be commenced. Subjects in the control group were then positioned at the angle normally used in our unit. The angle of inclination was then measured from the horizontal. Patients in the intervention group were positioned at an angle of inclination of 30˚ from the horizontal. The measurement of this angle was confirmed by two investigators using a smartphone application, the Clinometer. The back of the operating table is raised from the horizontal to elevate the patient's head. The table is then placed in the Trendellenberg position to raise the patient's legs relative to the heart. The table is then broken at the knees or a pillow is placed under the patient's knees to increase flexion. Pneumatic calf compressors is then placed on the patient. All pressure points are carefully protected.

## Intervention

Interventions were divided into interventions for decreases in MAP and interventions for decreases in $Scto_2$. Decreases in MAP was treated with Epinephrine or Phenylephrine as per the preference of the anaesthetist involved with the case. Decrease in the $Scto_2$ was treated by increasing the fraction of inspired oxygen ($FiO_2$), Epinephrine or Phenylephrine to increase the MAP or the change the positioning of the patient by lowering the angle of inclination.

***Table II Cerebral desaturation events and treatments***

| | Normal (n=22) | 30˚ (n=23) | Difference | P-value |
|---|---|---|---|---|
| Scto2 decrease >20% | | | | |
| Patients | 2 (9%) | 1 (4%) | 5% | 0.607 |
| Episodes per patient | 0 (0-2) | 0 (0-1) | 0 (0-1) | |
| Episodes per group | 3 | 1 | | |
| Scto2 <55% | | | | |
| Patients | 9 (40%) | 8 (34%) | 6% | >0.99 |
| Episodes per patient | 0 (0-2) | 0 (0-3) | 0 | |
| Episodes in group | 12 | 11 | | |
| Interventions for MAP | | | | |
| Patients | 16 (72%) | 15 (65%) | 7% | 0.749 |
| Interventions per patient | 2.5 (0-8) | 2 (0-9) | 0.5 | |
| Interventions per group | 55 | 65 | | |

*$Scto_2$, Cerebral oxygenation (%), MAP, mean arterial pressure*

*Continues data is given as median (range) and categorical data as number of patients (%).*

## Results

45 patients were included in the study, with 22 in the "normal" angle group and 23 in the 30˚ group. There was an even distribution of open and arthroscopic procedures between the two groups with no significant difference in average anaesthetic time and blood loss. The average angle of inclination used in the "normal" group was 38.7˚ (range 30˚-55˚). This is a reflexion of the usual angle of inclination used to position patients in our unit. This is very similar to the 30˚ used in the intervention group.

Baseline observations were on average equal between the two groups for all parameters examined. During surgery all these observations were documented every 3 minutes. Decreases in MAP that required intervention were observed in 72% of patients in the "normal" group and in 65% of the intervention group. The median number of interventions for the "normal" group was 2.5 and for the 30˚ group was 3. It was not possible to show a statistically significant difference between the two groups (p 0.749).

Cerebral oxygenation monitoring showed no significant difference between the two groups at baseline. During surgery the goal was set to maintain the $Scto_2$ within 20% of the baseline. In the “normal” group 9% of patients suffered CDE’s. In the 30˚ group, 4% of patients suffered CDE’s. We could not achieve a statistical significant difference between the two groups (p 0.607).

An 80% power calculation using these results showed that a sample size of 760 subjects would be needed to prove a statistically significant difference.

In the control group 40% of patients had absolute $Scto_2$ levels below 55% recorded. In the intervention group it was recorded in 34% of the patients. It was not possible to show a statistically significant difference between the two groups ($p > 0.99$).

***Table 3 Comparison with previous studies***

| | Angle of inclination | Incidence of CDE’s |
|---|---|---|
| Koh et al Asleep group | ±70˚ | 56.7% |
| Murphy et al Beach chair group | 80˚-90˚ | 80% |
| Naude et al Normal angle | 37˚ | 9% |
| Naude et al 30˚ group | 30˚ | 4% |

**Discussion**

Since the 1970’s shoulder arthroscopy have been gaining in popularity. The two positions used for this procedure is the lateral decubitus and the semi-sitting or beach chair position. In 1988 Skyhar et al published their results of arthroscopic shoulder procedures in the beach chair position. They reported no complications and listed the benefits of using this position[21].

