ORIGINAL ARTICLE

Development of the Pelvic and Lower Limb Immobilization Device: A Universiti Kebangsaan Malaysia (UKM) Innovation Project

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ABSTRAK

Pendarahan tidak terkawal yang disebabkan kepatahan tulang pelvis menyumbang kepada morbiditi dan mortaliti berkaitan trauma. Tiga strategi utama yang telah digariskan untuk merawat keadaan ini adalah mengurangkan isipadu ruang pelvis dengan mewujudkan kesan tamponade, menghentikan pendarahan melalui kaedah angioembolisasi keatas salur darah besar, dan penstabilan tulang pelvis melalui fiksator luaran. Ini haruslah dimulakan seawal mungkin. Alatan prahospital yang mampu membenarkan kaedah diatas dilaksanakan akan banyak membantu didalam perawatan pesakit yang mengalami keadaan ini. Buat masa ini kebanyakan alatan atau kaedah yang digunakan di prahospital mempunyai keistimewaan mereka tersendiri namun tidak kurang juga terdapat beberapa kekangan. Bagi mengatasi masalah ini, satu senarai semak yang mengandungi ciri-ciri alatan yang sempurna telah dibangunkan. Sepasukan penyelidik dari Universiti Kebangsaan Malaysia (UKM) telah menyahut cabaran untuk merangka dan membina alatan perubatan berpandukan ciri-ciri tersebut. Projek dua fasa selama tujuh tahun telah dilaksanakan melibatkan kajian anthropometrik, biomekanikal, kadaver dan radiologikal dalam menghasilkan alatan yang diperlukan. Akhirnya BRIM™ Immobilizer, sebuah alatan perubatan yang mengimobilisasi pelvis dan anggota bawah terhasil. Ianya satu alat yang mesra pengguna, tahan lasak, kos efektif, lut sinar-x, ringan, dan boleh diguna-semula yang menjawab hampir seluruh persoalan alatan yang diperlukan untuk rawatan.

Kata kunci: pelvic binder, BRIM immobilizer, kecederaan pelvis, rawatan pra-hospital

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ABSTRACT

Uncontrolled bleeding due to pelvic fractures contributes to trauma-related morbidity and mortality. Three main strategies that have been outlined to combat this condition which include reduction of pelvic volume that lead to tamponade-like effect, arresting haemorrhage through angioembolization of the major vessels, and stabilization of the pelvic bone with external fixation need to be initiated early. A prehospital device that allow these strategies will aid significantly in the management of the patient. At present most devices used to treat pelvic fractures in the pre-hospital setting do have its' own advantages but also have some limitations. A characteristic 'wish-list' of a good pelvic and lower limb immobilization device was created and the research team from UKM takes the challenge to design and produce a device that concurs to it. A two phase development project that incorporate anthropometric, biomechanical, cadaveric and radiological study was carried out over a period of seven years. Finally, BRIM™ immobilizer, a new pelvic and lower limb immobilization device that is user friendly, tough, cost effective, radiolucent, light and reusable that answers most of the requirement of a good device was invented.

Key words: pelvic binder, BRIM immobilizer, pelvic trauma, pre-hospital care

INTRODUCTION

Trauma is the global leading cause of death in the first four decades of life (ACS 2008). Uncontrolled bleeding was the major cause of trauma-related morbidity and mortality, mainly from skeletal, intra-abdominal or intra-pelvic injuries due to blunt trauma (Trikha 2011). It has been reported that up to 20% of multiple injured patients sustained pelvic injury (McCormack 2010).

Severe pelvic injuries even though not common remains one of the most difficult clinical problems in terms of its management (Flint 2010). The mortality rates from all types of pelvic-related injuries have been reported between six to 17% (Pohlemann 1994). It was reported that pelvic fractures accounts for approximately three percent of all skeletal injuries (Brenneman 1997; Ertel 2001; Rommens 2002; Tucker 2000). In Malaysia, of more than 300,000 reported accident cases yearly, 1.55% was associated with pelvic fracture (Sabariah et al. 2009). Injuries to the pelvic girdle and limbs made up 17.7% of major trauma and were the second commonest body region involved after head and neck (Sabariah et al. 2009).

