Value Analysis Brief—
VAPR® VUE™ with COOLPULSE® 90 Ablation Technology

Methods

This value analysis brief presents information on the potential economic and clinical benefits of using the VAPR® VUE™ Radiofrequency System with COOLPULSE® 90 Technology in arthroscopic procedures. The referenced data were obtained through a search of MEDLINE for economic and clinical studies of ablation technologies in arthroscopic procedures and the medical resource utilization associated with these devices. Unpublished studies also were included in this analysis due to limited published clinical data for this technology.

Note: VAPR VUE with COOLPULSE 90 is unique to DePuy Mitek, thus all studies referenced herein pertain directly to this radio frequency ablation technology.

Background

The use of radiofrequency energy has become commonplace in arthroscopic surgery and companies are developing new devices to allow surgeons to efficiently remove (ablate) and coagulate targeted tissue. One way to assess the efficiency of a radiofrequency system is to measure the rate of targeted tissue removal. However, there are some concerns with regards to potential adverse effects on adjacent tissue, articular cartilage in particular, when using these systems due to the increased temperatures associated with radiofrequency energy. Several studies have reported on these thermal data effects from use of radiofrequency probes in joint spaces. [1-10]

There are a number of important factors that should be taken into consideration to manage the impact of heat in the joint space when applying radiofrequency energy for ablation procedures in a clinical setting. These factors include:

- Maintaining good irrigation fluid flow,
- Minimizing the duration of tissue exposure to increased temperatures, and
- Maintaining uninterrupted suction on the radiofrequency electrode.

DePuy Mitek's next generation radiofrequency system, the VAPR VUE with COOLPULSE 90 ablation technology addresses these factors with its ability to:

- Ablate tissue more quickly while generating equal or less heat compared to leading competitors,
- Precisely ablate and coagulate to achieve desired tissue effect,
- Offer clear and sustained field of vision with minimized bubbles and clogging, and
- Minimize the risk of accidental damage to healthy tissue through targeted ablation.

The design elements of COOLPULSE Technology translate into a number of potential clinical and economic benefits to various stakeholders.

Potential Economic Benefits

Faster ablation rate associated with COOLPULSE Technology may reduce operating room time leading to significant cost savings.

Tissue removal rate in arthroscopic procedures may have a substantial impact on procedure duration and surgical efficiency. Devices and techniques which can increase the ablation rate can achieve cost savings in the operating room setting.

DePuy Mitek recently estimated and compared the cost of arthroscopic subacromial decompression (SAD) using the VAPR VUE Radiofrequency System with COOLPULSE 90 Electrodes and the ArthroCare ArthroCare® Quantum™ System with Super TurboVac® Electrodes.[11] The data for average tissue removal rate was obtained from a comparative *in vitro* study of these systems. [12]

These values were then applied to an average procedure length for ablation procedures in the published literature in order to determine the procedure duration for each comparator (i.e., average time for SAD using Super TurboVac was 13 minutes).[13] Average selling price for each comparator was based on 2011 IMS data.

Assuming the cost of operating room time is $20 per minute, the estimated cost of ablation using COOLPULSE 90 versus Super TurboVac would be $436 and $480, respectively. [11]

Overall, tissue removal rate in arthroscopic procedures is an important factor in determining surgical efficiency and procedure duration. The *in-vitro* study demonstrated that COOLPULSE 90 Electrodes achieved a significantly higher tissue removal rate compared to Super TurboVac, which may translate into a reduction in procedure duration and substantial savings in operating room costs.

Potential Procedure Benefits

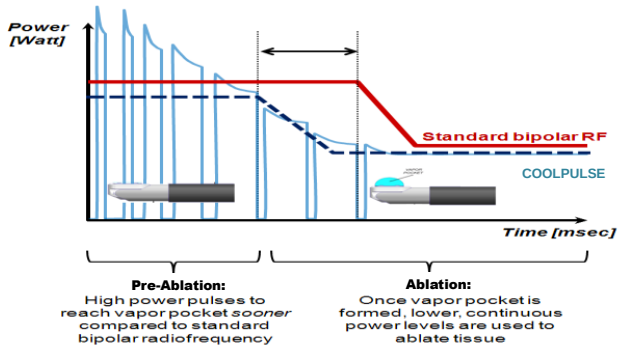
Faster and more efficient tissue ablation (compared to leading competitors) while generating equal or less heat.

All bipolar radiofrequency ablation occurs in a two-step process. In the "pre-ablation phase," an energy threshold must be reached to create a localized plasma field, the "vapor pocket". There is rapid heating of the saline and energy dissipates into the fluid. In the "ablation phase," a stable vapor pocket is formed; less energy is needed to maintain the vapor pocket.

Standard bipolar radiofrequency systems use *continuous high-power* in the pre-ablation phase of arthroscopic procedures to reach the energy threshold and create a vapor pocket.

With COOLPULSE Technology, unique high power *pulses* are used to break through the energy threshold in the pre-ablation phase to create the vapor pocket. No power is being applied between pulses (Figure 1).

Figure 1: Standard Bipolar RF vs COOLPULSE 90



In the ablation phase, the stable vapor pocket is formed sooner and the system reverts to a lower continuous power level to maintain the vapor pocket. This leads to less energy being dissipated into the surrounding saline as compared to standard bipolar radiofrequency.