The benefits they listed were ease of setup, excellent intra-articular visualization, lack of strain on the brachial plexus and ease of conversion to an open procedure[21]. The beach chair position was considered to be safe and it wasn’t until 2005 that case reports of complications started to appear. Devastating neurological complications have been suffered by patients following surgery in the beach chair position[4,9,20]. These reported complications have led too much interest in the pathophysiology of neurological complications, and possible ways to address the risks associated with placing patients in the beach chair position[10,15,26,27].

Various physiological changes occur when an anaesthetized patient is positioned with their head elevated. There is a decrease in mean arterial pressure (MAP), central venous pressure (CVP), cardiac output and partial pressure of oxygen ($PaO_2$). At the same time there is an increase in the alveolar-arterial oxygen gradient ($PAO_2$-$PaO_2$), pulmonary vascular resistance, and total peripheral resistance[4,10,20.25,27].

In the awake patient an increase in systemic vascular resistance compensates for these changes. These compensatory mechanisms are blunted by the vasodilatory effects of anaesthetic agents and loss of autoregulation experienced under general anaesthesia. This in turn leads to decreases in cerebral perfusion pressure (CPP)[9,13,17,22,28].

The exact pathophysiology of neurological complications associated with the beach chair is still not completely understood. It is postulated that the mechanism responsible for these complications is cerebral hypoperfusion caused by placing patients under general anaesthesia with their head in an elevated position[19].

The MAP of the brain when placed in the beach chair position is not the same as that measured by the blood pressure cuff placed on the arm. The difference in blood pressure between the brain and the arm is equal to the hydrostatic pressure gradient. The hydrostatic gradient is 0.77mmHg for every centimeter change in height. This pressure gradient is often overlooked when patients undergo procedures in the beach chair position[4].

In general the distance between the blood pressure cuff and the external auditory meatus is used to correct for cerebral perfusion pressure. The external auditory meatus is used as a surrogate for the base of the brain. This does not take into account the upper most part of the cerebral cortex which is another 10-12cm higher than the base of the brain and represents an extra pressure gradient of around 9mmHg. These areas of watershed perfusion are thought to be affected by decreases in cerebral perfusion pressure[4].

Recent literature have investigated the clinical significance of this phenomenon. Traditionally the belief was that cerebral autoregulation could maintain cerebral perfusion when the MAP was maintained between 50 and 150mmHg[4,8]. Currently the belief is that a higher minimum MAP of 80mmHg should be aimed for to prevent cerebral hypoperfusion due to loss of cerebral autoregulation[12,16,17,18].

A recent study by Laflam et al compared two groups of patients undergoing surgery in the beach chair and lateral decubitus positions. They showed that patients placed in the beach chair position had diminished cerebral autoregulation and lower cerebral oxygenation levels. There were however no difference in cognitive function at 7 days or 6 weeks post operatively.

Pohl et al showed in their case series that prolonged periods of hypotension is a significant risk factor for the development of severe ischaemic neurological complications. It is therefore of utmost importance to perform close monitoring of patients' blood pressure and to treat hypotension promptly when surgery is performed with the patient in the beach chair position. The improvement in pump technology used in arthroscopic surgery have decreased the need for hypotension to improve visualization.

In a 2014 Pant et al performed a systemic review of all the data that was available at the time regarding cerebral oxygenation monitoring of patients in the beach chair position. This review not only shows a strong correlation between CDE's and elevation in the beach chair position, but also suggests that one is able to stratify patients on the basis of age, history of hypertension and stroke, body mass index, diabetes mellitus, obstructive sleep apnoea and height. From the reported data it was clear that there is still a need for more high level studies.

In 2010 Murphy et al published their results when they looked at the number of cerebral desaturation events suffered by patients when operated in the beach chair position compared to patients operated in the lateral decubitus position. They showed that 8o% of patients operated in the beach chair position, under general anaesthesia, suffered CDE's compared to no patients placed in the lateral decubitus position. In this study there wasn't a significant difference in the MAP measurements between the two groups. There was no reference made to the number of interventions performed for decreases in MAP. The angle of inclination used in the beach chair leg of their study was 80˚-90°[15].

Koh et al did further research into the impact of the beach chair position on cerebral oxygenation. In their study they showed that patients in the beach chair position can maintain their cerebral autoregulation if they were not placed under general anaesthesia. Patients that had their surgery under conscious sedation and a regional block suffered no CDE's while 57% of patients under general anaesthesia suffered CDE's. 73% of the patients in the asleep group of this study required intervention for decreases in MAP with none of the patients in the awake group required intervention. They placed their patients at an angle of 70˚ inclination in the study[10].

