PEAK PlasmaBlade and Pulsed Plasma Technology: A Summary of Preclinical Results

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TITLE	MODEL	SUMMARY	PRESENTED
Comparative healing of surgical incisions created by standard electrosurgery, PEAK PlasmaBlade, and standard scalpel blade	*In vivo* porcine skin	PlasmaBlade showed: · 75% less thermal damage vs. ES · 66% less scarring vs. ES · 63% greater wound strength vs. ES · 60% less bleeding vs. scalpel · Less inflammation vs. ES	Podium. The American College of Surgeons Annual Meeting (2007) New Orleans, LA
Evaluation of PEAK PlasmaBlade for obstetric and gynecologic surgery vs. traditional electrosurgery	*Ex vivo* human abdominal skin and *in vivo* porcine skin	PlasmaBlade caused significantly less thermal damage vs.: · Uncoated electrosurgery tip · PFTE (Teflon) coated electrosurgery tip · Epitome® Scalpel (fine wire, ceramic)	Poster. The American College of Obstetrics and Gynecology Annual Meeting (2008) New Orleans, LA
Preservation of tissue integrity and decreased tissue damage with PEAK PlasmaBlade	*In vivo* porcine skin	Histological scoring for injury showed no difference between PlasmaBlade and scalpel; both were significantly less than the ES group. Scar formation was similar between scalpel and PlasmaBlade, but significantly less than ES.	Podium. The Plastic Surgery Research Council Annual Meeting (2008) Springfield, IL
Evaluation of the PEAK PlasmaBlade in Neurosurgery Applications Compared to Standard Electrosurgical Tools and Standard Scalpel Blade	*In vivo* bovine brain	Histological evaluation of the brain tissue showed that PlasmaBlade cuts and spot coagulation produced little collateral damage compared to cuts made with an electrosurgical needle, or coagulation from bipolar cautery.	Poster. Congress of Neurological Surgeons Annual Meeting (2007) San Diego, CA
Evaluation of PEAK PlasmaBlade Needle for Plastic and Reconstructive Surgery Compared to Standard Electrosurgery	*In vivo* porcine skin, bovine cartilage, and *ex vivo* human abdominal skin	Histological evaluation of human skin, porcine skin, and cartilage samples showed that the PlasmaBlade Needle cuts produced minimal collateral damage (about 50% of the thermal damage demonstrated by the Colorado Needle). In the porcine skin cuts, bleeding was significantly reduced in the PlasmaBlade Needle versus scalpel wounds while bleeding was similar to cuts produced with the Colorado Needle.	Poster. American Academy of Facial Plastic and Reconstructive Surgery Annual Meeting (2008) Chicago, IL

INTRODUCTION

The PEAK PlasmaBlade™ tissue dissection devices are a family of new surgical instruments that use PEAK Surgical's proprietary Pulsed Plasma Technology™ for soft-tissue cutting and coagulation with minimal thermal injury. These PlasmaBlades work in conjunction with the PULSAR™ Generator to create the PEAK Surgery System (Fig 1).

Working with a number of surgeon investigators, PEAK Surgical has conducted preclinical studies of the PEAK Surgery System in a variety of *in vivo* and *ex vivo* animal models. Overall, these studies have demonstrated that the PEAK Surgery System has a wide range of capabilities. The system can cut with the same precision as a scalpel with minimal to no thermal damage at the low settings, but also can be dialed up to deliver hemostasis capability equivalent to conventional electrosurgical technology. This paper presents a summary of the experimental approaches, results and conclusions from the preclinical studies performed using the PEAK Surgery System. The key features and benefits determined from these studies are summarized in Table 1.

Figure 1.

