Positioning and Thermoregulation of Surgical Patients

Volume I

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Executive Summary

There are over 45 million surgeries performed under general anesthesia in the United States each year. The majority of these surgeries require advanced heating and positioning techniques. Properly positioning a patient entails leaving access to the surgical site, IVs, and other tubes, while keeping the patient secure on the operating-room table. Improperly positioning the patient can lead to pressure sores, nerve injury, blood clots, and even vision loss. The lateral position, in which a patient is on his or her side, is a particularly difficult position to maintain. Preventing an immobile, anesthetized patient from tipping requires bulky positioning elements. In addition to the challenge of positioning a patient, it is also difficult to keep a patient’s core body temperature between the desired 36-38°C range. A typical operating room is about 20°C, and general anesthesia accelerates temperature loss from a patient. Without supplemental warming in this environment, a patient’s core body temperature would quickly drop below 35°C to a hypothermic state. This leads to increased rates of blood clots, wound infection, and also cardiac arrest.

Positioning elements limit the surface area on the patient available for heating. The bulkier the positioning elements and the larger the surgical site, the less space there is to actually warm the patient. To overcome this problem, the design team’s concept (shown in the figure on the right) combines the positioning and heating elements into one device. This results in a significantly larger patient surface area used to warm the patient. The design uses an airtight beanbag to position the patient. By removing air, the beanbag becomes rigid in its current configuration and remains that way until air is re-added. In this way, a patient is held on his or her side in the lateral position. There are 8 electrical resistance heating elements directly beneath the outer layer of the beanbag. The heating elements are placed on top of a layer of foam to protect them from excessive strain due to beanbag folding and to provide a more even pressure distribution for the patient. Each heating element’s temperature is measured with a thermistor and controlled to keep the surface temperature of the device below 42°C for patient safety. As soon as an individual heating element reaches 42°C, it is shut off until its temperature drops below 42°C.

Meanwhile, the other heating elements will continue warming until the patient core temperature set-point temperature is reached. The anesthesiology team selects and can vary the set-point temperature for each patient.

To evaluate the efficacy of the design, a series of tests were conducted. Using a torque versus deflection curve, positioning effectiveness of the foam-beanbag device was found to be equivalent to a standard surgical beanbag (deflecting only an additional 1.8mm over a 90N range). To test ease of use, a panel of medical experts were surveyed and found the device to be as easy to use as a surgical beanbag used in conjunction with a Bair Hugger, the current standard for patient warming. The ability keep the device below 42°C required knowing the temperature profile of the electrical resistance heating elements, in order to choose the thermistor location and number of heating elements. This was done using an infrared camera. The experiment showed that smaller elements have more even heating, especially when wrapped in foil; however, that there is a balance to be struck between the number and cost of resistive heating elements and the complexity and cost of the control system for the elements. As a result, 8 resistance heating elements are recommended. The rate of heat transfer of the device was also measured to confirm that a patient may be sufficiently heated to prevent hypothermia. The heat loss from a patient in surgery was calculated to be 90W at maximum. The rate of heat transfer of the prototype (which uses a single, smaller heating element) was found to be 40W. By extrapolating this result to eight larger heating elements, it was found that the patient will be sufficiently heated to prevent hypothermia.
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3.1 Problem Scope

During surgery it is necessary to both maintain the patient’s body temperature as well as position the patient. While under general anesthesia the body loses its normal ability to regulate temperature. Consequently, it is necessary to warm the patient to prevent hypothermia. Proper positioning allows for appropriate surgical access and ensures patient safety. Various devices exist that help to either position or warm the patient, but no single device currently does both. Moreover, current methods of positioning and warming often come into conflict. Warming devices cannot be applied to areas of the patient’s body that have been covered by positioning devices. This results in less available surface area for warming and makes it very challenging to keep the patient sufficiently warm. It would be beneficial to have a device that incorporates both positioning and warming of the patient. The design team has developed a device that is capable of supporting a patient on the operating table in the lateral position as well as providing near circumferential warming.

