The Effects of the PlasmaJet® System on Tissue

A review of tissue studies performed using the PlasmaJet® System and comparisons with electrosurgery techniques

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BACKGROUND: This report provides a summary of the tissue effects associated with the application of plasma energy from the PlasmaJet® System, an innovative device that provides a new energy source for use in surgery. Since the use of neutral plasma energy represents a novel approach to the cutting and coagulation of tissue, this paper reviews studies which assess the effects of the PlasmaJet on a range of living tissues and compares these effects with those observed using conventional electrosurgical technologies. METHODOLOGY: In order to describe the effects of the PlasmaJet System on tissue, three preclinical studies and four human studies were reviewed. The three preclinical studies included in this report tested the device on a range of tissues and included observations of both the tissue effect immediately following use of the technology and post-surgical histological findings. Four clinical studies which measured tissue effects associated with the use of the PlasmaJet System for gynecology, gynecological oncology and ovarian endometrioma procedures were also reviewed. CONCLUSIONS: The plasma energy from the PlasmaJet System has a remarkably gentle effect on tissue, providing a precise means of cutting and coagulating a tissue surface and generating a thin and flexible layer of sealed tissue with minimal thermal damage to the underlying and adjacent tissues. By contrast, the thermal damage produced by electrosurgery techniques is shown to cause deeper damage to the underlying tissue.

INTRODUCTION

Of the many conventional technologies that are available to aid surgeons with the dissection and coagulation of tissue during surgical procedures, most are based on the use of electrosurgery or alternatively ultrasonics. More recently, the use of pure and electrically neutral plasma has provided a new and potentially more useful energy source. A key consideration when selecting which of these technologies to use is the amount of thermal spread and the depth of tissue necrosis produced by the device, since the need to protect surrounding tissues and organ systems is an important consideration in reducing post-operative complications.

THE PLASMAJET® SYSTEM

The PlasmaJet System (Plasma Surgical, Inc. Roswell, Georgia, USA) introduces a new surgical technology which is designed to facilitate cutting, coagulation and ablation of tissue. This technology provides a unique and novel approach to producing these tissue effects that offers a series of advantages over the use of electrosurgery and argon beam coagulation. The PlasmaJet System uses a low DC voltage applied between internal bipolar electrodes to produce highly energetic pure argon plasma that is electrically neutral. When the plasma comes into contact with tissue, it rapidly gives
up its energy in three useful forms; first as light that is useful for illuminating the surgical field in laparoscopic procedures, secondly as heat that results in coagulation of bleeding surfaces, and thirdly as kinetic energy, which is harnessed to cut and ablate tissue. The kinetic energy produced by the device first removes blood and liquids from the tissue surface. This is followed by the transfer of thermal energy to the tissue resulting in the formation of a thin and flexible yet complete sealing layer. This device is currently utilized for a wide variety of surgical procedures including gynecology, surgical oncology, plastic surgery, thoracic surgery, hepatic and general surgery.

Numerous studies have been conducted to assess the tissue effect of the PlasmaJet System and to determine the depth of tissue penetration associated with the use of this device compared to conventional electro-surgical methods of tissue cutting and coagulation. In order to summarize the findings from these studies we report below on a compilation of the results from these studies.

PRECLINICAL STUDIES

Several preclinical studies designed to identify the tissue effect of the PlasmaJet System have been conducted. Parhomenko et al. identified the differential effect of this technology on tissue compared to the use of argon enhanced electrosurgery and saline-coupled electrosurgery. The objective of their studies was to determine the effect of these technologies, when used for coagulation, on a range of different tissues. They compared the tissue effects immediately after surgery and at days 10 and 21 following surgery.

A second preclinical study by Suslov et al. examined the tissue effect associated with the use of the PlasmaJet System for both cutting and coagulation of tissue in a porcine model.

The tissue effect of the device was compared with those of conventional electrosurgery and argon beam coagulation. The authors reported on the depth of tissue effect associated with the use of the device on a wide range of tissues including liver, spleen, kidney, lung, muscle and bone. This included a histological examination of tissues 3 hours after surgery and 8 days following surgery.

A third study completed by Drecoll and Höfller reported on further histological examinations of the tissues obtained from the above two studies. The objective of this study was to provide a more detailed investigation of the degree and type of tissue effect including the degree of healing and revascularization associated with the use of the PlasmaJet System compared to conventional electrosurgery techniques.

