Ultrasonic Energy in Laparoscopic Surgery

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The ideal energy form for use in laparoscopic surgery should provide controlled, hemostatic cutting. A good dissection technique should be further characterized by minimal thermal injury to surrounding tissue, no smoke obscuring the visual field, cutting ability equal to or superior to a conventional scalpel, coagulative ability equal to or greater than electrosurgery, lack of danger to the patient such as from stray energy, no toxins from exposure to smoke in the pneumoperitoneum elevating patient levels of methemoglobin or carboxyhemoglobin, no need for special preparation of the patient (grounding pad) or surgeon (glasses), and no need for special training. For a technology to replace that which is the current standard, this should all be provided at a cost similar to the cost associated with electrosurgery.

Traditionally, ultrasonic energy in surgery has been primarily considered in its lowest power form as a diagnostic modality. However, ultrasound can be used in a more powerful form as a surgical tool. Ultrasonic energy is a safe energy form that has been used in tissue emulsification with the ultrasonic cavitational aspirator, and more recently for laparoscopic surgical cutting and coagulating with the ultrasonically activated scalpel. We will discuss the physics involved in both of these instruments, and describe briefly the mechanism of action of the ultrasonic cavitational aspirators in order to differentiate the respective applications, and distinguish the ultrasonically activated scalpel.

Ultrasonic energy belongs to the family of mechanical wave energy. Mechanical waves transport energy through a medium by means of the motion of a disturbance in the medium rather than the matter itself. For example, an ocean wave is a mechanical wave in which energy is delivered by the motion of the wave and not movement of the ocean itself. Audible sound waves (sonic waves) are longitudinal mechanical waves with frequencies in the range of 20 cycles per second to about 20,000 cycles per second, or hertz (Hz). Accordingly, an infrasonic wave, is a sound wave with a frequency below 20 cycles per second, such as an earthquake wave, and an ultrasonic wave is one whose frequency is above the audible range, or greater than 20,000 Hz. When electromagnetic energy is applied to either piezoelectric (also termed electrostrictive) or magnetostrictive transducers, mechanical vibration is created in response to electric or magnetic fields, respectively. Ultrasonic energy is the mechanical vibration that is produced. Ultrasonic waves applied at low power levels are used in diagnostic ultrasound imaging, in which no tissue effect occurs. However, higher ultrasonic power levels and densities can be harnessed to produce dissection of tissues, such as the ultrasonic cavitational aspirator, or UCA (CUSA™ System, Valleylab, Inc., or Ultra™ Ultrasonic Aspirator, Sharplan Lasers, Inc.), which operates at approximately 23,000Hz.

Work in our laboratory and that of others has lead to the development of an ultrasonically activated scalpel, or UAS (Harmonic Scalpel®, UltraCision, Inc., Smithfield, RI) operating at 55,500 Hz that effectively and safely cuts and coagulates tissue in animals, both in conventional, open surgery and in laparoscopic surgery. Both the UCA and the UAS rely on the mechanical propagation and conduction of sound, or pressure waves, from an energy source, through a medium to an active blade element. However similar the technologies, basic differences in the physics and mechanism of action of the ultrasonic cavitational aspirator and the ultrasonically activated scalpel lend them to distinctly separate applications.

THE ULTRASONIC CAVITATIONAL ASPIRATOR

An ultrasonic cavitational aspirator is composed of a microprocessor controlled, high frequency, power supply generator, providing electrical energy to the hand piece (Figure 1). The hand piece houses the ultrasonic transducer, vibrating at a frequency of 23,000 Hz, the energy from which is then conducted via a hollow tube (resonator) to a 3mm, tapered, hollow tip. The tip provides aspiration. The tube and tip are encased in a protective flue which provides irrigation. As the tip vibrates 23,000 times per second, there is a longitudinal displacement of 200 to 300 µm. The mechanism of action of the UCA is via the cavitation caused by the vibrational activity of the narrow hollow tip. The rapid forward and backward motion of the tip in contact with the tissue results in dramatic shifts in internal tissue pressures. As internal tissue or cellular pressure falls below the vapor pressure of tissue and cellular fluid, (water) vapor filled vacuoles form, expand, and contract with each excursion of the aspirator tip. Ultimately this fragments cells and expands tissue planes. The UCA combines this action with suction, allowing fragmentation and aspiration of collagen sparse tissue. The blade tip and tissue interface are cooled with an irrigant of saline, so there is little protein denaturation of the tissue. Heat will be generated in the blade and tissue if irrigant is decreased, but not sufficiently to reach the thermal coagulative levels comparable to those seen with electrosurgery unless irrigant flow is totally cut off.[1] Ultrasonic coagulation with the UCA is also minimized because the blade shape does not allow large surface tissue contact.