From these two studies it was clear that performing surgery in the beach chair under general anaesthesia places patients at risk of developing CDE's. The angles of inclination used in these studies stimulated our interest in the topic. These angles were far more than what is used routinely in our unit. The fact that patients in the lateral decubitus position suffered no CDE's led us to believe that decreasing the angle of inclination may be protective of cerebral oxygenation. The question was what degree of protection can be achieved by decreasing the angle of inclination.

Triplet et al showed that there is a direct correlation between brachial NIBP and temporal arterial MAP with both values decreasing in a defined ratio as the angle of inclination is increased with positioning of the patient[27]. Further research by the same group did however show that these values did not correlate with cerebral oximetry readings and therefore cannot accurately predict cerebral desaturation events. The conclusion that can be drawn from this is that patients in the beach chair position need not only NIBP monitoring, but also require cerebral oximetry to estimate cerebral perfusion[25].

Apart from all the physiological changes that occur during surgery in the beach chair position, there are also patient factors that must be considered. In 2013 Salazar published results from a study that looked at how CDE's may alter neurocognitive function. The study also looked at which risk factors may place patients at risk of developing CDE's. Of all the variables that were assessed, increased BMI was the only patient risk factor that lead to a statistically significant increased risk of developing a CDE during surgery.

In this study patients positioned at the usual angle of inclination used in our unit were compared to patients placed at an angle of 30˚. We hypothesized that decreasing the angle of inclination would improve cerebral oxygenation.

Cerebral oximetry is still not compulsory for patients operated in the beach chair position in South Arica. In the private setting, most medical aids require motivation from the anaesthesiologist to allow for the use of cerebral oximetry. This is due to the high cost of the sensors. Many government institutions do not have access to cerebral oximetry and therefore the use is limited in them. Even at institutions where it is available, it is not always used. The monitor is often reserved for higher risk procedures like cardiac surgery. Prior to the study, cerebral oximetry was not standard for all patients that underwent shoulder surgery in our unit.

The small difference in angulation (38.7˚ vs 30˚) used in this study led to similar results between the two groups. The angles of inclination used in previous studies were far more than what we use as standard in our unit, and it wouldn't have been ethical to place patients at increased risk for the sake of the study. All surgeries could be completed at these angles without the need to change the patient's position.

The two main outcomes that was of interest in the study was the number of patients that required intervention for decreases in MAP and the number of CDE's recorded. In total, 69% (65% in 30˚ group vs 72% in "normal" group) of all the subjects in our study required intervention for decreases in MAP. This difference was not statistically significant. The study from Koh showed similar results in their asleep group with 73.3% of the patients requiring intervention for decreases in MAP [10].

The very low number of CDE's observed in both groups in the study shows that decreasing the amount that a patient's head is elevated during surgery leads to fewer CDE's. The number of CDE's seen in the study (4% in 30˚ vs 9% in "normal" group) was significantly less than the number of CDE's previous studies showed for patients in the beach chair position, under general anaesthesia.

Several factors may contribute to the very low number of CDE's seen in this study. The lower angle of inclination used leads to a smaller height difference between the patient's head and heart. This leads to a decreased pressure gradient and improved cerebral perfusion pressure.

A recent study by Tauchen et al reported that placing thigh high compressive stockings on obese patients undergoing surgery in the beach chair position does lead to a significant decrease in the number of CDE's. Positioning patients in the Trendellenberg position with flexed knees and pneumatic calf compressors improves venous return and therefore stroke volume. This may improve cerebral perfusion pressure and protect patients against CDE's.

This study showed a relatively high number of patients that experienced absolute $Scto_2$ levels below 55%. Previous studies have shown that there can be variations in the baseline cerebral oxygenation levels between patients. The cerebral oxygenation monitors measures the average haemoglobin oxygen saturation in arterial, venous and capillary blood. In the brain, the average tissue haemoglobin is distributed in a 70% venous to 30% arterial ratio. Previous research have shown that there can be significant variation in this ratio between individuals. Cerebral oxygenation monitors uses a fixed ratio to calculate $Scto_2$ readings[15]. Furthermore, the variation in haemoglobin levels between patients, also influences baseline $Scto_2$ levels. It is therefore the changes in $Scto_2$ levels that is more important than the absolute cerebral oxygenation levels measured[15].

