Simplified Hydrodissection Device

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Abstract : *The development of a simplified hydrodissection device for use during operative laparoscopy is described. The device used mechanical-pneumatic operation, with CO_2 propellant gas and consists of control unit, fluid warmer system and irrigation/suction probe. The irrigation pressure is adjustable throughout a range of 100-760 mmHg and the flow rate ranges from 690 to 1,400 ml/min. The performance of the device using a commercial irrigation probe (maximal flow rate of 2,258 ± 28 ml/min at 760 mm Hg pressure) is comparable to a commercial irrigation device. For suction, the wall suction system is used. The device has been used in 20 operative laparoscopy cases, and is found to be cost effective, simple to operate, having a continuous high pressure flow rate and delivering homeothermic solution. The major defect that needs further development is in the locally made irrigation probe. (Thai J Obstet Gynaecol 1994;6:129-139.)*

Key words: hydrodissection, aquadissection, irrigation/suction device, laparoscopic surgery

Operative laparoscopy is being used for an increasing number of intra-abdominal procedures. Integral parts of most of these procedures are irrigation, hydrodissection with physiologic solutions (such as normal saline or lactated Ringer's solution) and suction[1-3]. Hydrodissection is a technique that makes use of hydraulic energy to facilitate separation of tissue planes with less trauma than if the maneuvers were carried out by mechanical means. Modern hydrodissection devices consist of adjustable hydraulic pressure at a relatively high flow rate with a fluid warmer system. Elaborated and sophisticated design has led to accuracy and simple operation, but at the expense of high capital and maintenance costs[3,4]. Many devices have been manufactured without a fluid warmer system, so the use of these high flow systems, especially during lengthy cases, may result in the use of a significant volume of hypothermic fluid. Because aqueous medium is an excellent coolant, this may contribute to the hypothermia which was reported to occur during some cases of operative laparoscopy[5].

The Aqua-purator (WISAP, Sauerlach, Germany) was the first of the high pressure irrigation/hydro-dissection devices[1]. It delivers fluid under 170 mmHg pressure at a rate of 1,500 ml/min without irrigation fluid warmer system. Recently, a nonelectric CO_2 powered irrigation system was introduced (CO_2 HYDROMAT, Karl Storz CO, Tuttlingen, Germany), in which the irrigation pressure can be varied between 0 and 800 mmHg. This device has an irrigation fluid warmer system as an accessory. Laparoscopic irrigation using a pre-warmed pressurized system was reported by Hurd et al[4]. This device was originally designed to deliver large volumes of homeothermic (37° C) fluid quickly to trauma and burn patients. The irrigation pressure is 300 mmHg, and the flow rate is approximately 650 ml/min. All these products are relatively expensive(more than US$4,000)[4]. In our Department, we have used an Endo-irrigator integrated in Endo-Surgery CO_2-Pneu (Richard Wolf, Knittlingen, Germany) with a Storz irrigation/suction probe (Karl Storz CO, Tuttlingen, Germany).

We have designed a simplified hydrodissection device that has low cost and possesses many desirable features, such as adjustable hydraulic pressure, fluid warmer system, valves and lumens of a strong dissection probe that were not easily obstructed, and simplicity in use. The device can be constructed and maintained locally, using available local materials.

Materials and Methods

Function and design[6,7]

The simplified hydrodissection device uses mechanical-pneumatic operation with CO_2 propellant gas. Figure 1 shows the block diagram of the device, consisting of pressure delivery unit with warmer and irrigation/suction probe. High-pressure gas from CO_2 cylinder is reduced with a pressure regulator. The system pressure is adjustable throughout a range of 100-760 mmHg (2-15 psi) and is displayed on the low-pressure gauge. Low-pressure gas is delivered to a solenoid valve which can be activated by a footswitch. Then gas passes through a flow-limiting valve that will cut off gas flow if the flow rate is more than 3 l/min, to prevent insufflation of high-flow propellant gas into the peritoneal cavity when the irrigation fluid bottle is empty. The irrigation fluid used is in a one-liter glass bottle with a trocar puncture cap. The glass bottles can tolerate pressure up to 100 psi according to Thai Industrial Standard (TIS 532-1984). Two fluid bottles can be simultaneously connected to the device, and are placed on the warmer to maintain the fluid temperature. A three-way valve is used to select the fluid bottle. The propellant gas is delivered to either fluid bottle via two silicone tubes connected to the pressure trocar by Luer-lock. A long sterile silicone irrigation tube with Luer-lock end is used to attach an irrigation trocar to the