CUT	SET POINT	COAG
· 60% less bleeding than a scalpel · Equivalent residual tissue damage to the scalpel's mechanical crush zone · 75 to 90% less thermal damage than traditional electrosurgery	1 2 3 4 5	· Equivalent hemostasis to traditional electrosurgery · 50% less thermal damage compared to traditional electrosurgery
· Equivalent simultaneous hemostasis to traditional electrosurgery · 50% less thermal damage	6 7 8 9 10	

TABLE 1: Setting-dependent properties of the PEAK Surgery System

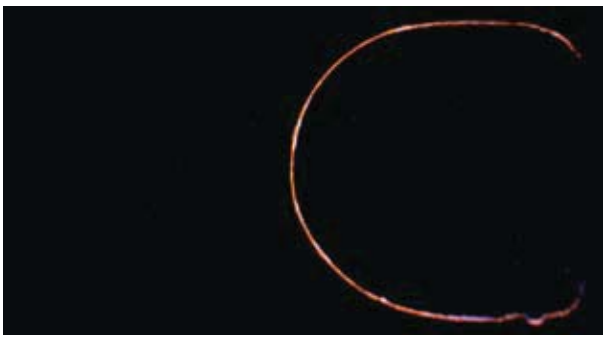
RESULTS

A wide range of outcomes were evaluated in a variety of studies and included system operating temperature, thermal effect, bleeding control, cutting ease and smoke generation during acute use. Chronic studies evaluated outcomes such as wound scarring, wound strength and inflammatory response. Studies were performed on a variety of tissues including skin, fat, fascia, and muscle. Highlights of the results from these various studies are discussed in more detail below.

Operating Temperature and Corresponding Thermal Effect:

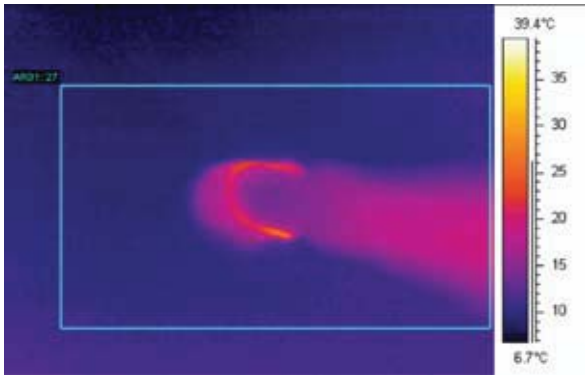
Results of preclinical research have shown that, due to the highly insulated electrode configuration (Fig. 2) and the use of pulsed electrical waveforms, the PEAK Surgery System uses about one-half the amount of energy (watts) used by traditional electrosurgical technology to achieve similar cutting and coagulation results.

This reduction in energy used has been found to translate into operating temperatures that are about one-half those of traditional electrosurgical technologies (Fig. 3), with a corresponding reduction in heat transfer and an approximately 50 to 90 percent reduction in the depth of thermal damage in adjacent tissues (Fig. 4).

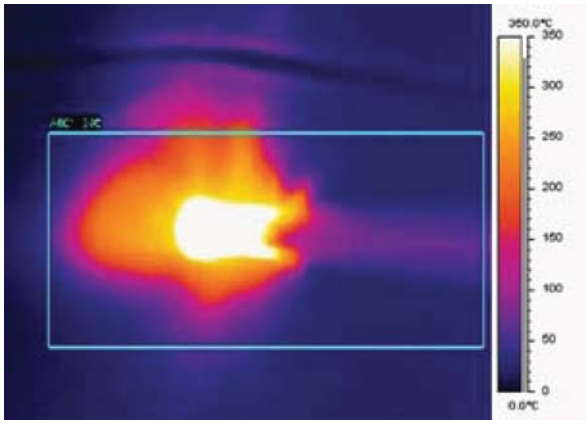


Plasma discharge along the exposed edge of the blade

Figure 2.



PEAK Avg temp 40 - 50 C



Electrosurgery Avg temp 250 - 350 C

Figure 3.