3.2 Technical Review

Background

According to the Centers for Disease Control and Prevention, there are 48 million inpatient surgeries in the US each year [1]. Every surgical operation requires placing a patient in a position suitable for that particular operation. For instance, the surgical team usually places a patient in the supine, or face up, position for many chest, abdomen, and limb surgeries. The prone, or face down, position is often used for back and ankle surgeries. Surgeons select the patient’s position to provide the best surgical access and to minimize potential harm to that patient. All surgical positions involve risk for a patient. Patient weight may be centered on a few points touching the operating table. This will create pressure points which could cause pressure sores or nerve damage [2, 3].

The lateral position (Figure 1) involves placing a patient on his or her side. The patient begins on the operating table in the supine position and is then rotated onto his or her side by the surgical team. The head is aligned with the spine to prevent any stress on the neck. A gel pillow or other device is placed beneath the head to ensure proper alignment. The dependent arm—the one against the operating table—is placed in front of the patient on an arm board at less than a 90° angle between the arm and chest to prevent shoulder stress. The non-dependent arm—the one off the operating table—is placed...
on top of the dependent arm with pillows between them. The arms are then secured to the arm board with straps or tape. Note that the definitions of ‘dependent’ and ‘non-dependent’ apply to other body parts as well.

An axillary pad is placed just below the dependent arm to alleviate pressure on the dependent shoulder to protect the brachial plexus nerve bundle running from the neck, through the armpit area, and into the arm [5]. The torso is stabilized with a beanbag, sand bag, pillows, or other similar device. The dependent leg is extended and the non-dependent leg is extended and slightly flexed with a pillow placed between the knees. The ankles and feet are padded along with any bony prominences to prevent pressure injuries. Tape is used to secure the shoulders and thighs to the operating table [6].

There are a number of risks associated with the lateral position. The dependent eye is in danger of corneal abrasions and vision loss. Pressure on the eye and intraoperative hypotension (lower blood pressure during surgery) lead to an increased incidence of retinal artery thrombosis, or blood clots in the retinal artery, which may cause vision loss. Nerve injuries due to increased localized pressure on nerves can also occur. The axillary pad and proper head alignment aim to protect the brachial plexus and suprascapular nerves. Padding the patient’s legs protects the patient’s common peroneal and saphenous nerves.

The axillary pad also helps with perfusion—the movement of blood throughout the body. Venous hypertension (increased blood pressure) in the dependent arm is less likely to occur when the axillary pad slightly elevates the upper torso. The pad also helps with ventilation—the movement of air into the lungs. The additional weight on the dependent lung makes ventilation less effective and increases perfusion in the dependent lung. Atelectasis or collapse of the dependent lung may even occur. The chance of fluid accumulation in the dependent lung is also elevated [7]. To avoid these risks, careful attention to all aspects of patient positioning in the lateral position is critical.

In addition to the importance of patient positioning, maintaining patient body temperature is also significant. The average operating room temperature is between 20° C and 23° C, but surgeons prefer the temperature at or below 21° C for their own comfort [8]. As a result, the operating room is relatively cold for a mostly unclothed patient. For the average sedentary person in a 20° C room to be thermally comfortable, the person would need to wear a light vest with a long sleeve shirt, trousers, undergarments, socks and shoes [9]. Placing a blanket over a patient in the operating room is not sufficient to keep a patient from losing heat.