The UCA is tissue selective, resulting in safe dissection of high water content tissues, with preservation of nerves, arteries and other collagen-rich (water sparse) structures. This is because collagenous tissues (blood vessels, nerves, ureters) require considerably more energy to fragment than high water content tissues such as liver, tumors and spleen. This UCA is useful and safe in open surgical procedures such as tumor debulking, neurosurgery, and liver surgery. More recently, laparoscopic applications

Figure 1a, b. An ultrasonic cavitational aspirator.

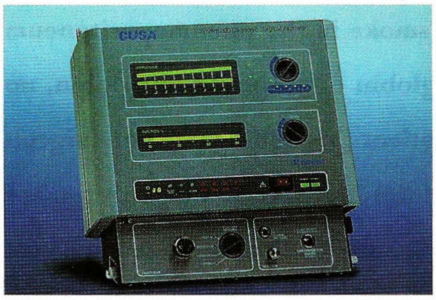

Figure 1a. Generator.

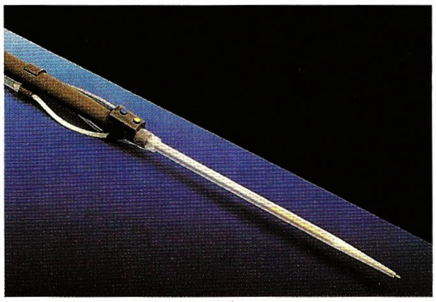

Figure 1b. Laparoscopic handpiece.

Figure 2a, b, c, d. The ultrasonically activated scalpel.

Figure 2a. Generator.

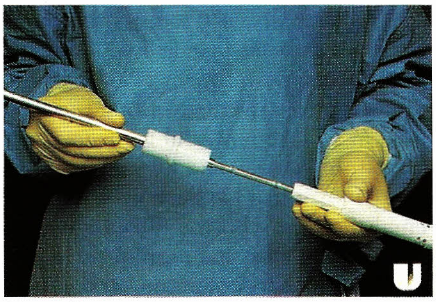

Figure 2b. Handpiece.

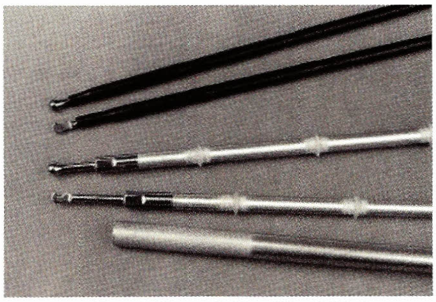

Figure 2c. 5 and 10 mm ball and hook blades.

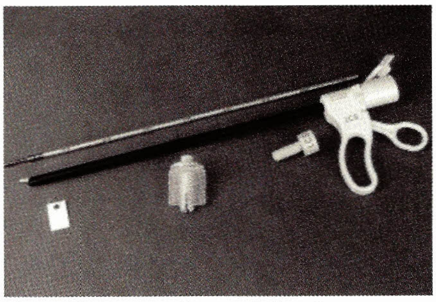

Figure 2d. Laparosonic coagulating shears.

have been identified, including laparoscopic cholecystectomy[2] and colectomy. Although limited in it's scope of use laparoscopically, it is an excellent tool for skeletonizing tissue. It is particularly useful in dissecting Calot's triangle, in the presence of adipose tissue or acute inflammation (edema) and for skeletonizing the mesentery during colectomy. The UCA has also been used to shell the gallbladder off the liver bed. However, in this application a tendency exists for the UCA to dissect the collagen sparse liver bed itself. Furthermore, it leaves collagenous tissue strands and blood vessels intact. Since the UCA is not a good cutting or coagulating tool, other modalities such as electrosurgery are necessary for complete hemostasis, and scissors for cutting. In this regard, electrosurgery has been added to some laparoscopic UCA (CUSA, CEM® Valleylab, Inc.) to limit instrument changes.