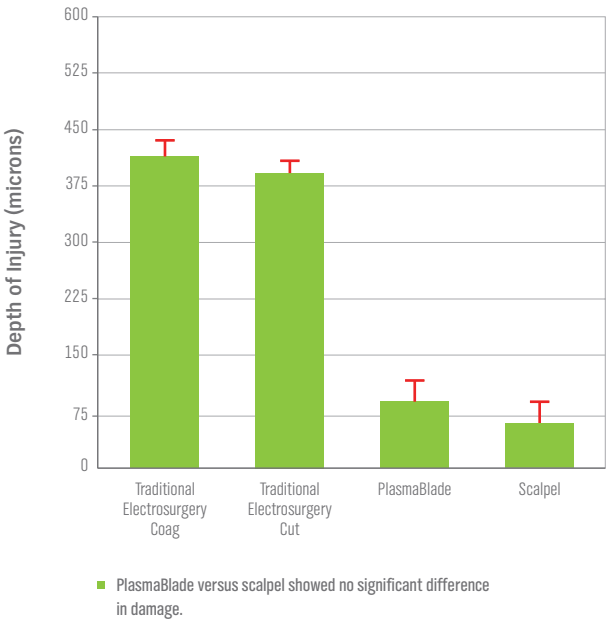


Figure 4.

Bleeding Control:

Even though the PEAK Surgery System causes significantly reduced levels of thermal damage compared to traditional electrosurgery, significant bleeding control is still built into the technology. Preclinical work has shown that incisions created while on the "low cut" settings bled 60 percent less than with a scalpel, while on the higher cut settings and in coagulation mode, the PEAK Surgery System achieved hemostasis equivalent to traditional electrosurgery but with half the amount of thermal injury (Fig. 5).

Bleeding Evaluation

Bleeding Following Incision for 60 Seconds

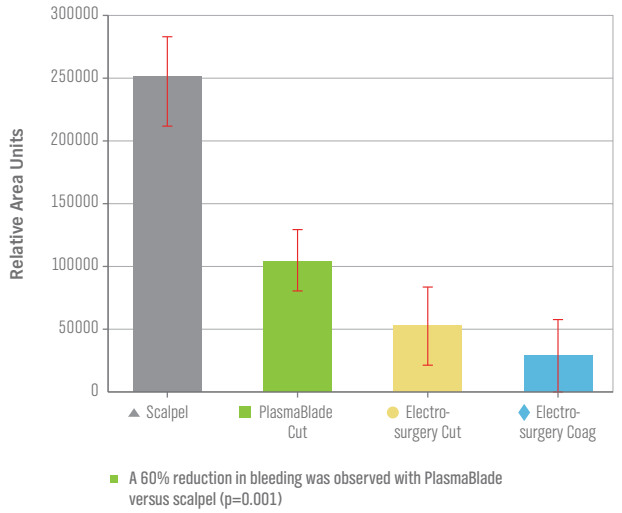
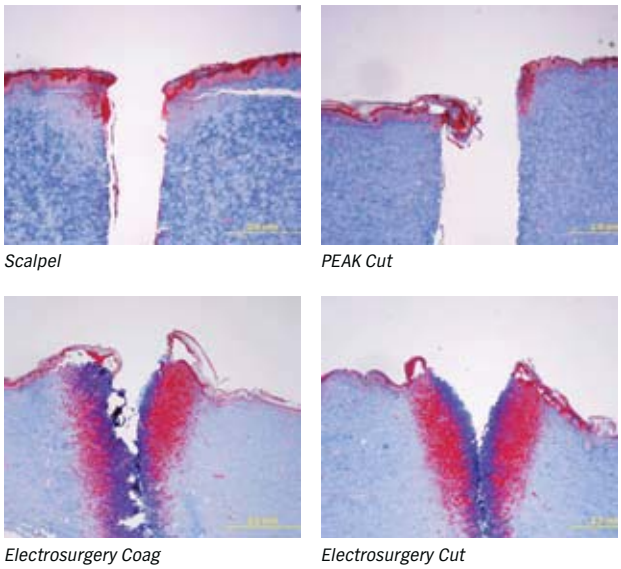


Figure 5.