The problem of temperature regulation is complicated by anesthetics. The body has natural defense mechanisms against becoming too hot or cold. If the body temperature rises above 37° C, sweating and vasodilation of the blood vessels occur. Both processes remove heat from the body, to cool it back to 37° C. If the body temperature drops below 37° C, the opposite processes occur: sweating is inhibited and vasoconstriction takes place. As soon as anesthetics are introduced into the body, these defense mechanisms are partially disabled. The degree to which they are disabled depends upon the amount of anesthetics introduced as well as factors like age, sex, and body type [10].
With the temperature regulation defense mechanisms disabled, hypothermia becomes a risk. Hypothermia occurs when the body temperature drops below 35.0° C. As the body temperature drops and a person becomes mildly hypothermic, a person’s blood pressure, heart rate, and breathing increase, and blood vessels constrict. As body temperature continues to fall, hypothermia becomes moderate and skin surfaces appear pale or blue as less blood is perfused. Finally, severe hypothermia leads to decreased heart rate and blood pressure, organ failure, and death [10]. Becoming even mildly hypothermic in the operating room may have negative consequences. There is an increased risk of blood clots in a patient during surgery. After surgery, the likelihood of heart attacks and wound infections is also greater [11]. For these reasons, it is very important to maintain a patient’s normal body temperature during surgery; and a warming device is required to maintain this normal body temperature.

**Prior Art**

There are no devices currently on the market which simultaneously provide heating and positioning capabilities; here positioning devices and heating devices will be discussed separately.

**Heating Devices**

There are multiple devices that can be used to warm a patient in an operating room. These include active heating through convection and conduction as well as passive warming which is meant to insulate the patient and prevent further heat losses. A common warming method used in many hospitals throughout the United States is forced-air convection.

The Bair Hugger and Bair Paws systems (US Patent Number 8105370) are products that use forced-air convection. This system uses a pump to blow warm air through a flexible hose and into a gown worn by the patient. There is a variety of gown configurations available which can either cover the entire patient, or specific portions of the body which are meant to be warmed during surgery. An example of the lateral configuration for the lower body of the Bair Hugger is shown below in Figure 2.

![Figure 2: Lateral Positioning of the Bair Hugger System](image-url)
From Figure 2, the patient’s lower body is warmed while the upper body is exposed, allowing for proper surgical access in the lateral position. The air heater for this device has a confined temperature range and variation which is shown in Table 1.

### Table 1: Bair System Operating Temperatures

<table>
<thead>
<tr>
<th></th>
<th>Bair Hugger</th>
<th>Bair Paw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model 505</td>
<td>32 to 43</td>
<td>Ambient to 40</td>
</tr>
<tr>
<td>Model 750</td>
<td>32 to 43</td>
<td>± 1.5</td>
</tr>
<tr>
<td>Model 850</td>
<td>32 to 43</td>
<td>± 3</td>
</tr>
<tr>
<td>Temperature Range (°C)</td>
<td>32 to 43</td>
<td>Ambient to 40</td>
</tr>
<tr>
<td>Variation (°C)</td>
<td>± 3</td>
<td>± 3</td>
</tr>
</tbody>
</table>

As can be seen from the temperature ranges of the Bair Hugger and Pair Paw systems, the Bair Hugger has a higher heating capability. The Bair Paw is used to maintain a patient’s body temperature (of 37°C) whereas the Bair Hugger is used to warm the patient as well as maintain his or her body temperature. The temperature variation of each device is also important as a certain set point temperature may not be maintained. If the temperature is too low there will be inadequate heating of a hypothermic patient; if the temperature is too high, overheating of the patient may occur which can cause burns [12,13].

There are both advantages and disadvantages when using a forced-air warming device. The Bair Paws heater allows for a portable heater to be brought along with the patient and keeps the patient warm both before and after an operation. When transitioning into the operating room, the same gown may be used for both systems. Once in the operating room, the concern shifts to being able to warm the patient, thus a more powerful heater is used – the Bair Hugger. Since the mode of heat transfer is through air warming however, the device will not heat the patient if there is no room for air to contact the skin, such as if a positioning device is pressed against the skin, or the portion of the patient that is in contact with the operating table. Finally, air is a poor conductor for heat transfer.

In addition to forced air convection, conduction is also used to warm a patient. Such a device is the HotDog Patient Warming device (US Patent Number 7851729). For this system, a reusable conductive warming blanket using electrical-resistance heating is used to warm the patient. As with the Bair system, the patient may be warmed with different blanket configurations which cover different portions of the body. Figure 3 shows a lower configuration in the supine position and upper body configuration in the lateral position for the HotDog system.
This electric-resistance warming system allows for proper access to specific surgical sites in the supine and lateral positions while providing warming to the patient. This device also has temperature ranges and variations as shown in Table 2 below.