There are several limitations to this study. The fact that there was such a small difference in the angles of inclination between the groups of subjects made it impossible to show a statistically significant difference for the results. Even if the study was adequately powered to show statistical significance, this would not necessarily equate to clinical significance. The low incidence of neurological complications leaves many unanswered questions. It is not clear yet what level of $Scto_2$ must be maintained to eliminate the risk posed by surgery in the beach chair position. The actual pathophysiology of these complications is also not completely understood. In future, large collaborative research will be needed to increase knowledge of what may lead to complications, and how safety can be improved for patients.

## Conclusion

We performed a single-blind randomized control trial evaluate the impact of decreasing the angle of inclination used in the beach chair position on cerebral oxygenation. We showed a significantly lower number of CDE's when compared to similar groups in previous studies. Placing patients at a lower angle of inclination during surgery in the beach chair position may reduce the risk for ischaemic neurological injury.

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**PART C: ADDENDA**

**INFORMATION FOR AUTHORS**

**PURPOSE AND POLICIES**

The *Journal of Shoulder and Elbow Surgery* is a scientific medical journal containing information relative to the investigation of the development, preservation, and restoration of the form and function of the shoulder girdle, arm, elbow, and associated structures by medical, surgical, and physical means.

The objectives of the *Journal* are to enhance the professional study and practice of shoulder and elbow surgery, to act as a stimulant to research by providing a forum for discussion of new scientific advances, and to further international cooperation among shoulder and elbow societies by serving as an official publication for recognized societies.

To accomplish these goals, the *Journal* accepts for publication original articles, descriptions of surgical and other patient care techniques, case reports, historical and current reviews, editorials, comments on published material, and announcements or proceedings of participating societies. Books are also accepted for review.

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All manuscripts which deal with the study of human subjects must be accompanied by Institutional Review Board (IRB) or Ethical Committee Approval, or the national or regional equivalent in your geographic area. The name of the Board or Committee giving approval and the study number assigned must accompany the submission, preferably by a scanned copy of the IRB or Ethical Committee Approval uploaded to the submission.

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Manuscripts and all other communications for the Editor(s) must be written in English. Submission of the materials in the correct format will expedite the review process and prevent unnecessary delay in publication.

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On receipt of the manuscript or other materials, peer review will be performed by an Editor and usually two additional reviewers. Should the material require revision, authors are requested to complete and submit revisions within three months.

**Levels of Evidence:** Although this will be reviewed by our Editorial Staff, and their opinion will be final, the *Journal* asks authors to assign a Level of Evidence to all clinically oriented manuscripts. The following table is offered to assist authors:

| Type of Study | Treatment Study | Prognosis Study | Study of Diagnostic Test | Cost Effectiveness Study |
|---|---|---|---|---|
| LEVEL I | Randomized controlled trials with adequate statistical power to detect differences (narrow confidence intervals) and follow up >80%. | High-quality prospective cohort study with >80% follow-up, and all patients enrolled at same time point in disease | Testing previously developed diagnostic criteria in a consecutive series of patients and a universally applied "gold" standard | Reasonable costs and alternatives used in study with values obtained from many studies, study used multi-way sensitivity analysis |
| LEVEL II | Lower quality randomized trials (follow up <80%, improper randomization techniques, no masking<br><br>Prospective comparative study | Lower quality prospective cohort study (<80% follow-up, patients enrolled at different time points in disease)<br><br>Retrospective study<br><br>Untreated controls from a randomized controlled trial | Development of diagnostic criteria in a consecutive series of patients and a universally applied "gold" standard | Reasonable costs and alternatives used in study with values obtained from limited studies, study uses multi-way sensitivity analysis |
| LEVEL III | Case-control study<br><br>Retrospective comparative study | Case-control study | Study of nonconsecutive patients and/or without a universally applied "gold" standard | Analyses based on a limited section of alternatives and costs, or poor estimates of costs |
| LEVEL IV | Case series with no comparison group | Case series with no comparison groups | Use of a poor reference standard<br><br>Case control study | No sensitivity analysis |
| LEVEL V | Expert opinion | Expert opinion | Expert opinion | Expert opinion |

**Treatment Studies** investigate the results of treatment on patient outcomes and complications.

**Prognosis Studies** investigate the natural history of a disease or disorder, and evaluate the effect of a patient characteristic on the outcome of the disease.