Acute Thermal Damage Histology

porcine skin



Scalpel

PEAK Cut

Electrosurgery Coag

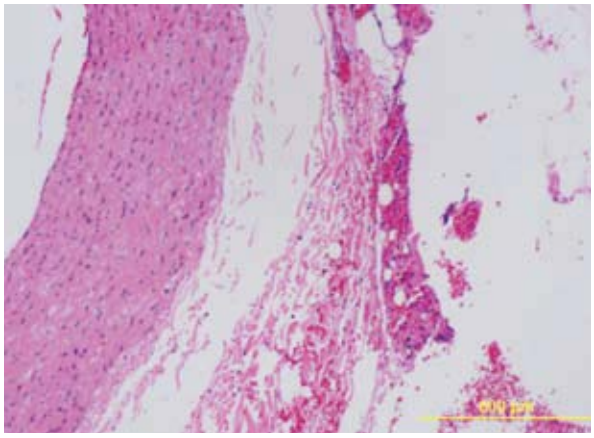
Electrosurgery Cut

Figure 6.

Histological Evaluation

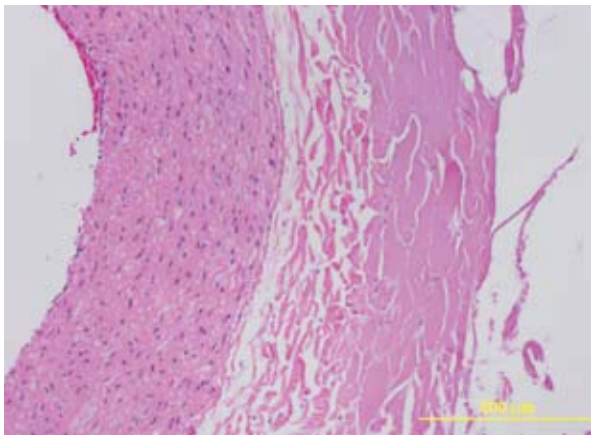
porcine thoracic artery

PEAK PlasmaBlade 10X



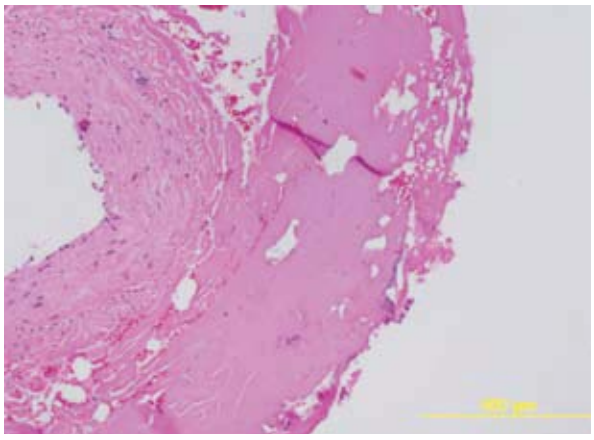
Edge of PlasmaBlade cut is clean, thermal damage 50-125 um

Harmonic Scalpel® 10X



Zone of damage 100-300 um

Electrosurgery 10X



Zone of thermal necrosis 250-500 um

Figure 7.

Ease of Cutting:

The PEAK Surgery System has been shown to cut easily and smoothly, requiring just one-quarter of the force needed for cutting tissue with a scalpel and one-half that needed for cutting with traditional electrosurgical technologies used in "cut" mode (Fig. 8). The PlasmaBlade has also been shown to operate in both wet and dry fields, allowing a surgeon to maintain superior cutting performance even through a bloody surgical field (data on file at PEAK Surgical).

Smoke Generation:

Another important preclinical finding is that the PEAK Surgery System generates significantly less surgical smoke than traditional electrosurgery when used in cut mode (settings 1 through 8, data on file at PEAK Surgical). As discussed in the literature, surgical smoke is a potential hazard to the health of both surgical staff and patients, and numerous agencies have called for measures to reduce surgical smoke exposure in the operating room (Occupational Safety and Health Administration, 2008; Barrett, 2003; Alp, 2006; Bigony, 2007).