<table>
<thead>
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<th>Table 2: HotDog Operating Temperatures</th>
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<tr>
<td>Model WC0x</td>
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<tr>
<td>------------</td>
</tr>
<tr>
<td>Overall</td>
</tr>
<tr>
<td>Temperature Range (°C)</td>
</tr>
<tr>
<td>Variation(°C)</td>
</tr>
</tbody>
</table>

As seen in Table 2, the HotDog warming system has temperature ranges similar to that of the air heater. Note that for model WC5x, it shows two sets temperature ranges and variations. This particular model has options for both a mattress pad for below the patient as well as a blanket to cover the patient. The temperature range for the mattress is decreased to reduce the risk of burns since the patient will be putting pressure on the heating element for the duration of a surgery [14]. Again, there are both advantages and disadvantages when using an electric-resistance warming device. Conduction is a better mode of heat transfer, which will allow heat to transfer directly into the body. Unlike the air-warming system, the patient may be heated on the lower portion of their body and from the top, with anything in between being heated through natural convection. While this may be a more effective heating method, it may also pose an increased risk of burns due to the direct heating of the skin.

A third option for heating is using a device similar to the Ranger Blood/Fluid Warming System (US Patent Number 6464666). This warming system uses conductive heating through aluminum plates to warm blood and other intravenous fluids. These fluids may then be administered into the body to internally warm a patient. A diagram of the device is shown in Figure 4.
Problem Definition

This device allows for internal warming of the patient through their bodily fluids which can allow for a more rapid way of heating the patient compared to surface warming as with the Bair or HotDog systems. Since the heart has been slowed down due to anesthesia however, the warming process may be slower due to decreased blood flow. In addition, using this system adds to the amount of intravenous lines coming from the body which may complicate a surgical procedure [15].

Positioning Devices

Positioning devices that are commonly used in the operating room include blankets, pillows, straps and gel pads. These devices serve to both secure the patient from falling off the table, as well as to reduce the risk of pressure point injuries on a patient’s body. An example of a common positioning method was shown in Figure 1. The patient’s arms are supported by folded blankets in between the arms as well as a strap which secures everything to the table. The patient’s upper body is supported by a beanbag which molds to the body to prevent tipping, and another strap. Finally, the legs are spaced by a pillow (an additional strap could have been included to secure them to the table). The straps, pillows, and blankets are relatively generic and straight-forward; the beanbag is more complex and is described below.

The beanbag is used for positioning to prevent patients from tipping or falling off the operating table. A typical beanbag is represented by the Olympic Vac-Pac as shown in Figure 5.
The Vac-Pac is filled with plastic beads which allows for the device to mold around the patient. A vacuum hose is then used to remove the air from the beanbag, causing the beanbag to become rigid. If repositioning is required, or after the surgery has been completed, opening the valve will increase the pressure inside the bag and make it soft again [16].

The beanbag has advantages and disadvantages. The design itself is simple and easy to use while providing stability for the patient. Furthermore, since the beanbag molds to the patient’s body it reduces the danger of pressure point related injuries. The beanbag design does not allow for positioning of the head as there needs to be access to the facial area.

Foam and gel positioning devices are also available, a variety of which are shown in Figure 6.

These positioning devices are designed strictly for reducing the pressure points between limbs or from the table [17,18].

Another device that may be used for positioning is the hipGRIP (US Patent Number 6298507). This device allows for lateral positioning using braces to prevent the patient from tipping over. The device is shown in Figure 7.
3-Problem Definition

This device would allow for access to many portions of the body while effectively constraining the patient’s upper body. In addition, other devices are sold (the legGRIP) which constrains the legs. This device however does not constrain the head or arms [19].

From this overview of heating and positioning devices which are currently available, it is clear that there are many devices which can provide heating, or provide positioning of a patient. To understand which options would be effective to combine into a single device, the design requirements need to be determined.