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**Economic/Decision Analysis or Modeling Studies** explore costs and alternatives or may either develop or assess the effectiveness of decision models.

**Systematic Reviews and Meta-Analyses** are assigned a Level of Evidence equivalent to the lowest level of evidence used from the manuscripts analyzed.

**Prospective Study-Defined** is a study in which the research question was developed, (and the statistical analysis for determining power) were developed before data was collected.

**Retrospective Study-Defined** is a study in which the research question was determined after the data was collected (even for studies where the authors collected general data prospectively).

**Cover Letter**

It is essential that the material be accompanied by two cover letters. The first letter must include information on prior or duplicate submission or publication elsewhere of any part of the work including details of any presentation of the study as an abstract at a professional meeting, a statement that the manuscript has been read and approved by all authors, and a statement that each author believes that the manuscript represents honest work. All manuscripts will be checked by an internet-based algorithmic searching method to check for possible duplication of previously published work.

This first letter also should identify the name, mailing address, and e-mail address of the author responsible for all future correspondence regarding the manuscript.

The second cover letter, **the conflict of interest (CoI) statement**, must deal with disclosures and must be signed and dated by all authors. This second cover letter must also be submitted online during the article submission process. Individual CoI statements may also be uploaded. All CoI statements should be in a pdf format.

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The *Journal* adheres to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (the Vancouver style) developed by the International Committee of Medical Journal Editors as described in the Journal of the American Medical Association (1993;269:2282-6) (also may be retrieved at http://www.icmje.org/ ), with the exception that the references must be placed in alphabetic order by author(s) name, numbered sequentially, and appear as superscript numbers in the text but without brackets (see section on "References").

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Randomized controlled trials should follow the CONSORT (Consolidated Standards of Reporting Trials) guidelines ( http://www.consort-statement.org ).

Case reports, case series, cross-sectional and other observational studies should follow the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines ( http://www.strobe-statement.org ). If the detailed methods are explicitly stated in the manuscript for single case studies, STROBE is not needed.

Authors producing systematic reviews and meta-analyses should follow the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines ( http://www.prisma-statement.org ).

Type the manuscript with margins of at least 25 mm (1 inch). Use double-line spacing throughout the entire manuscript, typing in Times New Roman font size 12, **and include continuous line numbering**. Please use Insert Page Break and begin each of the following sections on a new page: Abstract; Introduction; Materials and Methods; Results; Discussion; Conclusion; References; and Figure and Table Legends. **Figures and Tables should be uploaded separately and individually** (see below). Number the pages consecutively in the lower right-hand corner of each page beginning with the Title Page as number 1. Place a six-word short-form/running title in the header space of the manuscript document. The manuscript file must be in a Word format. Manuscripts without continuous line numbering will be returned to the author.

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Please also include on your title page Acknowledgments of those who have contributed to the paper but whose contributions do not justify authorship. They may be named and their contribution described. Such persons must have given their permission to be so named, because readers may infer their endorsement of the data and the conclusions reached. Technical help may also be acknowledged.

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The first text page of observational and experimental articles and review articles should be an abstract of no more than 250 words. This abstract should state the purpose of the study, basic procedures, essential findings, and principal conclusions, and should be formatted into: Hypothesis and/or Background; Methods; Results; and Discussion and/or Conclusion. The abstract should emphasize new and important aspects of the observation or study, but may not contain data that are not presented in the main text.

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For full research articles, include the Level of Evidence of the study performed (see above) and Keywords at the end of the abstract. The authors should assign their own Level of Evidence although this will be reviewed by the *Journal*'s Editorial Staff and should also list 6-8 Keywords that highlight the topic of the article, allowing for easier electronic retrieval.

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The text of observational and experimental articles is divided into 5 sections with the headings: Introduction; Materials and Methods; Results; Discussion; and, Conclusions. Each section should start on a new page. Longer articles may need subheadings within headings to clarify their content. Other articles, such as reviews, case reports and editorials need not take the form of manuscripts describing observational or experimental studies. A case report should include Keywords at the end of the Introduction.

All manuscript texts should be blinded for review purposes. Blind institute location, author initials and references by same authors. To blind an item, use Black Text Highlight Color to black-out the text.

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*Materials and Methods.* Clearly describe the selection of the observational or experimental subject(s). Identify the methods, apparatus, and procedures in sufficient detail to allow others to reproduce the results. Give references to established methods, including statistical methods. Identify precisely all devices or drugs used, including generic names, manufacturers, and manufacturer locations.