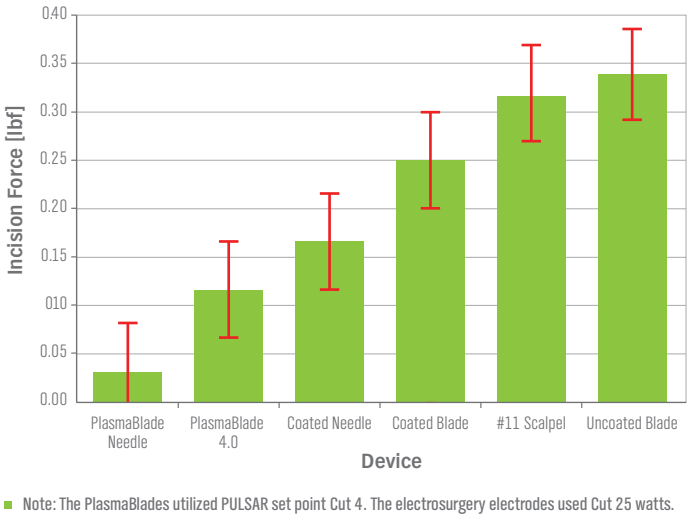


Figure 8.

Wound Healing:

Two chronic studies were performed to evaluate wound healing up to six weeks. One study was performed in a porcine skin model, and one in a rat fascia model. Both studies showed that wounds created by the PEAK Surgery System healed virtually identically to scalpel wounds, and that reduced thermal injury from the PEAK Surgery System resulted in a reduction in inflammatory response and an increase in wound strength.

The porcine skin study found that the PlasmaBlade was comparable to a scalpel in wound healing profile, with a 75 percent reduction in acute thermal damage and significantly reduced inflammatory response (as measured by inflammatory cell infiltration). Meanwhile, the burst strength of wounds created by the PEAK Surgery System was essentially identical to those created by a scalpel and were three times as strong as the electrosurgery wounds at six weeks ($p<0.005$) (Figs. 9,10).

In the fascia study, burst strength at one week in wounds created by the PEAK Surgery System was essentially equivalent to scalpel wounds, and was significantly better than traditional electrosurgery. Inflammation was also reduced with the PlasmaBlade relative to traditional electrosurgery (Figs. 11,12).

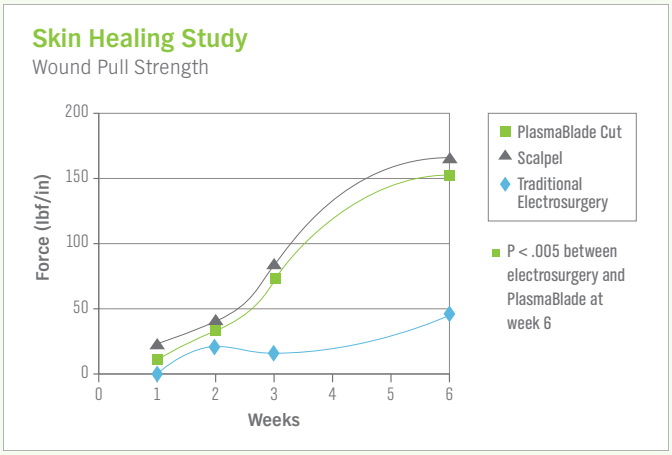


Figure 9.