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Fig. 1. Liver tissue following exposure to the PlasmaJet System for 1 second

Beneath a very thin carbonized layer (3), the desiccated or spongy necrotic layer (SNL) (1) was clearly defined and had a thickness of 150-250 µm. The compact coagulated necrotic layer (CNL) (2) was seen as homogeneous, coagulated tissue without fissures and had clearly defined borders. The thickness varied between 0.6 and 0.8 mm. A blood vessel (6) was coagulated in the CNL. The CNL was separated from the intact tissue (11) by a demarcation zone of inflammation (4).

TISSUE EFFECTS ASSOCIATED WITH THE USE OF THE PLASMAJET SYSTEM

The results of these preclinical studies demonstrated that the PlasmaJet System produces a similar effect on a wide variety of different tissues. Maximum depth of tissue necrosis in these studies was reported to be approximately 2.0 mm for dense and vascular tissues such as the liver (Fig.1), spleen and
kidney (Fig. 2). A slightly greater depth of the effect of almost 3mm was observed when the device was utilized on softer lung tissue (Fig. 3).

The effect was the same in all tissues studied. Beneath a very thin layer of carbonized tissue, a desiccated or spongy layer of tissue is observed, and beneath this lies a more compact layer of coagulated tissue. The overall effect was the formation of a thin, yet complete and flexible sealing layer.

Fig. 2. Tissue effect of the PlasmaJet on vascular tissue of the kidney

When applied at a single point for 30 seconds, the tissue surface is ablated to a depth of about 1mm, but the depth of the necrosis beneath the surface of the remaining tissue does not increase.

It was noted that a maximum depth of tissue necrosis with the PlasmaJet System was approached after only 5 seconds. Prolonged exposure more than is necessary to achieve coagulation led to ablation of tissue without a significant increase in the depth of necrosis in the remaining tissue.

In more vascular tissues, the authors noted that holding the PlasmaJet handpiece at an angle of about 30° to the tissue surface was more effective in removing surface blood to visualize and coagulate the underlying tissue. These studies also report that the PlasmaJet System was able to stop biliary leakage when used on the liver, and produce a high degree of aerostasis when used on the lung; with the thin flexible layer of coagulated tissue being homogenous and impervious to both blood and air (Fig. 3).

Fig. 3. Effect of the PlasmaJet on lung tissue.

Note the thin and contiguous film of coagulation on lung tissue preventing leakage from both blood vessels and bronchioles.

COMPARISON TO OTHER TECHNOLOGIES

Both argon beam coagulation and saline-coupled electrosurgery produced a greater depth of tissue necrosis when compared to the PlasmaJet System (Fig 4.)

Fig. 4. Comparison of depth of tissue necrosis for liver tissue.

When compared to the PlasmaJet System, the use of argon beam coagulation resulted in the formation of a deeper coagulated layer which also was punctuated by holes caused by sparks that penetrated deep into the underlying tissues (Fig. 5). The authors also reported that
the use of argon beam coagulation resulted in focal damage to blood circulation presenting as perivascular hemorrhages.

In studies with a saline-coupled electrosurgery (TissueLink) device (Salient Surgical Technologies, Portsmouth, New Hampshire, USA) no spark holes were observed in the tissue and there was no dry layer formation. Unlike the limited tissue effect produced by the PlasmaJet System, the saline-coupled electrosurgical device created a zone of tissue destruction that was much deeper (typically between 6 and 14mm). Similar to the observations that were seen with tissue treated with the argon beam coagulator, the tissue treated with the saline-coupled electrosurgical device also contained focal points of damage around blood vessels (Fig. 6).

Figure 7 shows the differential effect of the PlasmaJet on spleen tissue compared to the argon beam coagulator and saline-coupled electrosurgery based on detailed investigation of the degree and type of tissue effect. In contrast to argon beam and saline-coupled electrosurgery, the effect of the PlasmaJet application on spleen was characterized by the presence of only two zones of necrosis – the spongy (SNL) and compact layers (CNL).

In contrast to these findings, the use of argon beam coagulation had three zones of necrosis including areas of damaged blood circulation (ZDB). The use of saline-coupled electrosurgery had a deeper tissue effect producing a broader compact necrotic layer and a wide zone of damage to blood circulation. The use of the PlasmaJet did not produce focal damage to the blood circulation while also leaving surrounding tissues intact. Similar findings were reported on other tissue types.

POST-OPERATIVE HEALING

Post-operative tissue effects and healing have been compared for the PlasmaJet System versus other technologies at up to 21 days following surgery. All of the tissues demonstrated healing over time regardless of the technology utilized. For tissue treated with the PlasmaJet System, the scar was actively reconstructed, total scar mass diminished and a simple linear scar remained without any negative effect on deeper underlying tissues.