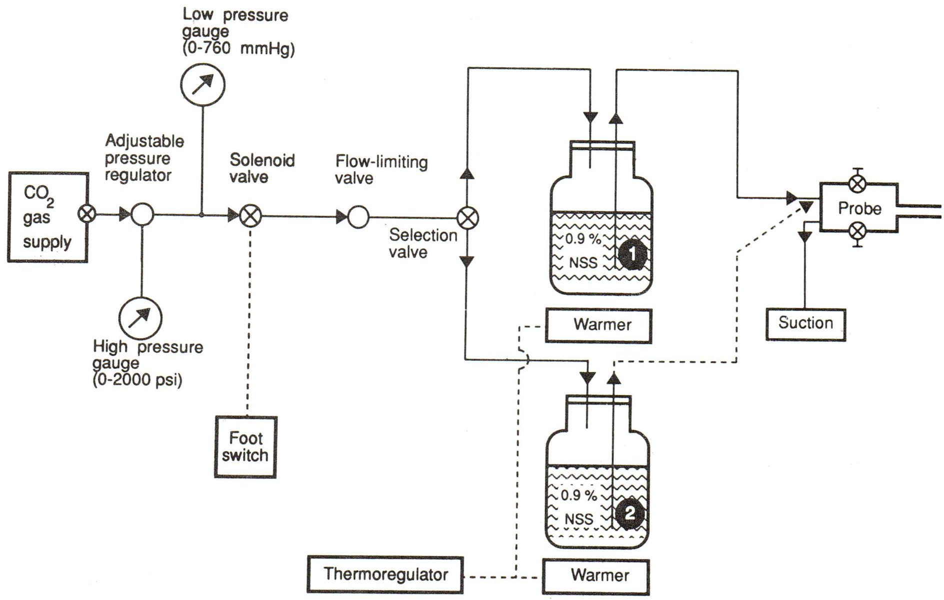

Fig. 1 Block diagram of the simplified hydrodissection device. (NSS : normal saline solution)

irrigation/suction probe. The probe has two trumpet valves, but a single channel for irrigation and suction to maximize irrigating and suctioning capacity. For suction, the wall suction is used. This device is designed to comply with the International Electrotechnical Commission(IEC 601-1:1988) for Class I equipment, and meets the appropriate current leakage requirements.

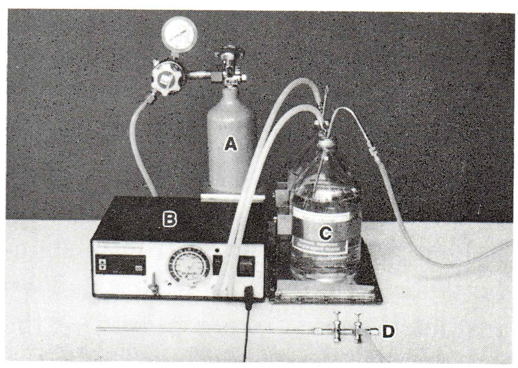

Fig. 2 Prototype of the simplified hydrodissection device. (A : CO_2 cylinder with pressure regulator, B:control unit, C:warmer with two bottle holders, D:locally made irrigation/suction probe)