THE ULTRASONICALLY ACTIVATED SCAPEL

The UAS, or Harmonic Scalpel, cuts and coagulates tissue at a frequency of 55.5 kHz. The UAS is composed of a microprocessor controlled, high frequency switching, power supply generator(Figure 2). The microprocessor senses changes in the acoustic system to maximize power and alert the user of system faults.[3] The UAS also consists of a hand piece housing the acoustic transducer, which transmits a mechanical vibration to an extending rod, housed either in a 10 mm hollow stainless steel tube or sheathed with plastic to produce a 5 mm diameter. Finally, blades of various shapes are attached to the extending rod (Figure 2).[3] The extending rod and blade vibrate harmonically at a frequency of 55.5 kHz with a maximum longitudinal displacement of 80 µm of the blade tip.[3]

Maximum hemostasis is achieved with a blade having a large, flat surface area, with a blunt edge. A blade of small surface area with a blunt edge applies the vibrational force to such a small area that it causes cavitational fragmentation and cavitational cutting rather than coagulation. Based on initial work in animals and confirmed in human laparoscopic cholecystectomies, the hook-spatula appears to be the optimum blade for laparoscopic use in that it provides an excellent balance of cutting and coagulating. The inner radius of the hook is sharp thereby offering maximum cutting. The outer, non-sharp radius, and relatively large surface area provided by the spatula configuration offer excellent coagulation. When coagulation is not easily obtained with the hook-spatula because of an awkward angle of application, a ball tip is used. Coagulation is enhanced with the ball tip because there is no edge to the ball and a relatively large surface area available to the tissue at a variety of angles (Figure 2 and 3).[4]

We have now performed over 400 laparoscopic cholecystectomies with these two types of UAS blades. Study of our initial 200 patients revealed there was no difference in operative time or length of hospital stay when compared to patients treated with electrosurgery. In addition, UAS resulted in a very low perforation rate of the gallbladder (2%), stable hematograms, no significant postoperative bleeding and never a need to evacuate smoke. Although at times the atomization of fluids during activation of the scalpel did reduce clear visualization of the operative field, it was transient and did not significantly impair our ability to safely continue dissection. Most importantly, only two of the initial 100 patients needed supplemental electrosurgical coagulation[5] and all of the next 300 patients were treated with UAS alone.

The ultrasonically activated scalpel offered three significant advantages over electrosurgery with respect to hemostasis. The first relates to the self cleaning nature of the ultrasonically activated

Figure 3a, b, c. Coagulation of a sinusoid vein in the liver bed:

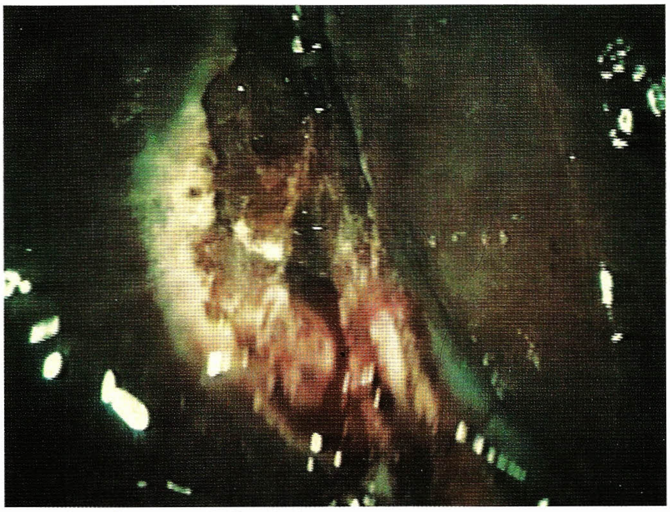

Figure 3a. Bleeding site in liver bed.

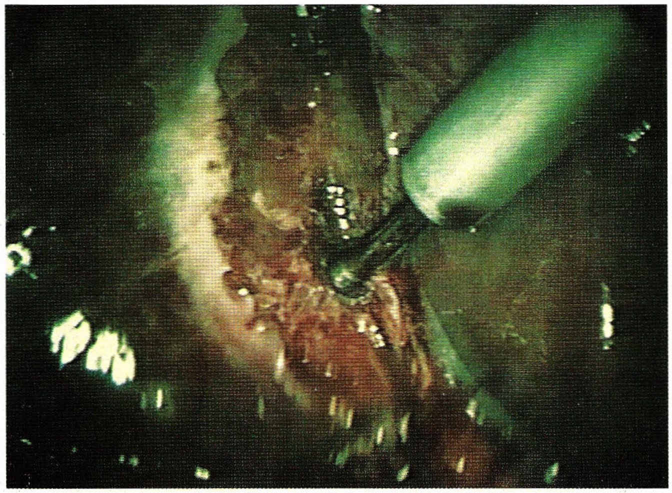

Figure 3b. Activation of the 10 mm ball coagulator for 5 second.