Detailed histological studies confirmed the findings of earlier studies, but demonstrated that on the boundary of the necrotic tissue there is a broad area of cell rich granulation tissue with distinct immunohistochemically
positive proliferative vessels. There was a clear demarcation between the thin sealing layer and the vital tissue, and no evidence of hemorrhage occurring after treatment with the PlasmaJet System.

There were much larger areas of tissue damage in both the argon beam and saline-coupled electrosurgery groups acutely and at 10 and 21 days (Table 1) with necrotic tissue still present at 21 days based on histological examination of tissue samples.

Table 1. Comparison of depth of tissue necrosis (mm) on various tissues types

<table>
<thead>
<tr>
<th>Tissue Type</th>
<th>PlasmaJet</th>
<th>Argon Beam</th>
<th>Saline-coupled Electrosurgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIVER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>1.8</td>
<td>3.2</td>
<td>7.1</td>
</tr>
<tr>
<td>10 days</td>
<td>1.6</td>
<td>2.7</td>
<td>5.9</td>
</tr>
<tr>
<td>21 days</td>
<td>1.0</td>
<td>2.4</td>
<td>5.5</td>
</tr>
<tr>
<td>SPLEEN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>2.2</td>
<td>3.7</td>
<td>8.2</td>
</tr>
<tr>
<td>10 days</td>
<td>1.9</td>
<td>3.4</td>
<td>6.8</td>
</tr>
<tr>
<td>21 days</td>
<td>1.6</td>
<td>2.8</td>
<td>5.6</td>
</tr>
<tr>
<td>KIDNEY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>2.1</td>
<td>2.7</td>
<td>6.6</td>
</tr>
<tr>
<td>10 days</td>
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<td>5.5</td>
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<td>1.9</td>
<td>4.3</td>
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<tr>
<td>LUNG</td>
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<tr>
<td>Acute</td>
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<td>10 days</td>
<td>1.9</td>
<td>9.5</td>
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</table>
CLINICAL EXPERIENCE

In addition to the above mentioned preclinical studies, several groups have reported results associated with the clinical use of the PlasmaJet System. This includes utilization of the technology for gynecologic, oncologic, hepatic and plastic surgery procedures by clinicians in the United States, the United Kingdom and France. Several of these studies reported to date relate to tissue effects and the depth of penetration associated with the use of the PlasmaJet System.

Sonoda et al. studied ex-vivo ovarian and peritoneal tumor samples following use of the PlasmaJet System and reported that lateral thermal damage associated with the use of the device was minimal with a mean depth of necrosis of 0.13 mm (range 0.08 to 0.2 mm). Deb et al. reported on the depth of tissue damage with the PlasmaJet System based on ex-vivo gynecological samples and confirmation via in vivo evaluation. Their findings were a mean depth of tissue damage of 0.63 mm in uterus, ovary and fallopian tube.

In a separate study, Madhuri et al. conducted histopathological examinations of ex vivo samples of omentum bearing epithelial ovarian carcinoma and reported a mean depth of tissue damage of 0.15 mm (range 0.07 to 0.4 mm) and a mean lateral thermal spread of 0.22 mm associated with the use of the PlasmaJet System.

In a further study focusing on the use of plasma energy in the management of ovarian endometrioma, Roman et al. reported on the benefits of tissue sparing in this vital tissue when this was treated with the PlasmaJet System. The authors reported that, based on histological analyses performed for this study, the mean depth of necrosis associated with the use of the device was 0.045 mm (range of 0.032 to 1.029 mm).

Other authors describing clinical applications of the PlasmaJet System have commented on the value of the minimal depth of damage to underlying tissue.

CONCLUSION

Preclinical and clinical studies performed to date with the PlasmaJet System confirm that this technology produces limited tissue damage and decreased depth of necrosis on a variety of tissue types when compared to conventional technologies. The use of plasma technology may provide an important alternative approach for cutting, coagulation and ablation of tissue when minimal lateral damage and decreased depth of tissue are desired.

REFERENCES

1. Parhomenko Y, Tartynski S, Kachikin A. The effect of the PlasmaJet when used for coagulation on a range of different tissues and comparison with the effects of argon enhanced electrosurgery and fluid coupled electrosurgery. Institute of Human Morphology at the Russian Academy of Science, Moscow, 2005.


CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. For listing of indications for use, precautions and warnings please refer to the instructions for use provided in the Operator Manual for the PlasmaJet System.

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