Description of prototype

The prototype of the simplified hydrodissection device essentially consisted of a one-liter CO_2 cylinder with pressure regulator (Fig. 2-A), control unit(Fig. 2-B), warmer with two bottle holders (Fig. 2-C), and irrigation/suction probe (Fig.2-D). A Model 101 Harris CO_2 pressure regulator (Harris Calorific CO, Cleveland, OH, USA) consisted of high-pressure gauge (0-2,000 psi) to display the pressure in CO_2 cylinder, and a pressure control knob, rotated to adjust the pressure in the system. Clockwise rotation of the knob increased system pressure and anti-clockwise rotation decreased system pressure. The adjusted pressure was displayed in mmHg by the low-pressure gauge. A solenoid pneumatic valve was used to control propellant gas. The flow-limiting valve was modified from the inner tube of a Rotameter used for oxygen therapy (Ohmeda, Columbia, MD, USA). This was out of use because the outer tube has been broken. The inner tube could tolerate pressure up to 50 psi. If the propellant gas flow was over 3 l/min, when the fluid bottle was empty, the ball of the flow-limiting valve would be pushed up to block the gas flow to less than 1 l/min. The usual irrigation fluid used was 0.9% normal saline solution (USP XXII) in a one-liter glass bottle, that could be prepared by the Pharmacy Department of Songklanagarind Hospital. The warmer with two bottle holders was constructed from a stainless steel plate, 1 mm thick. Two insulated heater were placed in the waterproof warmer tray and the maximum power was about 60 W. A Model MC311 Thermoregulater (SAE, PN,Italy) with thermostat differential of 0.2° C was used to control the warmer temperature. The pressure trocars were 14 gauge stainless-steel needles of 1.5 mm internal diameter (ID) and 51 mm in length. The irrigation trocars with Luer-lock end were constructed from locally available standard brass tube, 4.70 mm outer diameter (OD), 3.40 mm ID and plated with nickel. The irrigation/suction probe consisted of the body with two trumpet valves and irrigation/suction cannula, 295 mm in length(the same size as the irrigation trocar): all parts were constructed from standard brass tube and plated with nickel. The lumen of each trumpet valve was only 3 mm(smaller than that of irrigation/suction cannula), because of the limitations of the available standard brass tube(7.35 mmID) used as valve cylinder. For suction, the Ohmeda Suction System (Ohmeda, Columbia, MD, USA) with 3,000 ml bottle mounted on a stand and connected to wall suction, was used. The components and costs of the prototype are shown in Table 1.

Operating instructions

After turning on the main switch, the thermoregulator is set at 55° C and the warmer is switched on. Two one-liter irrigation fluid bottles, prewarmed to about 37° C, are placed in bottle holders on the warmer. Pressure trocars and irrigation trocars puncture each bottle cap by sterile technique. Each propellant gas tube is connected to the pressure trocar of each fluid bottle. The long sterile silicone irrigation tube with Luer-lock end is used to attach the irrigation trocar of bottle I to the irrigation valve of the probe. Before the CO_2 cylinder valve is turned on, the pressure control knob is rotated anti-clockwise until it moves freely. When the CO_2 cylinder valve is

Table 1 ***Simplified hydrodissection device components***

Components	Price (Baht)
One-liter CO_2 Cylinder	1,400
Pressure regulator with high-pressure gauge	1,350
Solenoid valve	550
Flow-limiting valve	300
Low-pressure gauge (0-760 mmHg)	2,000
Selection valve + connector	600
Footswitch + cable + case + circuit	500
Thermoregulator unit	2,700
Warmer with 2 bottle holders	1,000
Pressure and irrigation trocar	200
Locally made irrigation/suction probe	1,800
Silicone tube (4.85 mm ID,8.70 mm OD) 5 meter	535
	total cost 12,935 Baht (US$520)

turned on, the high-pressure gauge will show pressure in the cylinder. Then the pressure control knob must be rotated slowly clockwise, so that propellant gas pressure will show on the low-pressure gauge in mmHg, until the desired system pressure is reached. Once the system pressure is set, the pressure will almost constant and require only a little adjustment in subsequent use. Low system pressure (100-300 mmHg) is used for irrigation, while high system pressure (300-760 mmHg) is used for tissue dissection. The selection valve is turned to bottle I position. The sterile silicone suction tube is connected to the suction valve of the probe. Now the device is ready to use, fluid will flow out of the irrigation cannula of the probe when the footswitch and irrigation trumpet valve of the probe are simultaneously pressed. When bottle I is empty, the procedure can be continued quickly by turning the selection valve to bottle II position and changing the irrigation silicone tube from the irrigation trocar of bottle I to that of bottle II.

Instrument tests

Both laboratory and clinical tests were carried out to assess the performance of the prototype. We determined the maximal flow rate produced by the prototype for different irrigation pressures (100-760 mmHg) and for different irrigation probes (locally made irrigation probe versus Storz irrigation probe). The performance of the prototype using locally made and Storz irrigation probe were then compared with the Endo-irrigator using either probe and the Stewart system[3] at the same irrigation pressure (150 mmHg). The Stewart system in this study consisted of the routine intravenous tube and fluid suspended at a height of six feet. The flow rate at the tip of the irrigation probe was measured using a Model 22G02 Urodyn1000 Uro flowmetry connected to a Model 22K10 Uroflow Transducer (Dantec, Skovlunde, Denmark). All the flow rates represented the maximal flow rate obtained.