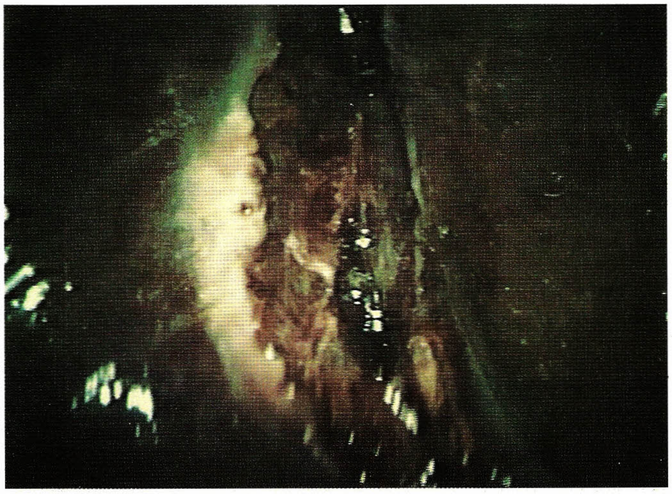

Figure 3c. Bleed stopped and mild charing noted.

scalpel. Tissues that are coagulated do not stick to it because of its vibration and low heat generation. This eliminated the common situation with electrosurgery in which hemostasis is achieved during contact with the electrosurgical probe, but once the probe is removed the clot comes with it, resulting in renewed bleeding. The second advantage is the lack of smoke generation during coagulation. Finally, coagulation with the ultrasonically activated scalpel relies on coaptation of the bleeding site. This coaptation immediately stops the bleeding which results in better visualization of the area. This feature also allows coagulation of the vessel from the side. In electrosurgery, the blood vessel is usually not coapted significantly because of the concomitant reduction in power density as the surface area of contact increases, because of the need for establishing arcs for fulguration[6] and because coaptive pressure with electrosurgery often leads to cutting instead of coagulation. The blood within the vessels walls has a high heat capacity. This allows one side to coagulate prior to the other with resultant bleeding from a hole in the wall of the vessel that was in contact with electrosurgery. In contrast, the ultrasonically activated scalpel relies on pressure and coaptation of the vessel walls for maximum energy transfer to the tissue. Thus the vessel is sealed together without bleeding from the surface closest to the blade.

Ultrasonic coagulation and sealing of vessels is achieved by tamponading and coapting with a denatured protein coagulum. However, where electrosurgery and lasers form the coagulum of denatured protein by heating the tissue, the UAS mechanically denatures protein by disrupting hydrogen bonds, and therefore, breaking down the tertiary structure of the protein, in combination with heat generated as a result of internal tissue friction that results from the high frequency vibration. Charring and desiccation of tissue are minimized. Vessels up to 2 mm are first coapted as pressure is applied with the side of the blade, and the blade vibrated for a brief period of time (2-3 seconds). Then the blade is rotated and the sharp edge used to transect the coagulated vessel.

The limited heat generation limits the zone of thermal injury. Animal studies at the University of Pittsburgh found the ultrasonically activated scalpel to cut and coagulate tissue without significant thermal damage.[7] Skin incisions made with the ultrasonically activated scalpel at the lowest power setting and cold steel scalpel healed almost identically and were significantly superior to electrosurgery.[7] The reduced tissue injury may explain the low incidence of gallbladder perforation during dissection with the UAS. Unlike electrosurgery in which energy is transmitted to all tissues that are in contact with the electrosurgical probe, the ultrasonically activated scalpel primarily cuts and coagulates tissue that is in contact with the blade and has pressure exerted on it. Therefore, as one elevates the peritoneum with the blade to cut it, there is little or no pressure on the gallbladder itself. This results in little energy being effectively transmitted to the gallbladder.

Another possible explanation for the low incidence of gallbladder perforation during dissection is the lack of charring and melting of tissues with the scalpel. The tissue planes remain distinct thereby allowing a clear visualization of the plane between the gallbladder and the liver bed.

The cutting mechanism for the UAS, like the UCA, differs from that of electrosurgery or laser surgery. The first cutting mechanism for the UAS is the cavitational fragmentation noted with the UCA, but to a much lesser degree. Tissue planes separate ahead of the blade of the UAS, which actually allows visualization of the tissue plane as it is being dissected. In contrast to the mechanism of thermal desiccation on which electrosurgery and laser surgery rely, the second, concurrent mechanism of cutting with the UAS is the "power cutting" offered by a relatively sharp blade vibrating 55,500 times per second, over a blade excursion of 80 μm.