Give numbers of observations. Report any losses to observation. Provide details about randomization. Describe statistical methods in enough detail to enable a knowledgeable reader who has access to the original data to verify reported results. Avoid sole reliance on statistical hypothesis testing, such as the use of *P* values, which might fail to convey important quantitative information. Avoid nontechnical uses of technical terms in statistics, such as random or significant. All recent clinical studies should be performed with Institutional Review Board (IRB) approval, and confirmation of IRB approval should be given in this section.

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*Results.* Results should be presented in a logical sequence in the text, illustrations and/or tables. Do not repeat in the text the data presented in tables and illustrations, but emphasize or summarize the important observations. For reports on reconstructive procedures, a minimum 2-year evaluation period is recommended.

*Discussion.* New and important aspects of the study should be emphasized, and conclusions that follow from them should be made. It is not desirable to repeat the data or material given in other sections of the manuscript. The discussion should describe the implications of the findings and their limitations, including suggested future research needs. The observations can be related to relevant studies. Unqualified statements and conclusions incompletely supported by the data should be avoided. Recommendations may be included.

*Conclusions.* A short concluding paragraph summarizing the hypothesis and reason for the study and its results should be included.

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These formats for video will be accepted
• MPEG-1 or MPEG-2 (.mpg)
• QuickTime (.mov)
The *Journal* will not edit any video, but a reviewer may suggest that the author make changes.

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- Include in your CoI statement (second cover letter) a statement confirming that the video is part of your submission and has been viewed by all authors.
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- Sound narration is highly desirable and is requested.

**Units of Measurement**
Measurements of height, length, weight, or volume should be reported in metric units. Temperatures should be given in degrees Celsius; blood pressures should be given in millimeters of mercury. All laboratory measurements should be reported in the metric system.

**Abbreviations**

Only standard abbreviations should be used, and abbreviations should be avoided in the title or abstract. The full term for an abbreviation should precede its first use in the text unless it is a standard unit of measurement.

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UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Department of Orthopaedic Surgery
H49 Old Main Building, Groote Schuur Hospital, Observatory ,7925
Tel: (27 21) 406-6157 Fax: (27 21) 407-2709

**This consent form is for patients undergoing shoulder surgery in beach chair position:**

**Principle investigators:**
Dr S Roche Consultant Orthopaedic Surgeon, Groote Schuur Hospital
Dr PH Naude Registrar Orthopaedic Surgery, Groote Schuur Hospital
Dr B Vrettos Specialist Orthopaedic Surgeon, Vincent Pallotti Hospital
Dr R Dachs Consultant Orthopaedic Surgeon, Groote Schuur Hospital
Dr A Roberts Specialist Anaesthesiologist, Vincent Pallotti Hospital

**Introduction:**

I am Dr PH Naude, I am working as a registrar in the Department Orthopaedic Surgery at Groote Schuur Hospital. We are conducting a clinical trial regarding the positioning of patients during shoulder surgery.

**Purpose:**

We are trying to see whether positioning the patient at less of an angle during surgery may be safer for the oxygen supply to the brain than the traditionally used angle.

**Type of Intervention:**

We will select at random which patients will undergo the surgery at the traditional level and which patients will have the surgery at less of an angle.

**Participant Selection:**

Patients undergoing shoulder surgery planned to be positioned in the beach chair position, will be asked whether they will participate in the study.

**Voluntary Participation:**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change.

**Procedure and Protocol:**

When you present to the hospital for your shoulder operation you will be randomised to either having the surgery in the traditional position or in the lower position. You will not be told to which group you have been randomised.

The procedure used for measuring the blood flow and delivery of oxygen to the brain is non-invasive (ie all external) and therefore carry no risk to the participant. Many hospitals use it as a standard part of their cerebral monitoring.

Your operation will proceed as normal and there will be no difference in the treatment that you will receive.

All complications of the procedure and anaesthetic will treatment according to the normal protocols followed in the unit.