High energy forces are required to injure the pelvic ring (Trikha 2011 & Starr 2003). As a result, patients with high energy pelvic fractures often have associated injuries and may be hemodynamically unstable. In the case of vertical shear injury to the pelvis, patients presenting with hypotension were significantly more likely to die than those who were normotensive (44% versus 17%) (Dickson 2000). In the Burgess and Young classification,

anterior-posterior compression type (APC) injuries were associated with large amounts of blood loss. Among all trauma patients, hemorrhage is the major reversible contribution to mortality in about 42% of all cases. (ACS 2008; Heetveld 2004)

The source of bleeding in unstable pelvic fracture can come from the bone, vessels (venous and arterial) as well as intra-pelvic visceral injury (Flint 2010). Majority of bleeding were from small and medium size venous tributaries around the cancellous bone (Huittinen 1973). However, bleeding from the artery is the most significant contributor to massive blood loss, leading to shock and mortality (Flint 2010). Usually, when someone succumbed to pelvic injury, it was a result of multiple combined sources.

The goal of initial treatment for controlling hemorrhage should focus on several important aspects namely: 1) reduction of pelvic volume that lead to tamponade-like effect; 2) plugging of the major vessels through angioembolization and 3) stabilization of pelvic bone with external fixation or plating (Flint 2010). The earlier these goals are achieved the better the outcome will be. The presence of an instrument or gadget that can facilitate the achievement of these goals right from pre-hospital phase will certainly help in the management of the patient.

At present, pre-hospital providers use circumferential linen sheet, commercially available binders or clamps to achieve these targets. However, there are some limitations with the current instruments used. Some of the limitations of using linen are the ineffectiveness of linen sheets where it depends heavily on its application, and the technique varies with different devices. Once applied, it is difficult to examine the perineum. There are invasive and non-invasive clamps. Invasive clamps need expert skills for its applications like surgeons, who most of the time are not available in the field. The problems with non-invasive clamp is it may slip during patient transportation and produces high amount of pressure to the skin which could give rise to a pressure sore over the area. As for most pelvic binders, they do not provide immobilization for the associated lower limb fractures, therefore extra splints are required, which lead to difficulty during transport. On top of that some of the binders were meant for single use, which contribute to cost-benefit issues especially for developing or under developed countries.

In order to address all the above issues and limitations, a team of researchers and innovators from Universiti Kebangsaan Malaysia (UKM) embarked on a project to develop a device that can answer most of the issues mentioned earlier.

MATERIALS AND METHODS

Development of the new pelvic and lower limb immobilization device was initiated in 2006 by a group of researchers and healthcare providers from Universiti Kebangsaan Malaysia Medical Centre (UKMMC). The team comprises of emergency physicians, orthopedic surgeons, a senior assistant medical officer (paramedic) and an engineer. The team took seven years

from 2006 until 2011 to finally produce the prototype. All the processes were completed locally with collaboration between UKM and the local industry.

The project was started by identifying limitations and drawbacks with current available devices faced by the pre-hospital care and Emergency Department personnel. This resulted in the development of a new device that took into consideration all the following characteristic features: 1) User friendly, simple, easy to handle, and safe to use; 2) Reproducible (in large quantities); 3) Light; easy to carry and store; 4) Cheap; 5) Reusable; 6) Radiolucent; 7) Tough; 8) One device fits all; 9) Value added; 10) Allow access for life-saving surgical procedures; and 11) Availability of pressure measuring and monitoring.

For 1) User friendly, simple, easy to handle, and safe to use: it should be an uncomplicated device which does not require a special qualification for its use that would not cause harm. 2) Reproducible (in large quantities): the device is reproducible, can be easily manufactured and does not need high technology in order to keep the cost down. 3) Light, easy to carry and stored: the devices have to be light and stored without taking up much space, especially in the ambulance and is suitable for pre-hospital setting. 4) Cheap: the material used to develop this product should be locally available and cheap yet durable. 5) Reusable: the product should be reusable which can reduce the cost. 6) Radiolucent: This device should not obscure with radiological imaging studies. 7) Tough: The material itself should be strong to withstand the force applied. 8) One device fits all: a single device that caters for both pelvic as well as lower limb fractures. 9) Value- added: This device also addresses immobilization for a concomitant lower limb fracture. 10) Allow access for life-saving surgical procedures: it should allow life-saving hemorrhage control and structure stabilization like angio-embolization and external-fixation of the pelvis. It also should allow adequate access for emergency laparotomy to be performed. 11) Availability of pressure measuring and monitoring: compression against pressure points needs to be monitored, this help to reduce the chance of pressure necrosis.