Figure 4a, b, c. Division of tissue with the hook blade.

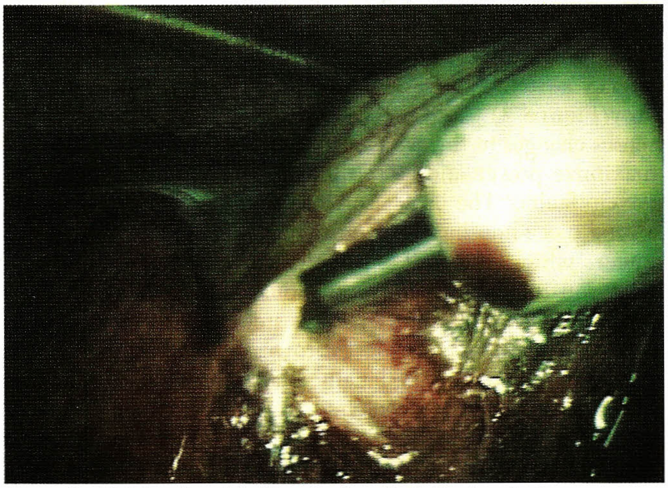

Figure 4a. Division of gallbladder attachments to the liver bed.

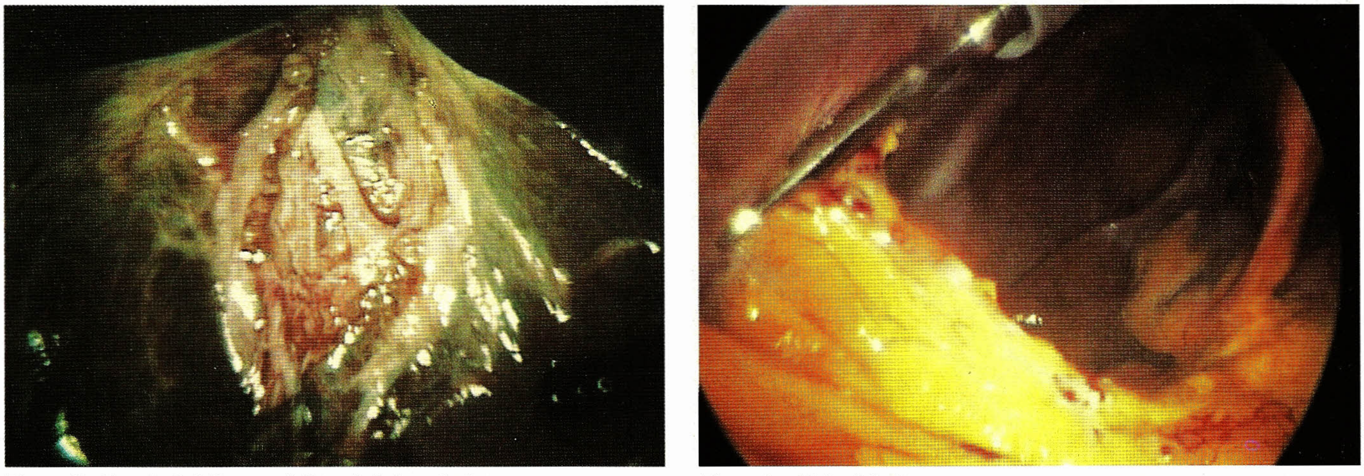

Figure 4b. Liver bed at the completion of cholecystectomy.

Figure 4c. Adehesiolysis.

This is best demonstrated in proteinaceous tissue, such as collagen or muscle rich tissues (Figure 4).