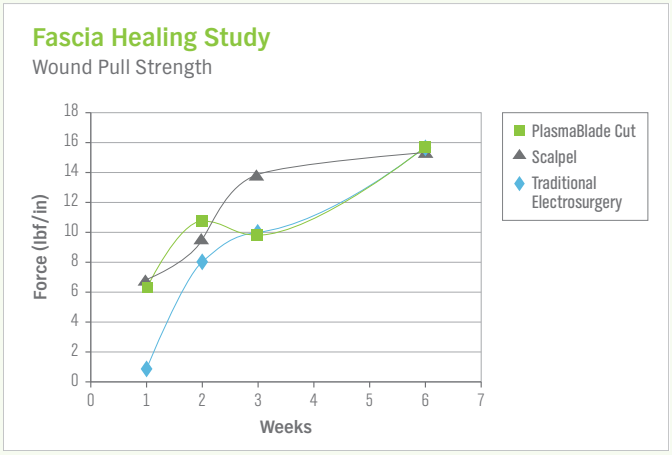
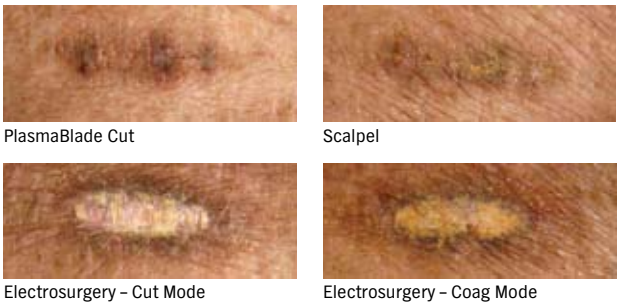


Figure 11.

Scarring:

Results of the chronic skin healing study also demonstrated that wounds created with the PlasmaBlade heal well, and the scar looks virtually identical to that of a wound created by a scalpel. When compared to traditional electrosurgery, the PlasmaBlade had 66 percent less scarring (Fig. 13).



Note: Scar formation at six weeks post-incision was comparable between PlasmaBlade and scalpel incisions, but significantly less that in the incision made by traditional electrosurgery (p=0.02 and 0.03, respectively)

Figure 13.

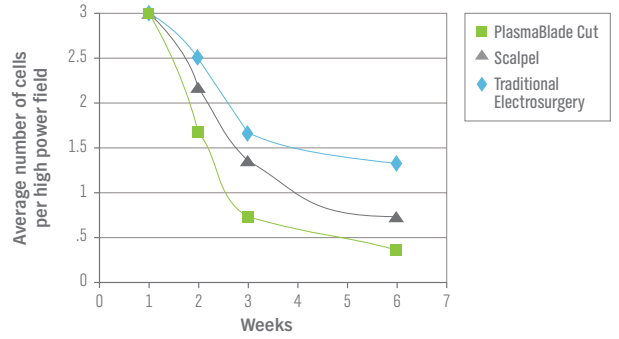


Figure 10.

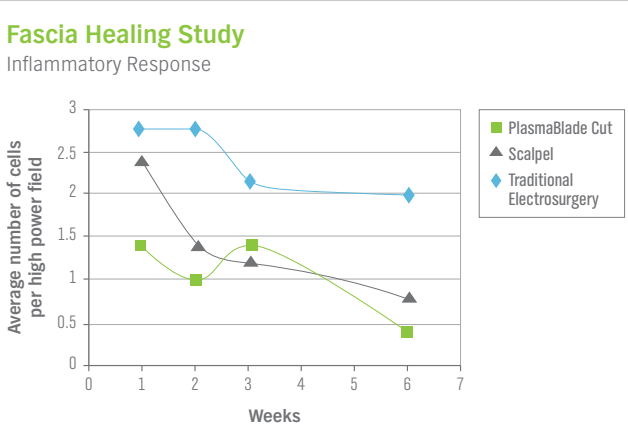


Figure 12.

Independent Research Studies Support PEAK Surgical's Findings:

Also of note, a group of investigators at Stanford University has independently published work investigating the use of an earlier version of the PEAK Pulsed Plasma Technology in human *ex vivo* and *in vivo* models for ophthalmological applications. (please see studies in Appendix A at the end of this paper). The technology was successfully evaluated in humans for vitreoretinal and cataract surgeries providing further demonstration of the extreme precision of which the technology is capable.