The efficiency of the fluid warmer system was assessed at maximal warmer setting (55°C) at room temperature (24° C). The prewarmed (37° C) and room temperature fluid in one-liter glass bottles were placed on the warmer, and the changes of fluid temperature were compared with those of the prewarmed(37°) fluid in one-liter glass and plastic bottle without warmer. We used a Temperature recorder (Amprobe Instrument, NY, USA) to evaluate changes of fluid temperature.

The clinical performance was assessed by surgeons and operating room staff. This instrument has now been used satisfactorily during twenty elective and emergency operative laparoscopy cases.

Data points in all laboratory tests represent the results of ten measurements. The data obtained are presented as mean ± SD and do not conform to a normal distribution, so Mann-Whitney U test has been used to assess differences between the groups and the significance of difference was $p < 0.05$. To determine a correlation between the irrigation pressure and flow rate, a linear regression analysis of the data has been performed.

Results

The maximal flow rate of the prototype using locally made irrigation probe at a maximal irrigation pressure(760 mmHg) was 1,456±25 ml/min. When the prototype used the Storz irrigation probe, the flow rate increased to 2,258 ± 28 ml/min. The correlation between irrigation pressure (100-760 mmHg) and flow rate(ml/min) using either locally made or Storz irrigation probe was linear. The linear regression was formulated for each probe. The flow rate of the locally made probe was 546 ± 1.16 (pressure) and the flow rate of the

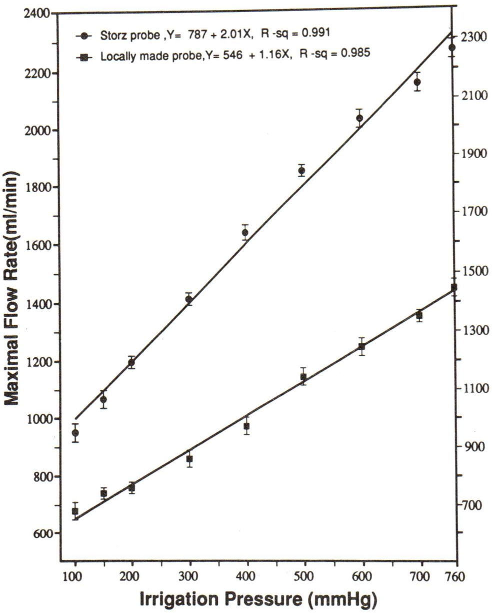

Fig. 3 The correlation between the maximal flow rate and irrigation pressure obtained with locally made (■) and Storz (●) irrigation probe.

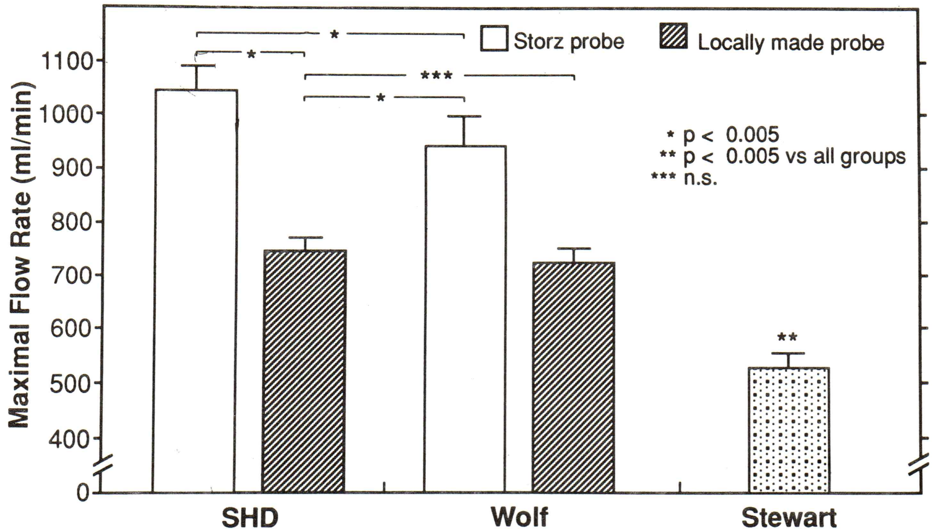

Fig. 4 Comparison of the maximal flow rate obtained with the simplified hydrodissection device(SHD) and Endo-irrigator (Wolf) using locally made or Storz irrigation probe, and the Stewart system at the same irrigation pressure(150 mmHg). (*P<0.005,P<0.005 vs all groups,***no statistical significance)**

Storz probe was 787±2.01(pressure) with R-squared of 0.985 and 0.991 respectively (Fig.3).