The development of the prototype was divided into two phases. In phase one, we concentrated on the design of the device to achieve the characteristic features listed above. In phase two, the emphasis was on obtaining the appropriate material and assessing its biomechanical properties to fit its function.

Phase One: Design

Based on the discussion from the team members, the basic structure of the device follows a 'double-I' (Figure 1A) construct for the main frame. This frame consists of the 'base' for the pelvic area, and two 'arms' for the thighs. The arm piece is connected to the base, making the whole design into one piece. For the base component, a double tightening belt was attached to encircle the device. Each of the arms, which are meant to hold the thigh, has a single tightening belt, and three longitudinal sleeves were made on each arm for placement of a thermoplastic piece, which acts as

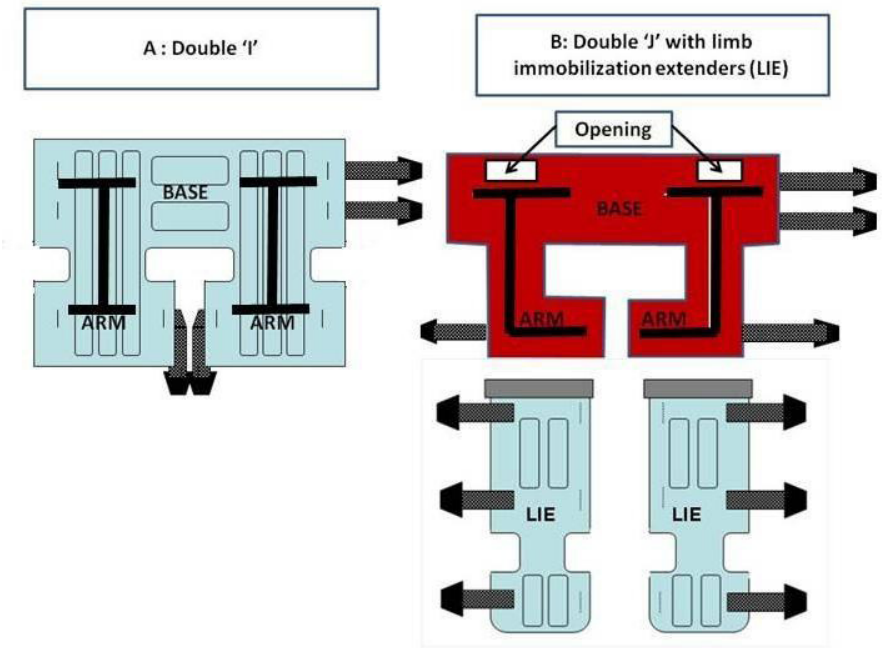

Figure 1: A) 'Double-I' construct. B) new improved double 'J' with limb immobilization extenders (LIE)

a strut in order to provide longitudinal strength. The technical drawing was then given to the private manufacturer for production. The device was made of Poly Vinyl Chloride (PVC) and weighs less than one kilogram.

There were a few limitations noted with this first prototype, namely: the design; material used; size; locking mechanism; accessibility for life-saving procedures, lack of pressure measuring-monitoring and leg immobilization component.

Phase Two: Scientific testing

Based on the limitations encountered at the end of phase one, the research team developed a new improved design of the prototype (Figure 1B) through several studies, which includes anthropometric study, biomechanical study and radiolucency test. Biomechanical study comprised of device tensile strength, buckle pull-out strength, and a pressure distribution study. As a result of all these studies, a new prototype was produced.

An anthropometric study was performed on 30 subjects of different body habitus measuring several points around the pelvis. The measurements taken include hip circumference, mid-line to Anterior Superior Iliac Spine (ASIS); mid-line to femoral artery; ASIS-to-ASIS; and greater trochanter-to-greater trochanter. The results of this study will be included in another publication.