Since pressure and coaptation are key to the coagulative ability of the UAS, the dissection hook blade of the UAS is unable to seal unsupported tissue, such as blood vessels and hollow visci not already under traction and which cannot be coapted by applying pressure of the blade to the structure. This limitation is overcome by the ultrasonically activated coagulating scissor (Laparosonic® Coagulating Shears, or LCS™, by UltraCision, Inc., Smithfield, RI). This instrument consists of a hollow cannula attached to a pistol-grip handle through which a 33 cm blade shaft is extended. The blade at the distal end has both a sharp and a blunt edge, selection of which is made by rotating a proximal ring at the grip (Figure 5). An opposing passive (not ultrasonically activated) tissue pad is clamped against the vibrating blade by squeezing the pistol grip. This presses tissue against the active, vibrating blade thereby allowing effective coupling of the tissue with the mechanical energy transmitted via the vibrating blade. Control of cutting speed, or preference for coagulation versus cutting, is achieved when blade edge choice is combined with modulation of power levels (one through five) delivered to the blade, and with grasping force applied to the pistol grip. This device allows unsupported tissue to be grasped and coagulated without difficulty, or coagulated and cut, like a scissors with electrosurgery. The LCS™ tissue grasping shears have been able to successfully coagulate vessels in animals up to 5 mm in diameter[8] (Figure 6).

Investigators at the University of Pittsburgh found that porcine skin incisions made with the UAS or cold steel scalpel healed almost identically, and both were significantly superior to electrosurgical incisions.[7] In thermal injury studies in the pig model, lateral thermal damage with the UAS was limited, and consistent, while ES lateral thermal damage continued to increase over time until a maximum was reached(unpublished data). When compared with electrosurgery (ES) and laser surgery (LS) in the porcine model for laparoscopic cholecystectomy, it has been demonstrated that the UAS results in decreased thermal damage to adjacent tissue. Furthermore, a marked reduction in postoperative adhesions to the liver bed following laparoscopic cholecystectomy with the ultrasonically activated scalpel (22%) was noted when compared to electrosurgery (66%) or laser surgery (78%)(9). Tulandi, et.al., found that the UAS produced no more adhesions than a regular scalpel blade, in their study conducted in the rat model.[10] Speed of cutting of the UAS has been equal to or greater than that of ES, with no difference in operative time, complications or bleeding.[9] Advantages of the UAS over ES and LS in the porcine laparoscopic cholecystectomy model have been duplicated in the porcine seromyotomy models, as well, demonstrating four times less lateral thermal damage with the UAS than with ES.[11]

Since this developmental work in the laboratory, use of the UAS clinically has demonstrated at least equal efficacy and superior safety to ES in laparoscopic cholecystectomies in man.[12] In addition to laparoscopic cholecystectomy, because of its ability to both cut and coagulate, the UAS has been used in other general surgical procedures, including seromyotomy, appendectomy, herniorrhaphy, and liver biopsy. The LCS™ has been a particularly enabling technology for dissection of the mesentery in laparoscopic colectomy[13] and in dividing the short gastrics in Nissen fundoplication. Gynecological applications with the UAS include endometrial excision and ablation, myomectomy and BSO. The LCS™ is an enabling technology in LAVH, allowing greatly reduced reliance on linear staplers, and decreased instrument exchanges.[14, 15]

The primary perceived disadvantage of the UAS noted during its use is that the ultrasonically activated scalpel was slower during coagulation when compared to electrosurgery. Three to five seconds are usually required to coagulate most bleeding sites. Despite this there is no overall significant difference in operative time between patients treated with the UAS and those with electrosurgery because fewer instrument changes are required and more rapid cutting is achieved with the ultrasonically activated scalpel. Although the time of coagulation is considered a disadvantage, we believe this may actually represent an advantage, since it is this slower, controlled coagulation which is responsible for the absence of charring and melting of tissues that maintains a clear discrimination of tissue planes.

SUMMARY

Ultrasonic energy can be used as a safe means of tissue cutting, coagulation and emulsification during laparoscopic surgery. The UCA is tissue