Fig. 4 shows the performance of the prototype (SHD) with Endo-irrigator(Wolf) and the Stewart system at the same irrigation pressure (150 mmHg). The prototype using locally made irrigation probe has a flow rate less than that obtained by the Endo-irrigator using the Storz irrigation probe (Wolf/Storz system) [743 ± 11 vs 941 ± 58 ml/min, p<0.005]. When assembled with the Storz irrigation probe, the prototype had a flow rate increase to 1,043 ± 43 ml/min, significantly highter than the Wolf/Storz system (P<0.005). The flow rate of the prototype using the locally made irrigation probe was comparable to the Endo-irrigator using the locally made irrigation probe (743 ± 11 vs 726 ± 20 ml/min, P = 0.09). Both the prototype and Endo-irrigator using either probe had a flow rate higher than that of the Stewart system (524 ± 12 ml/min, P<0.005), and the flow rate of the Stewart system decreased rapidly, needing frequent inflation of the pressure cuff to maintain the flow rate.

There was some leakage of the irrigation fluid from the valve of the locally made irrigation probe during use both with the prototype and the Endo-Irrigator. The suction capacity using the locally made irrigation/suction probe at maximal suction pressure (-400 mmHg) was approximately 1.5 l/min.

The changes of the fluid temperature in the laboratory test of the warmer of the prototype are shown in Fig. 5. The warmer heated the room temperature (24° C) fluid very slowly

Table 2 ***The specifications of the simplified hydrodissection device***

Irrigation pressure	760 mmHg (max)
Instillation capacity	1.4 l/min (max)
Vacuum pressure	-400 mmHg (max) (depends on wall suction)
Suction capacity	1.5 l/min (at max vacuum pressure)
Mains voltage/Fuse	220 Vac, 50 Hz/ 0.5 A
Warmer	60 W (max)
Irrigation fluid	0.9% NSS in one-liter standard glass bottle (TIS:532-1984)
Dimensions	42 cm x 13 cm x 31 cm (wxhxd; not including CO_2 cylinder)
Weight	5.5 kg (not including CO_2 cylinder)

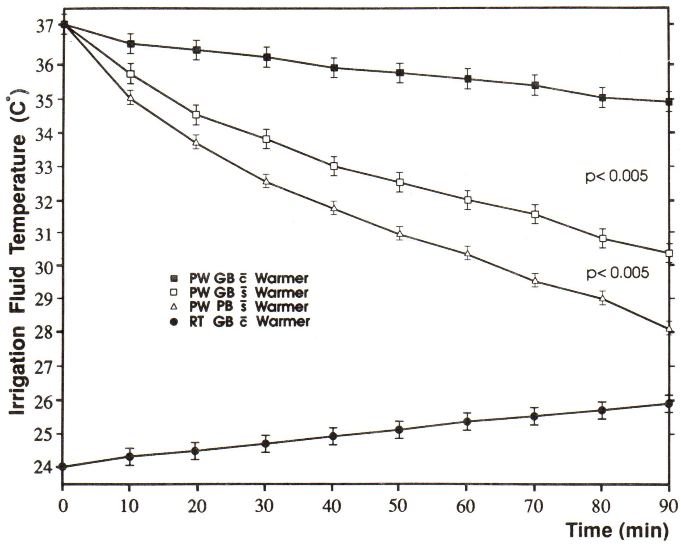

Fig. 5 Effect of the warmer on the irrigation fluid temperature. The irrigation fluids were prewarmed (37°C) fluid in glass bottle with warmer (■: group I), prewarmed fluid in glass bottle without warmer (□: group II), prewarmed fluid in plastic bottle without warmer (Δ: group III), room temperature(24°C) fluid in glass bottle with warmer (●:group IV). The prewarmed fluid group II cooled down significantly compared with group I (P<0.005) and group III cooled down more rapidly than group II(P<0.005), both after 10 minutes.

(approximately 1° C/h), whereas for the prewarmed (37° C) fluid, the warmer minimized the cooling down of the fluid temperature. When the warmer was not used, the prewarmed fluid temperature decreased rapidly compared with the fluids using the warmer (P<0.005) and there was significant reduction of the fluid temperature in the plastic bottle compared with the glass bottle (P<0.005) after ten minutes. The specifications of the prototype are shown in Table 2.