3.3 Design Requirements

1. Safety:
The product must be safe to use on an unconscious patient. If a patient suffers burns or other injuries during the surgery it will slow his or her recovery as well as leave the hospital vulnerable to a lawsuit. In order to prevent burns, the temperature of the heating element must be well-controlled such that it never exceeds 42°C. The device should provide stability while the patient is in a lateral position. There should be little risk of the patient falling off the table when the device is used in conjunction with the current practice of securing the torso with straps or tape. Additionally, the device must not position the patient in a manner that would cause pressure ulcers or nerve injuries.

2. Effective Warming:
The device must provide enough heat to replace that lost by vasodilatation while the unclothed patient is under general anesthetic in a cool (20-23 °C) operating room. The approximate maximum rate of heat loss is 90W. If the device cannot compensate for this heat loss, the patient
may become hypothermic and the risk of complications increases. The device must maintain the patient’s body temperature at or above 36 degrees Celsius.

3. Effective Positioning:
The device must be able to secure the patient in the lateral position. It must allow access to the area of the body that is being operated on and must not interfere with IVs and monitoring devices that are attached to the patient. Additionally, the patient’s breathing tube must be visible and accessible while the device is in use.

4. Ease of Use:
The device must be easy for surgical staff to use. It must be light enough to be easily picked up and transported. After setup, the device should keep the patient warm with little or no effort by the surgical staff. Surgical staff is more likely to be comfortable using the device if it is similar to technology already in use.

4.1 Summary of the Design
The proposed design is a surgical positioning beanbag with integrated resistive heating elements. The beanbag may be wrapped around the torso of a patient in the lateral decubitus position. When the air is evacuated the bag becomes rigid and secures the patient in place. A feedback control system controls the heating element. The anesthesiologist may set a value for the desired core temperature of the patient, and the control system will use information from a patient temperature probe to determine how much power to send to the heating element. Additional sensors embedded in the device monitor the device surface temperature to ensure it does not reach a temperature that might cause burns. A disposable cover allows for easy cleaning.

4.2 Detailed Design Description
The device has two main functions: positioning and heating. An airtight beanbag provides lateral stability. A vacuum line attached to a valve in the beanbag is used to evacuate air in order to make the beanbag rigid. After surgery, the valve is opened by hand, refilling the beanbag with air to make it flexible again. Heating is accomplished using electrical resistance heating elements and a feedback control system. In the control system, core patient temperature is compared with a user-specified set point (ideal patient temperature) to determine the amount of energy which must be provided to the patient. A thin, flexible layer of pyrolytic graphite is on top of the heating elements to more evenly distribute the heat. An array of sensors is used to measure the temperature of the heater and this is compared to the maximum temperature allowed (to prevent patient burns). This temperature difference determines the rate at which heat may be added to the patient. Using the amount and rate calculations, the control system activates the heater to warm up the patient to the set point as quickly as possible. The disposable cover is made of plastic and prevents the device from being contaminated. A flap of thermally reflective mylar is attached to the cover and can be folded over the patient to prevent heat loss.
4.2.1 Functional Block Diagram

![Functional Block Diagram](image)

Figure 8: Functional Block Diagram

4.2.2 Functional Description

**Positioning:**

To provide lateral stability to a patient, air must be evacuated from the beanbag portion of the device. Urethane was selected to provide an airtight shell around the beanbag beads. Virgin polystyrene was used for nearly spherical and uniform beads with 3.2 mm diameter. A rubber valve that fits standard hospital vacuum lines was chosen for air removal and addition to the beanbag. When a vacuum is applied to the valve for a few seconds, air is removed from the beanbag, and the structure becomes rigid. To soften the beanbag at the conclusion of a surgery, the valve is squeezed by hand, and air quickly re-enters.