The pressure-distribution study was performed among three healthy subjects in the Department of Electrical, Electronic and Systems Engineering,

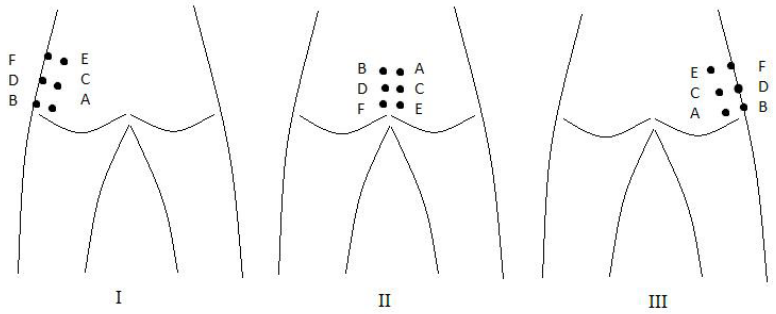

Figure 2: Six pressure sensors location at I:Left, II. Middle, III: Right. A- Left Pelvis (above); B- Left Pelvis (below); C- Right pelvis (above); D- Right pelvis (below); E- Posterior pelvis- sacral area (above); F- Posterior pelvis- sacral area (below)

Faculty of Engineering and Built Environment, UKM. Several regions around the pelvis were assessed, this includes bony prominents in the right and left flank of the pelvis and over the sacral area as shown in Figure 2. The data were acquired from six regions for 50 seconds and the sampling rate is one Hertz. The average reading from each region was tabulated.

For the biomechanical properties of the device, the test was done in the Department of Mechanical & Materials Engineering, Faculty of Engineering and Built Environment, UKM. Tensile strength test was performed on the 'base' section of the device main frame. Ten readings were observed. The buckle pull-out test was performed on the device locked-buckle that was made of high density plastic using a similar technique. Five readings were observed.

The device was also exposed to several radiological exposures to assess its radiolucent properties.

RESULTS

At the end of Phase 2, the team managed to produce a new pelvic and lower limb immobilizer which was a two-in-one immobilization device. It not only enable immobalization of the fractures but also facilitated life-saving procedures to be carried out while maintaining the stability of the fractures.

The final product was a 'double-J' construct (Figure 1B) with three different sizes that caters sizing issues. The final prototype of the new device (Figure 3) has a base and two arms that form the main frame. It has two main straps, which was the Greater Trochanter (GT) strap and the Iliac (I) strap, which is meant to secure the new device to the body. The GT strap is the main strap, placed at the level of the patient's greater trochanter, to produce the compressive effect of the new device. It has two apertures located at the flank of the anterior part of the device's main frame for insertion of the external fixator pin. It's anterior portion can be folded down anteriorly to give more space for a surgeon to performe laparotomy while it still provides immobilization of the patient. As a result of the 'J' shape limb instead of 'I', femoral vessel catheterization for angioembolization can be performed while maintaining compressive forces.

A B

Figure 3: The new construct 'Double J' design, A-anterior aspect with sleeve (arrowed) and B-the posterior aspect (Black arrows shows flappable area and blue arrow the essential GT belt)

There were straps to secure the device's arm to the patient's leg, and this is fortified with a thermoplastic strut in order to provide a splinting effect for the femur. Limb immobilization extenders (LIE) are attached to the main frame arm via Velcro in order to give further immobilization distal to the knee until the foot.

It weighs less than one kilogram and is made of polyurethane (PU) material. The strap was made of nylon while the lock-buckle is made of high density plastic. All of these features were to ensure that the whole device was radiolucent.

The results of the pressure distribution study on the left, middle and right pelvis at six different locations are presented in Table 1. Figure 4, 5 and 6 showed the pressure distribution for 50 seconds at six different locations on the left, middle and right pelvis.

Results of the biomechanical properties of the device which include tensile strength and buckle pull-out strength of the device was shown in Table 2.

Table 1: Pressure distribution testing around the six tested points

Sensor Location	Mean Pressure (kPA)					
	A	B	C	D	E	F
Left	12.0	9.05	3.59	21.8	2.45	6.23
Middle	26.9	16.9	15.2	29.4	72.9	79.9
Right	14.7	7.43	3.16	24.5	3.29	6.62

A- Left Pelvis (above); B- Left Pelvis (below); C- Right pelvis (above); D- Right pelvis (below);
E- Posterior pelvis- sacral area (above); F- Posterior pelvis- sacral area (below)

Table 2: Biomechanical Testing Result

	Maximum load (N*)	Mean S.D (N*)
Tensile Testing	12237.9	7028.25±2245.83
Buckle pullout Testing	903.86	758.03±140.38

* N = Newton

DISCUSSION

The development and production of the prototype for the pelvic and lower limb immobalization device took a long time because of several factors that were encountered. One of the main limiting factors was due to financial constraint where the first prototype was built without funds obtained from any sources. It was only in the second phase that some financial support was obtained from the university research fund.