A recent *in vitro* study comparing the VAPR VUE Radiofrequency System using COOLPULSE 90 Electrodes with the ArthroCare Quantum System using Super TurboVac probes demonstrated both a 20.4% faster ablation rate and equal or lower heat generation with COOLPULSE 90 Electrodes (Figures 2 & 3). [12]

Figure 2. Faster Ablation vs Leading Competitor[12]

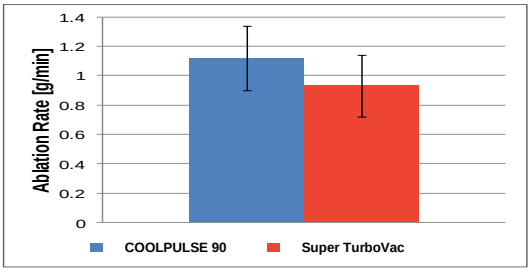
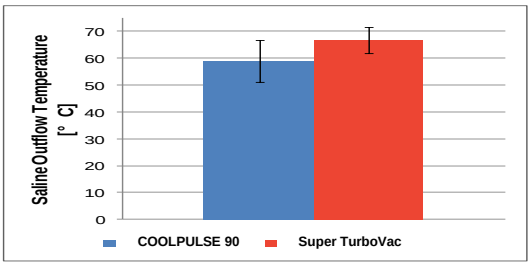


Figure 3. Equal or Lower Heat Generation vs Leading Competitor[12]



Additionally, in a second *in vitro* study comparing COOLPULSE 90 with the Styker 90-S™ Electrode, COOLPULSE 90 Electrodes showed a 13.1% higher tissue removal rate and an equal or lower temperature at the electrode tip. [14]

Overall, COOLPULSE Technology allows for faster and more efficient tissue ablation while generating less or equal heat when compared to leading competitors.

Minimizes clogging and bubble generation leading to a clearer and sustained field of vision.

Today's arthroscopic procedures are increasingly complex. Manipulation of devices and surgical instruments in a confined joint space requires skill and a clear surgical field. Orthopedic surgeons have been quick to recognize that visualization is key to a successful arthroscopic procedure.

COOLPULSE Technology improves arthroscopic visibility by precisely removing unwanted tissue, minimizing clogging and bubbles generated, and providing for fast debris removal though the use of suction.

A recent *in vitro* study comparing the VAPR VUE Radiofrequency System using COOLPULSE 90 Electrodes with the ArthroCare Quantum System using Super TurboVac probes demonstrated significantly minimized clogging with COOLPULSE 90 Electrodes (Table 1). [12]

Table 1. Minimized Clogging Compared to Leading Competitor[12]

Results	COOLPULSE 90	Super TurboVac
Number of Clogged Runs	0/36 (0%)	7/36 (19.4%)

Additionally, in a second *in vitro* study comparing COOLPULSE 90 Electrodes with Styker 90-S probes, COOLPULSE 90 Electrodes demonstrated a 0% clogging rate compared to a 19% rate for the Styker 90-S system.[14]

Overall, COOLPULSE 90 Technology improves arthroscopic visibility and allows the orthopedic surgeon to focus more on the procedure, thus improving operating room efficiency.

Minimizes charring and risk of accidental damage to healthy tissue through *targeted ablation and coagulation.*

Targeted ablation and coagulation allows a surgeon to achieve the desired tissue effect. COOLPULSE Technology is designed to provide precise ablation of targeted tissue (which minimizes charring and risk of accidental damage to healthy tissue) as well as targeted coagulation of bleeding vessels.[15]

Additionally, the VAPR VUE Radiofrequency System allows for easy and quick adjustments of ablation and coagulation power settings to refine probe performance based on anatomical considerations.

Flexible design of the VAPR VUE System and COOLPULSE 90 Electrodes offer excellent control and operating room convenience.

The VAPR VUE System offers a variety of ablation controls and display settings for operating room convenience. The choice of activation controls includes hand controls, wireless footswitch or wired footswitch controls (Figures 4 and 5). Key features include:

- Direct access to ablation settings from hand controls or footswitch,
- Easy to switch activation mode from hand controls to wired or wireless footswitch, and
- Wireless footswitch featuring interference-resistant technology for exceptional performance and operated by less expensive, standard alkaline batteries.

Figure 4. COOLPULSE 90 Hand Controls

Figure 5. VAPR VUE Wireless Foot Switch

COOLPULSE Technology is powered by the VAPR VUE Generator (Figure 6). The VAPR VUE Generator is compatible with DePuy Mitek's broad portfolio of electrodes and the software on VAPR VUE Generator can easily be updated in the field.

Figure 6. VAPR VUE Generator

Overall, DePuy Mitek's VAPR VUE Radiofrequency System with COOLPULSE Technology has the ability to ablate tissue more quickly while generating less or equal heat compared to leading competitors, precisely remove unwanted tissue leading to a clearer and sustained field of vision, and minimize the risk of accidental damage to healthy tissue through targeted ablation. These design elements translate into a number of potential economic and clinical benefits.

Citations

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