DISCUSSION

The many preclinical studies conducted using the PlasmaBlade and the PEAK Surgery System have demonstrated the PlasmaBlade's ability to cut a variety of tissues with scalpel-like precision and control bleeding as well as traditional electrosurgery, but without all the thermal injury. These findings suggest that use of the PlasmaBlade may be beneficial in a number of ways:

1. Potential for reduction in incidence of collateral tissue injury

As described previously, the PlasmaBlade has the potential to reduce the incidence of unintentional tissue injury because the pulsed electrical waveforms and highly insulated cutting electrode are specifically engineered to minimize collateral thermal damage. Preclinical studies have shown that the PlasmaBlade's cutting is more comparable to the incision made by a traditional scalpel than to conventional electrosurgery, and the thermal damage zone has typically been reduced in depth by a factor of two to ten, depending on the tissue tested and the instrument settings.

Additionally, cuts made with the PlasmaBlade were achieved with much less force and with significantly less tissue sticking than a traditional scalpel or electrosurgical tool during preclinical experiments. The tissue did not have to be put under tension during cutting, suggesting that the PlasmaBlade may allow greater control over the depth of cutting and reduce the chances of slippage, tearing, unintentional extension of incisions and accidental cutting of adjacent tissues or organs.

2. Potential for reduced bleeding, improved wound healing and reduced scarring

Surgeries that require a scalpel's precision must nevertheless have a method for controlling bleeding during surgery, both for the sake of minimizing blood loss and for maintaining adequate visualization of the field. While pre-clinical data suggest that the PlasmaBlade possesses many of the positive cutting qualities of a traditional scalpel, its observed ability to control bleeding makes it an appropriate device for use on numerous soft tissues. Unlike a scalpel, the PlasmaBlade has the coagulation capabilities of conventional electrosurgery, so that bleeding can be controlled without switching instruments.

Furthermore, the results of skin and fascia healing studies suggest that surgeries with the PlasmaBlade may have a very desirable wound healing profile. The PlasmaBlade incisions healed virtually identically to the scalpel wounds and the reduced thermal injury from the PEAK Surgery System resulted in a reduction in inflammatory response and an increase in wound strength. With fascia tissue, early return of wound strength is important to avoid wound herniation.

These findings corroborate work previously published in the scientific literature that shows an association between thermal injury to the tissue and compromised surgical incision wound healing (Gelman et al.,1994).

3. Potential to increase operating room efficiency and/or staff safety

A number of mechanisms can be postulated by which the PlasmaBlade may also enable greater surgical efficiency and enhanced safety for the OR staff. Fast, smooth cutting with integrated bleeding control could potentially shorten the amount of time needed for a given procedure, as could the ease with which the PlasmaBlade can be wiped clean with a simple piece of gauze (a scratch pad is not required).

During preclinical studies, tissue could be cut with precision, coagulated, and directly manipulated with the PlasmaBlade, without concern of a loss of performance when the surgical field filled with blood, liquefied fat or other fluids. With all of these capabilities in one instrument, the PlasmaBlade could be used without repeatedly switching tools during surgery, improving workflow efficiency and potentially reducing the chance for sharps injuries or burns encountered when switching between a scalpel blade and an electrosurgery device.

And, because the PlasmaBlade cuts tissue via a plasma-mediated mechanism, the system produced little to no surgical smoke during preclinical studies when used in "cut" mode (data on file at PEAK Surgical). It is currently estimated that more than 500,000 surgeons, nurses and other OR staff are exposed to surgical smoke every year, with potentially serious long term health consequences. This gaseous byproduct of thermal electrosurgery contains a complex mixture of intoxicants, toxins, carcinogens and irritants such as carbon monoxide, acrylonitrile, hydrogen cyanide and benzene and has been estimated to have the mutagenicity of cigarette smoke. Surgical smoke also contains aerosolized viable and non-viable cellular material, which have been demonstrated to carry intact, infectious virions and could represent a vehicle for transmission of human papillomavirus (HPV), human immunodeficiency virus (HIV) and other dangerous viruses. The U.S. Occupational Safety and Health Administration, the Association of periOperative Registered Nurses and others have issued warnings regarding the potential health risks to those exposed to surgical smoke, and have published guidelines that recommend the purchase of equipment to mitigate exposure (Occupational Safety and Health Administration 2008; Barrett, 2003; Alp, 2006; Bigony, 2007).