**Warming:**

Feedback Control System:

The feedback control system takes the signal from the temperature set point sensor, the patient core temperature sensor, and the surface temperature threshold sensors as input. The feedback control system outputs the value of the current required to warm the patient. The control system uses the temperature set point as the target value for the system. It compares the patient core
temperature to the set point and uses the error to adjust the current output to the warming device. The surface temperature threshold modulates the rate of heat transfer because this value is the highest allowable surface temperature of the device. All of these signal inputs, along with the electrical energy are used to calculate the power required in the device. The feedback control system then allows this power into the device.

**Sense Set Point**
The set point sensor reads the desired core temperature of the patient, as set by the surgical staff through an interface on the device. The staff can select from a range of temperatures. This value is sensed and sent to the feedback control system.

**Sense Surface Temperature Threshold**
The threshold value is set internally to 42°C, and is not adjustable. This is the maximum allowed value of the device surface temperature. It is set at 42°C to prevent patient burns. If this temperature is reached the feedback control system will reduce the heat being produced to ensure safe operation.

**Accept External Energy**
This is a variable power source that accepts power from the wall (120V AC) and uses the output from the control system to send the correct amount of current into the device.

**Sense Current Overload**
The current overload sensor detects an over draw of current into the resistance heating elements. If there is too much current into the heating elements the circuit switches off, which will prevent excess current from heating the patient to the point of causing skin damage. This is a fail-safe mechanism that will only trip if the other safety mechanisms built into the control system malfunction and allow for too much current. This current sensor will be factory set to a maximum current value such that burn risk is minimized.

**Converts Energy to Heat**
This block represents the electrical resistance heating element. The energy that has been passed to the element from the external energy source is converted to heat here, resulting in a warmed patient. It utilizes high resistivity wires in a flat pad to accomplish this task.
4.2.3 Overview Drawings

Figure 9 depicts the positioning function; Figure 10 shows the heating function.

Figure 9: Positioning function of the device
4.3 Additional Uses

The device is designed to be used by surgical and anesthesia staff for positioning and warming patients during surgery. It may also be used for surgical positions other than the lateral decubitus position. Additionally, the device has potential for other functions. The device allows for rigid conformation as well as heating of the body, or anything that it is wrapped around. There are a few concepts which could utilize both of these functions. For example, an alteration to a typical beanbag chair may be applied, thus allowing for a form fitting chair that also heats the user. Another use may be for a special type of cast which for those who have a broken or sprained limb that allows protection as well as heating of the affected area. A final application may incorporate the two qualities into a device used when shipping an item which must remain warm, thus allowing for the item to remain safe and warmed during the shipping process.
5-Design Evaluation

5.1 Evaluation Plan
A brief description of the design evaluation methods is shown in Table 3. For a more detailed description, refer to the evaluation reports in Volume II, section 3.1 of the design report.

Table 3: Evaluation Plan

<table>
<thead>
<tr>
<th>Design Requirements</th>
<th>Evaluation Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>To ensure the surface temperature of the device can be well-controlled, an IR camera was used to image the temperature profile of the prototype device.</td>
</tr>
<tr>
<td>Effective Warming</td>
<td>To determine if the device can provide enough heat to compensate for heat lost under general anesthesia, the heat transfer rate of the prototype device was measured.</td>
</tr>
<tr>
<td>Effective Positioning</td>
<td>The addition of the foam layer must not be detrimental to the device’s ability to position a patient. A force deflection curve was created to compare the design with a standard surgical beanbag.</td>
</tr>
<tr>
<td>Ease of Use</td>
<td>A panel of clinicians was asked to qualitatively evaluate the design’s ease of use relative to the standard beanbag used in conjunction with a Bair Hugger.</td>
</tr>
</tbody>
</table>

5.2 Evaluation Results

Safety
This experiment utilizes an infrared camera to analyze and view an 8” by 8” and a 2” by 2” square electrical resistance thin film heater both with and without a layer of aluminum foil to better distribute the heat. The final design features eight heating elements of this type arranged under the surface of the device. The camera was used to check for hot spots on the heater to determine where thermocouples should be placed to accurately measure maximum surface temperatures. The heater was controlled at various input voltages, from 1-30V. The camera, while not calibrated, gave an accurate representation of the temperature profile on the surface of the heater. The temperature differences between the hot and cold spots were determined to be improved by the addition of the aluminum foil. Based on the results of this experiment, and a cost analysis of the heating elements it is suggested to use 8 heating elements for the final design.