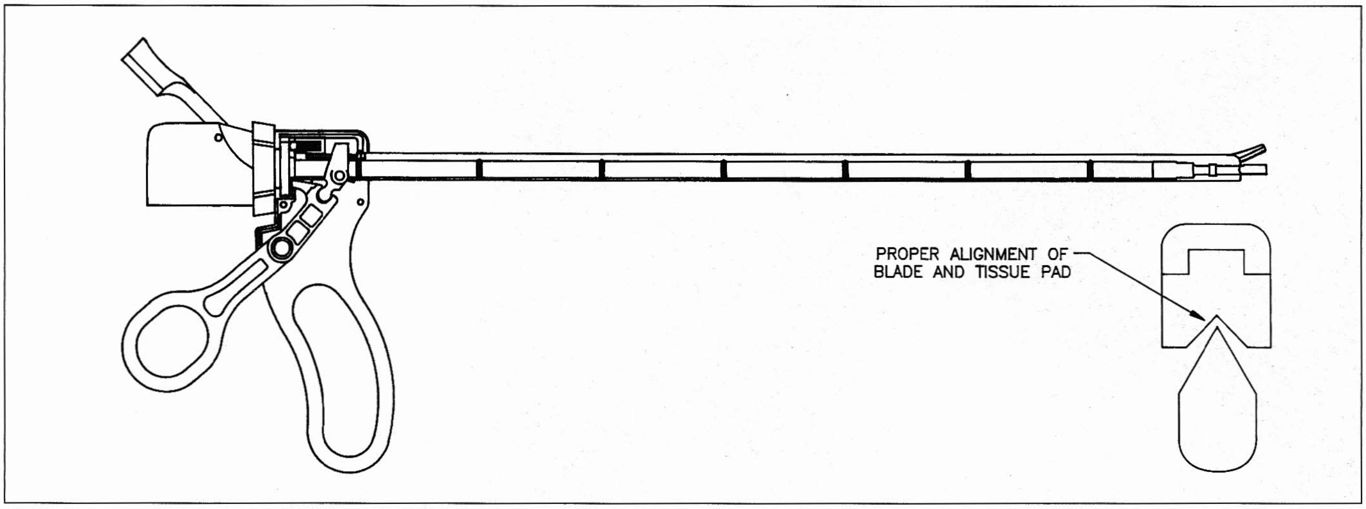

Figure 5. Laparoscopic® Coagulating Shears (LCS™).

Figure 6a, b, c. Application of the Laparosonic coagulating shears in laparoscopic surgery.

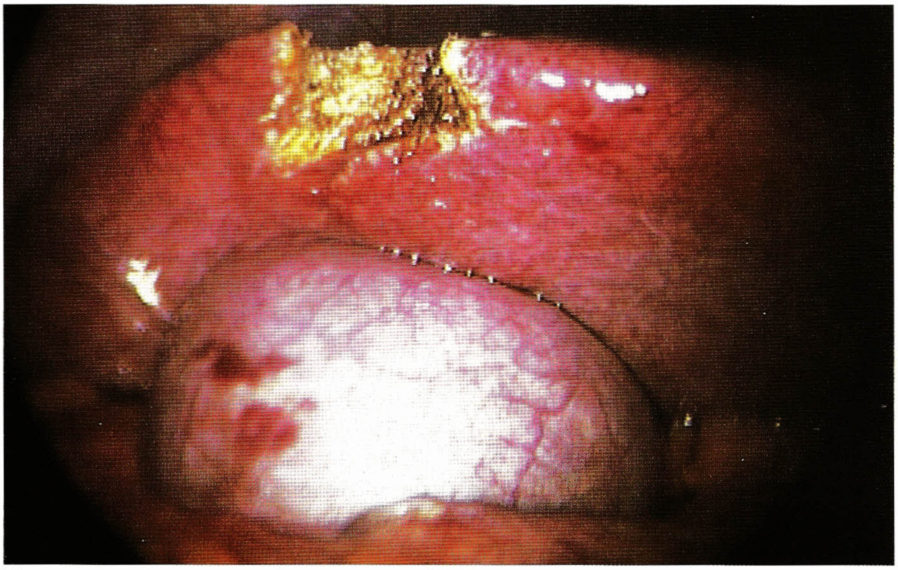

Figure 6a. Completion of wedge liver biopsy with LCS™.

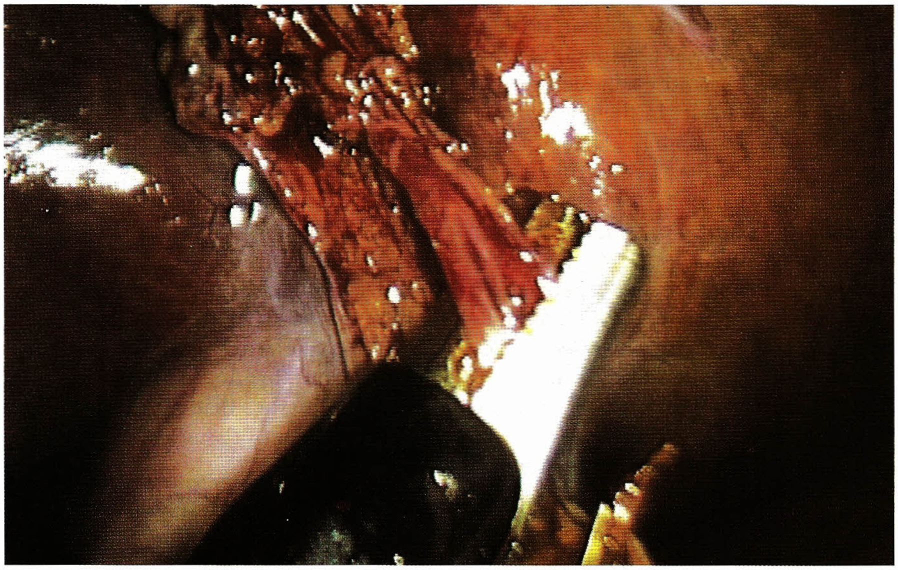

Figure 6b. Division of cystic artery with the LCS™.