**Contact details:**

If you have any questions regarding the trial please feel free to contact us with any questions:

Dr. S Roche:
H49
Old Main Building
Groote Schuur Hospital
Observatory
7925
Tel: (021)404-5118

Dr. P Naude
H49
Old Main Building
Groote Schuur Hospital
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Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24
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7925
Tel: (021)406-6338
Fax: (021) 406-6411
shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

**This proposal has been reviewed and approved by Research Ethics Committee, which is a committee whose task it is to make sure that research participants are protected from harm.**

## Certificate of Consent:

I have been invited to take part in a clinical trial regarding the positioning of patients for shoulder surgery in the beach chair position. I will be randomized to either having the operation in the normal position or at a 30˚ angle.

I have been informed of all the risks attached to the procedure.

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.**

Print Name of Participant__________________

Signature of Participant ___________________

Date ____________________________
Day/month/year

**If illiterate**
A literate witness must sign
**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

Print name of witness_____________________ AND Thumb print of participant

Signature of witness ______________________

Date _________________________
Day/month/year

**I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

Print Name of Researcher_________________________

Signature of Researcher __________________________

Date ____________________________
Day/month/year
A copy of this Informed Consent Form has been provided to participant

# Beach-chair study

Patient sticker

Baseline pressure: (include mean)

Baseline pressure after pre-induction opiate administration:

Baseline INVOS: (positioned on beach-chair and breathing room air):

Baseline mean – 20%:

INVOS %

Interventions:

1. Vasopressor: E= Ephedrine; P= Phenyephrine; A= Adrenaline
2. Positioning change: ↓ or ↑

**PROTOCOL**

# Prospective study to compare the difference in cerebral perfusion with the standard beach chair position compared to 30˚ inclination

Investigators: Dr P Naude (Principal), Dr S Roche, Dr B Vrettos, Dr R Dachs, Dr F Montoya
Department of Orthopaedic Surgery
University of Cape Town
Groote Schuur Hospital
Vincent Palloti Hospital

**Introduction and aim of study**

The traditional beach chair position used widely during shoulder surgery is currently under much debate. There is evidence that shows that this position leads to cerebral desaturation which may lead to devastating neurological events.

Previous research have shown that patients undergoing surgery with their head in an elevated position may suffer cerebral desaturation events (CDE's), where their cerebral oxygenation levels drop by more than 20%. It is believed that this may place patients at risk for ischaemic neurological events.

Previous research have shown that it placing a patient in the beach chair position leads to decreases in cerebral perfusion pressure due to the hydrostatic pressure gradient created by elevating the brain relative to the heart. Furthermore, the fact that general anaesthesia blunts cerebral autoregulation places patients at even greater risk of developing neurological complications when undergoing shoulder surgery

This sparked our interest in the safety of the practice of placing patient in the beach chair position with their heads elevated. Previous studies all used angles of inclination of 70˚ or more. This angle is significantly more than the angle we normally use when positioning a patient.

The aim of the study is assess the impact of lowering the head up position to 30˚ on the number of cerebral desaturation events experienced during general anaesthesia.

**Relevance of the study**

The safety of the beach chair position is currently under question. During the last 10 years there have been case reports of patients suffering devastating neurological complications following surgery in the beach chair position.

This have led to an increased interest into the pathophysiology of these complications, and possible ways to decrease the risk to patients. Previous research have shown that placing a patient in the lateral position leads to significantly fewer CDE's when compared to the beach chair position.

However, there are several advantages to placing a patient in the beach chair position. These advantages include ease of setup, excellent intra-articular visualization for all types of arthroscopic shoulder procedures, and ease of conversion to the open approach if needed.

Proving that decreasing the amount of inclination used during the beach chair position may improve cerebral perfusion will be of great value during shoulder surgery. This will allow surgeons to continue using the beach chair position but with less risk to the patient.

**Study hypothesis**

We hypothesise that decreasing the amount of inclination used in the beach chair position to 30˚ will lead to a decrease in cerebral desaturation events.

**Study population**

The study will consist of 50 consecutive patients undergoing elective shoulder procedures in the beach chair position.

**Study design**

Prospective, single-blind, randomised trial.

**Study method**

A prospective comparison of patients undergoing shoulder surgery, comparing the number of cerebral desaturation events during procedures performed in the traditional beach char position compared to procedures with the patient placed at 30˚ head up.

Measured parameters:

1. Cerebral oxygenation
2. Mean arterial pressure

Record of all interventions to maintain mean arterial pressure and cerebral tissue oxygenation will be kept.