The prototype was as useful

surgically as the Wolf/Storz system during fifteen cases of elective operative laparoscopy and five emergency ectopic pregnancies managed by laparoscopic salpingectomy or salpingo-oophorectomy. The fifteen cases of elective operative laparoscopy inclunded ten cases of adnexal cysts managed by salpingo-oophorectomy or cystectomy, two cases of laparoscopic hysterectomy and three cases of pelvic endometriosis managed by lysis adhesion and laser vaporization. There was no appreciable drop in the patients' temperature and no postoperative shivering after 2-4 liters of irrigation.

Discussion

Irrigation is an integral part of surgery performed by either laparotomy or laparoscopy. In contrast to laparotomy, where the use of warmed irrigation fluid is routine(8), irrigation fluid used during laparoscopy is often at room temperature. In other endoscopic procedures where large volumes of room temperature (21° C) fluid are used, such as transurethral prostatectomy, significant cardiac stress has been attributed to rapid cooling of the patient(9). Because hypothermia is a real risk during lengthy laparoscopic procedures(5,10), the use of warmed irrigation fluid may be advantageous for laparoscopy as well. One common approach to this problem is the use of prewarmed containers of solution pressurized for irrigation by various methods(3). However, the actual temperature of the fluid reaching the patient may vary widely depending on the initial temperature of the fluid, the length of time the fluid container is exposed to room temperature before use, and the type of container. Fluid that is too warm (>37° C) may actully increase the risk of postoperative adhesion formation(11). Conversely, fluid that is allowed to cool before use offers little advantage to the patient, and from this study the plastic bottle cooled down more rapidly than the glass bottle. So we designed a method of using prewarmed fluid at 37° C in a glass bottle normally used for laparotomy, and a warmer system to reduce the cooling down of the fluid. A fluid warming system that can warm up room temperature fluid quickly is sophisticated and costly.

The flow rate of the prototype using locally made irrigation probe ranges from 690 to 1,400 ml/min. The flow rate at 150 mmHg pressure is significantly higher than that achieved by the Stewart system(3), and remains constant during the irrigation period. Although this rate is not as high as the rates of up to 3,000 ml/min possible with some commercial irrigation units (Cabot Medical, PA, USA)(4), flow rates and pressure obtained with the prototype are more than adequate for rapid irrigation and hydrodissection during operative laparoscopy.

The three major defects of the prototype are in the locally made irrigation probe and flow-limiting valve. First, the internal diameter of the irrigation cannula is smaller than that of the commercial irrigation probe. Second, there is some leakage of the irrigation fluid at the valve, which explains why the constant and slope in the formula of the locally made irrigation probe are less than those of the commercial irrigation probe. Third, the flow-limiting valve cannot cut off but only decrease propellant gas flow to 1 l/min instead of over 15 l/min when the fluid bottle is empty.

The setup and operation of the prototype is remarkably simple. Once both the system pressure and the warmer are preset, it rarely requires adjustment. The irrigation fluid in a one-liter glass bottle can be prepared locally by the Pharmacy Department of most hospitals: the cost is low and it can reduce the wast of disposable plastic fluid bottles.

As with any new technology, the cost per case should be considered. Because this simplified device has an initial cost of only 13,000 Baht (US$ 520) and the irrigation fluid costs only 10 Baht (US$ 0.4) per liter, it is therefore extremely cost effective.

Our initial clinical experience suggests that the prototype of the simplified hydrodissection device performs well. However, this device is at the prototype stage and there are certain aspects which need further development. These include a high efficiency probe which has an accessory channel for electrosurgery or laser surgery, a good heat-conducting warmer and a flow-limiting valve that can completely cut off the propellant gas flow.

In conclusion, this paper has shown that the simplified hydrodissection device for operative laparoscopy is effective, simple to operate, having a continuous high-pressure flow rate and delivers a homeothermic solution. It is a very cost-effective and appropriate piece of technology for developing countries.

Acknowledgements

This study is financially supported by the Faculty of Medicine, Prince of Songkla University. We are most grateful to Mr.Udomphon Puetpaiboon,M.Eng, and Mr.Punyarak Ngamsritragul, M.Eng, Faculty of Engineering for their valuable advice. The data analysis assistance of Mrs.Oermporn Krisanapan,MS, is gratefully acknowledged. The authors would like to thank Urodynamic Unit, Department of Surgery, for the Urodyn1000 instrument. The authors would also like to thank Mr.Desmomd Burton for manuscript amendment and the operating room staff for their kind cooperation and valuable help.

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