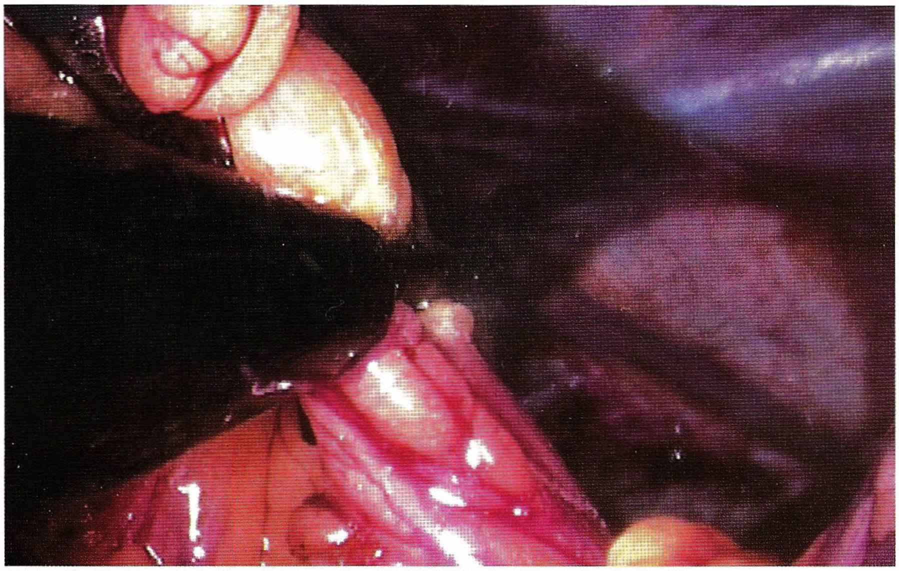

Figure 6c. Division of short gastric vessels with LCS™ during Nissen fundoplication.

selective, resulting in safe dissection of high water content tissues, with preservation of nerves, arteries and other collagen-rich (water sparse) structures. It is useful and safe in open surgical procedures such as tumor debulking, neurosurgery, and liver surgery and in laparoscopic applications such as colectomy because of it's ability to skeletonizing tissue through emulsification. Since the UCA is not a good cutting or coagulating tool, other modalities such as electrosurgery are necessary for complete hemostasis, and scissors for cutting.

The UAS (as well as LCS™) eliminates many of the disadvantages of monopolar electrosurgery. It is able to cut and coagulate tissue with minimal or no generation of smoke. Thus, there is minimal disruption of visualization during the procedure and no need to evacuate the pneumoperitoneum to clear accumulated smoke. In addition to the inconvenience associated with smoke generated by electrocautery or laser devices, the patient's exposure to smoke itself has been shown to cause clinically elevated levels of methemoglobin and carboxyhemoglobin.[16] Atomization of fluid resulting from tissue disruption creates a transient mist, this settles out of the field of view immediately, and does not significantly impair the visual field. Since there is no electrical current flow through the blade or patient, the UAS eliminates the risks of electrical shock, thermal injury, or capacitive coupling, to the patient and surgeon, and in fact, can be used as a blunt dissector when not activated. The ability to consider alternate insufflation gasses, such as nitrous oxide, is also a benefit, since no electrical current is applied to the field, so risk of explosion is greatly minimized.[17]

The 10 mm hook blade with which we have the most experience in laparoscopic cholecystectomies, is now a reusable blade, addressing the concerns of cost containment in most institutions today. Introduction of the 5mm blades has allowed use of smaller trocars, minimizing trauma in gynecological procedures and some GI procedures, such as herniorrhaphy, while providing the same safe cutting and coagulation.[18] Finally, the LCS™, allows unsupported tissue to be grasped, coagulated, and safely transected, with minimal lateral thermal tissue effect, and no stray current to adjacent organs.[8]

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