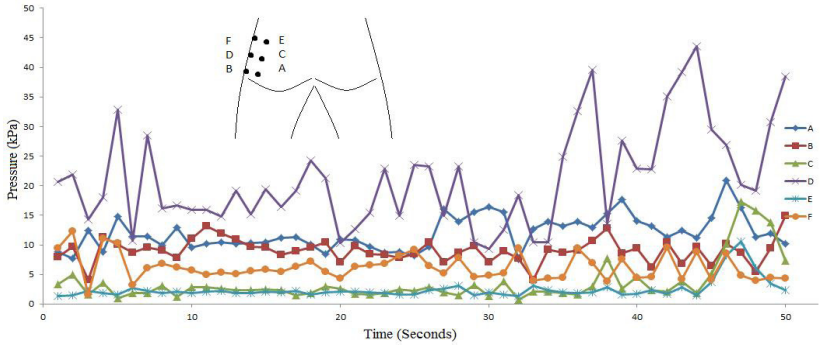

Figure 4: Pressure measurements on left pelvis for 50 seconds

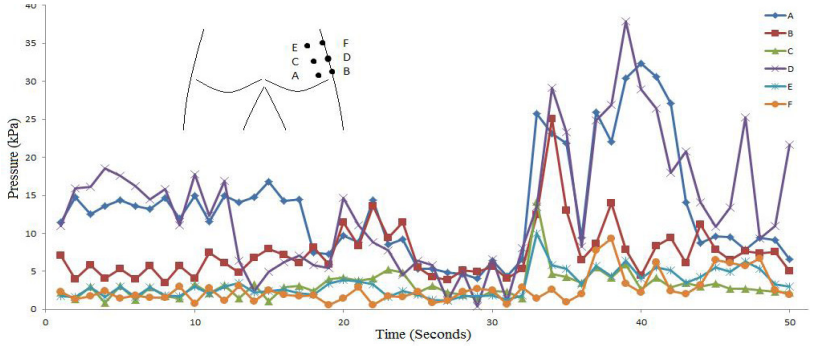

Figure 5: Pressure measurements on right pelvis for 50 seconds

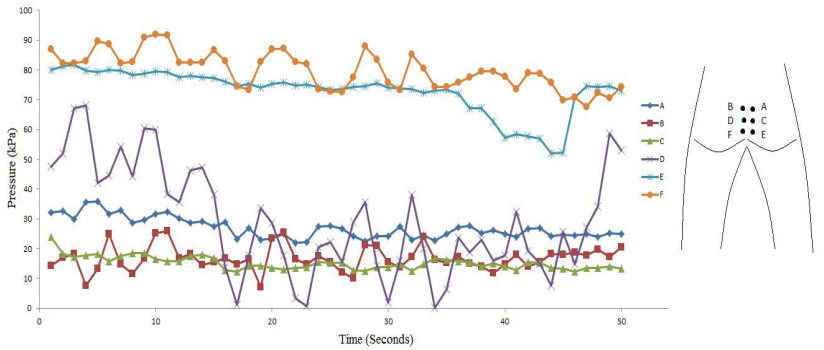

Figure 6: Pressure measurements on middle pelvis for 50 seconds

Some of the factors that were improved from the first phase study was the design; material used; size; locking mechanism; accessibility for life-saving procedures, lack of pressure measuring-monitoring and leg immobilization component.

There was a problem with accessibility for surgeon or interventional radiologist to perform life-saving procedures to

help secure haemostasis. As a result of limited accessibility, the design was changed from a 'double-I' to a 'double-J' construct. This new design allowed procedures like external fixation and femoral catheterization for angioembolization to be performed. In addition, two openings were made on the anterior part of the base component which created a flap and it can be flipped down thus offering more accessibility for abdominal procedures like laparotomy especially for posterior pelvic packing in a pelvic fracture patient (Flint 2010).

Financial reasons also contributed to the decision to used PVC in the first prototype. PVC, a non-breathable material was found to be uncomfortable to the patient since it trapped heat. A suitable substitute flexible polymer, polyurethane (PU), was used to replace the PVC, which would address the fore mentioned issues. Strength, durability and skin-friendliness were achieved with the new material after the biomechanical testing and discussion with material experts.

Other problems that we encounter at the end of the first phase were the sizing issue. One size will not fit the whole population. For this reason an anthropometric study was performed in the second phase to determine the best size that could fit all or most of the population. One-size-fits all was the 'ideal characteristic' wish-list, but from our study we found that we need at least three sizes to fit the population at large.