**Analysis of the study**

During analysis of the results we will be looking at the following points:

- Number of cerebral desaturation events (decreases in cerebral oxygenation levels by >20% from baseline)
- Interventions for decreases in maintain mean arterial pressure
- Number of interventions for decreases cerebral oxygenation levels
- Number of times an absolute cerebral oxygenation level <55% is measured

**Report of findings**

Results will be submitted for publication in a peer reviewed journal. Results will also be discussed at national or international orthopaedic conferences and research or faculty meetings.

**Ethical considerations**

The patients that will be enrolled in the study will be informed of the nature of the study. Subjects enrolled in the study will not be placed at an increased risk when compared to the risks that is inherent to performing surgery in the beach chair position.

The control group of patients in our study will be placed at the angle that is normally used in our unit. This angle of inclination theoretically place them at more risk than the lower angle that will be employed for the patients in the intervention group of the study.

**References**


1. Skyhar MJ, Altchek D, Warren R, Wickiewicz T, O'Brien SJ. Shoulder arthroscopy with the patient in the beach-chair position. Arthroscopy 1988;4:256-9.
2. Koh JL, Levin SD, Chehab EL, Murphy GS. Cerebral oxygenation in the beach chair position: a prospective study on the effect of general anesthesia comparedwith regional anesthesia and sedation. J Shoulder Elbow Surg. 2013; 22 (10): 1325-1331.
3. Murphy GS, Szokol JW, Marymont JH, Greenberg SB, Avram MJ, Vender JS, et al. Cerebral oxygen desaturation events assessed by near-infrared spectroscopy during shoulder arthroscopy in the beach chair and lateral decubitus positions. Anesth Analg 2010;11(1):496-505.
4. Bhatti MT, Enneking FK. Visual loss and ophthalmoplegia after shoulder surgery. Anesth Analg. 2003;96:899-902.
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**Faculty of Health Sciences**
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**Email:** shuretta.thomas@uct.ac.za
**Website:** http://www.health.uct.ac.za/fhs/research/humanethics/forms

30 May 2014

**HREC REF: 179/2014**

**Dr S Roche**
Orthopaedic Surgery
H49, OMB

Dear Dr Roche

**PROJECT TITLE:** ***PROSPECTIVE STUDY TO COMPARE THE DIFFERENCE IN CEREBRAL PERFUSION WITH THE STANDARD BEACH CHAIR POSITION COMPARED TO 45° INCLINATION (MMED - Dr Petrus Naude)***

Thank you for your response to the Faculty of Health Sciences Human Research Ethics Committee dated 30 May 2014.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

**Approval is granted for one year until the 30th June 2015**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

**We acknowledge that the MMED student, Dr Petrus Naude is also involved in this study.**

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC reference no in all your correspondence.

Yours sincerely

**PROFESSOR M BLOCKMAN**
**CHAIRPERSON, FHS HUMAN ETHICS**
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

HREC 179/2014

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**FACULTY OF HEALTH SCIENCES**
Human Research Ethics Committee

# Form FHS006: Protocol Amendment

| **HREC office use only (FWA00001637; IRB00001938)** | | |
|---|---|---|
| ☑ Approved | ☑ Type of review: Expedited | ☐ Full committee |
| This serves as notification that all changes and documentation described below are approved. | | |
| Signature Chairperson of the HREC | Date | 8/7/15 |

**Note:** All major amendments should include a **PI Synopsis** justifying the changes for the amendment (please see notice dated 23 April 2012)

### Principal Investigator to complete the following:

### 1. Protocol information

| | |
|---|---|
| Date (when submitting this form) | 22/06/2015 |
| HREC REF Number | HREC/REF: 179/2014 |
| Protocol title | Prospective study to compare the difference in cerebral perfusion with standard beach chair and 45° inclination |
| Protocol number (if applicable) | |
| Principal Investigator | Petrus Naudé |
| Department / Office Internal Mail Address | Dept. Orthopaedic surgery |

| | | |
|---|---|---|
| 1.1 Is this a major or a minor amendment? (see FHS006hlp) Major (tick box) Minor (tick box) | ☐ Major | ☑ Minor |
| 1.2 Does this protocol receive US Federal funding? | ☐ Yes | ☑ No |
| 1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval? | ☐ Yes | ☐ No |

### 2. List of Proposed Amendments with Revised Version Numbers and Dates

**Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.**
This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.

- We want to decrease the study angle of inclination from 45° to 30° because most of our standard procedures are performed around 45°
- We ~~want to include a group in the lateral decubitus position just for comparison~~ without ~~changing their~~ position