4. Potential economic benefits

Although the disposable PlasmaBlades are more expensive per unit than conventional electrosurgical pencils or electrodes, they are similarly priced to ultrasonic and other advanced energy devices, and the PEAK Surgical System is significantly less expensive than laser based surgical systems. Furthermore, it is possible that the potential efficiency and safety enhancements discussed above could translate to long term economic savings that would more than offset the initial investment in equipment.

CONCLUSION

Taken all together, these results have demonstrated the system's utility in a wide number of soft tissue types and in delicate applications where the PlasmaBlade may provide a marked improvement over conventional electrosurgical technologies, including:

- Surgical incision of skin with minimal bleeding, tissue injury and scarring and improved surgical incision wound healing *(in vivo* porcine and *ex vivo* human skin models)
- Nerve- and vasculature-sparing dissection (porcine internal mammary artery, rabbit and human retinas)
- Dissection of tissues that would be encountered as successive layers during surgery, e.g. skin, fat, muscle, fascia, etc.
- Extremely delicate tissue dissection (bovine lenses and capsules, porcine corneas; human cataracts and retinas *in vivo* as studied by an independent group at Stanford University)

Additional research studies are ongoing, but the preclinical results to date suggest that the PlasmaBlade may be useful in a wide range of procedures in which the minimization of thermal damage is highly desirable.

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Gelman, C. L., Barroso, E. G., Britton, C. T., Haklin, M. F., & Staren, E. D. (1994). The Effect of Lasers, Electrocautery, and Sharp Dissection on Cutaneous Flaps. *Plast Reconstr Surg,* 94, 829.

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APPENDIX A: Bibliography

Presentations

- "Comparative Healing of Surgical Incisions Created by a Standard Electrosurgery, PEAK Electrosurgical Cutting Tool, and Standard Scalpel Blade." SA Loh, GA Carlson, EI Chang, EJ Huang, and GC Gurtner. Podium presentation at the American College of Surgeons Annual Meeting, October 9, 2007, New Orleans, LA.
- "Comparative Healing of Surgical Incisions Created by a Standard Electrosurgery, PEAK Electrosurgical Cutting Tool, and Standard Scalpel Blade." EI Chang, SA Loh, GA Carlson, E Huang, GC Gurtner. Podium Presentation at the Plastic Surgery Research Council 2008 Annual Meeting, May 28-31, 2008, Springfield, IL.

Posters

- "Evaluation of PEAK PlasmaBlade Needle For Plastic and Reconstructive Surgery Compared To Standard Electrosurgery." GS Keller, HL Rosenberg, E Huang, and GA Carlson. American Academy of Facial Plastic and Reconstructive Surgery Annual Meeting, September 18-21, 2008, Chicago, IL.
- "Evaluation of PEAK PlasmaBlade for Obstetric and Gynecologic Surgery vs. Traditional Electrosurgery." P Blumenthal, MT Jacobson, E Huang, GA Carlson, and JS Berek. American College of Obstetrics and Gynecology 2008 Annual Meeting, May 3-7, 2008, New Orleans, LA.
- "Evaluation of the PEAK Electrosurgical Tool in Neurosurgery Applications Compared to Standard Electrosurgical Tools and Standard Scalpel Blade." LM Shuer, GA Carlson, and S Taylor. Congress of Neurological Surgeons Annual Meeting, September 15-20, 2007, San Diego, CA.

Publications describing clinical use of the PEAK® technology

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- "Pulsed Electron Avalanche Knife (PEAK-fc) for Dissection of Retinal Tissue." Arch Ophthalmol. 2005; 123:1412-18.

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- Palanker D, Vankov A, Freyvert Y, and Huie P. "Pulsed Electrical Stimulation for Control of Vasculature: Temporary Vasoconstriction and Permanent Thrombosis." Bioelectromagnetics. 2008; 29:100-7.
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