The initial locking mechanism was not user-friendly since the buckle tends to give way with minimal force. The buckle was changed to allow a better locking mechanism that minimizes toggling and buckle pullout. The new buckle helps to improve the buckle pull-out strength, where in the biomechanical study an average load of more than 750 Newton (N) was needed to create a pull-out. This was sufficient since most of the time a tensile force lesser than that is sufficient to bind the pelvis.

Though the first prototype was able to immobilize the pelvis and the thighs, it did not immobilize a fracture of the lower legs (tibia–fibula). Therefore, a lower limb immobilization extension (LIE) was created with additional traction capability. These features help stabilization of the lower limbs better and will enable easy transportation and care especially in the prehospital setting.

The amount of pressure applied to the skin was not measurable in the first prototype since it does not incorporate a pressure measurement device. From our pressure distribution study, we also noted that the area at the posterior aspect of sacrum was very high (72.9-79.9 kPa). A sleeve was created at the posterior base component to enable an air cushion-pad to be slipped in and off-load the higher pressure at this area thus preventing pressure sores on prolonged use. We planned in our next prototype to incorporate a pressure gauge meter connected to the air-cushion pad that can measure pressure continuously and at the same time off-load the pressure area.

Another important aspect in the creation of the new device pertaining to the material used was to ensure that the

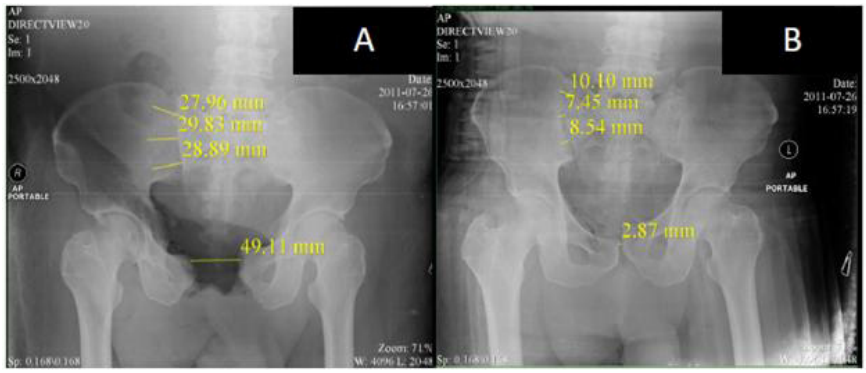

Figure 7: A) Open book pelvic fracture. B) Radiolucent property of BRIM and the ability to close/reduced the pelvic volume tested

whole device was radiolucent since it was very essential for use during patient management. That was the reason why only radiolucent-friendly material was used throughout the whole device.

Radiological testing proves its radiolucent property (Figure 7). The material used allows the device to be washed and cleaned with decontamination solution, making it reusable. The new device was assembled locally with minimal cost.

Following a series of modification and improvement of the initial design, the first prototype was patented in 2008 (IP Pattern: PI 2008 1332–10th JUNE 2008) while the second was filed for patency in 2011 (IP Patent: PI2011004592-27th September 2011).

SUMMARY

A new pelvic and lower limb immobilization device, BRIM™ Immobilizer, was designed and produced according to the characteristic wish-list that incorporated suitable but relatively affordable material with a design that allows life saving intervention to be carried out while the patient is still on it. It addresses some of the local problems faced by our prehospital care providers with the current treatment methods. It is also radiolucent, reusable, light but yet tough.

ACKNOWLEDGEMENT

The second phase of the study was fully funded by a research grant from the Universiti Kebangsaan Malaysia (research project code: UKM-IF-1-10-005 UKM innovation fund 2010). We would like to extend our appreciation to the staffs of the Department of Emergency Medicine UKMMC involved with the projects directly or indirectly. We would also like to thank Ms Nur Solehah Mohtar, Ms Norhidayu Mohd Norapi and Ms Nur Hazwani Mamat for helping in the study. Special thanks to Prof. Dr-Ing. Nik Abdullah Nik Mohamed, Department of Mechanical & Materials Engineering, Faculty of Engineering and Built Environment, Prof. Dr. Ahmad Kamal Ariffin Mohd. Ihsan,

Department of Mechanical & Materials Engineering, Faculty of Engineering and Built Environment and Prof. Dr. Mohd. Alauddin bin Mohd. Ali, Instute of Space Science (ANGKASA) for their undivided support.

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