Effective Warming
As a device that heats a patient during surgery, it is important to understand how much energy the heater provides. An experiment was performed to determine if the design team’s concept would provide enough heat to warm a patient. The experiment used a setup that simulated the
final design. The heat loss from a patient in surgery was calculated to be 90W at maximum. The rate of heat transfer of the prototype (which uses a single, smaller heating element) was found to be 40W. The results from this experiment show that by using this device, when scaled up to full size, a patient may be sufficiently heated to prevent hypothermia.

**Effective Positioning**
A surgical positioning device for a patient in the lateral position must support the patient in the lateral position with minimal lateral deflection, as the patient’s weight shifts slightly. Surgical beanbags are a current standard for maintaining patients in the lateral position. Adding a layer of memory foam on top of a surgical beanbag could affect the overall lateral stability provided by the combined foam-beanbag device. Through an experiment comparing the deflection of a surgical beanbag due to an external force with the deflection of the combined foam-beanbag device, it was demonstrated that the device deflected at most 1.8mm beyond the deflection of the surgical beanbag alone. This result implied that the foam-beanbag device is as effective at positioning a patient as the surgical beanbag.

**Ease of Use**
The device must be user-friendly and intuitive for surgical staff to use. A survey was conducted on a small panel of doctors in order to ascertain the concept’s ease of use and to acquire feedback on the concept. Respondents were asked to evaluate the device relative to the standard beanbag used in conjunction with a Bair Hugger. On a scale of 1-5, with 3 being comparable to standard practices, the concept averaged a 3.25 in terms of ease of use, indicating that the concept was as easy to use as the Bair Hugger and beanbag combination in general.

**5.3 Discussion**

**5.3.1 Strengths and Weaknesses**
The results of the positioning test indicate that the added layer of foam is not detrimental to the positioning effectiveness of the device. The design is comparable to the ordinary surgical beanbag and is effective for positioning patients.

In the effective warming test, the small prototype which contains an 8’’ x8’’ heating element outputs 40W. When scaled up to the full size, this is more than enough energy to replace that lost by an average sized patient during surgery (approximately 90 W). It might be possible to use heating element that are less powerful to achieve the required heat transfer rate.

The temperature distribution of the prototype heating element was not as uniform as was anticipated. This makes it more difficult to ensure that the surface temperature of the device does not exceed 42°C. The addition of a thermally conductive layer of pyrolytic graphite will help to mitigate this problem.
5.3.2 Next Steps

The next step in the project is to construct a full-scale prototype with eight heating elements and two thermistors per heating element. Figure 11 shows the general layout for the heating elements and thermistors. Thought must be given to the method of attaching the thermistors to the heater or urethane cover. Also, the method of attachment of the heating elements to the urethane must be finalized. It may become necessary to add a thin layer of foam on top of the heater to prevent the thermistors from protruding into the urethane layer.

It would be preferable to add the thermistors to the underside of the heating element, if adding them there can still guarantee a safe surface temperature of the device. The effective positioning, temperature distribution and effective heating tests should then be rerun to verify operation of the full-scale device within the design parameters. The experimental thermal results should be compared with the ANSYS model to verify its accuracy. When the ANSYS model corresponds closely with the full-scale prototype, optimization of the design geometry may be carried out as needed.

![Diagram of heating element and thermistor layout](image)

Figure 11: Top view of heating element and thermistor layout

Components for the full circuit must still be selected and the circuit constructed and tested. Also, more thought should be given to the general packaging of the circuitry and layout of the operator interface. Finally, the attachment mechanism for the disposable blanket must still be designed and the heat-retaining capacity of the blanket tested. If the device does little to retain patient heat, different thermo-reflective materials should be tested.
References


