White Paper

The Cannuflow® TwoVu™ ST Outflow Sheath provides superior fluid flow for better management of joint fluid temperature when using radiofrequency energy

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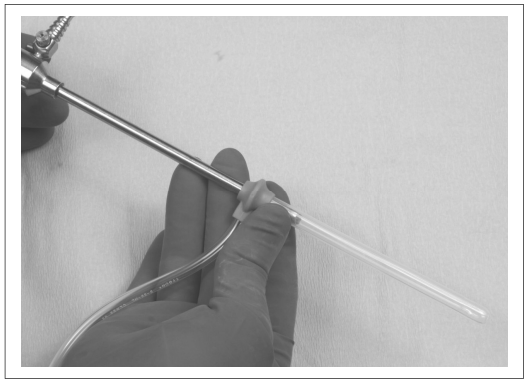
SUMMARY

Radiofrequency energy (RFE) in arthroscopic knee and shoulder surgery has gained widespread use over the past several years. But along with the benefits of this type of treatment come some risks and possible complications. Although a good deal of research has been conducted regarding the efficacy and viability of using RFE in the treatment of joint instability and in the smoothing of chondromalacic articular cartilage, little attention has been paid to the residual effects RFE may have on surrounding normal articular surfaces due to increases in irrigation fluid temperature.

Cartilage damage is one of the most significant factors leading to the development of osteoarthritis; one of the hallmarks of cartilage damage is chondrocyte death.[1] It is well known that chondrocytes have very limited ability to regenerate or to repair when damaged.[2] One of the ways of causing cartilage damage and bringing about cell death is through exposure of chondrocytes to uncontrolled heat.[3]



TwoVu ST Outflow Sheath slips easily over a scope's own sheath to create a continuous inflow-

Clinical research has shown that chondrocytes in articular cartilage begin to die at 45°C, 50 percent of chondrocytes are dead at 55°C, and all chondrocytes are dead at 65°C.[4] In a recently published study, *Effect of Simulated Shoulder Thermal Capsulorrhaphy Using Radiofrequency Energy on Glenohumeral Fluid Temperature*,[5] the opportunity for detrimental increases in joint fluid temperatures during treatment with RFE were evaluated. It was indicated in the study that without efficient fluid flow during an arthroscopic procedure, joint fluid temperatures could quickly exceed safe levels (above 45°C) creating the potential for irreparable injury to articular cartilage from the heated fluid exposure.[6] Cannuflow Inc. offers a simple, easy to use, and truly effective method for managing fluid flow to help maintain consistent and safe joint fluid temperatures throughout a procedure.

BACKGROUND

Duration for RFE treatments is usually dependent on a surgeon's judgment and can vary widely in time and intensity depending on procedure requirements and equipment. This can make it difficult to consistently regulate fluid temperature changes in the joint. If fluid flow happens to be interrupted during a procedure due to instrument adjustment or blockage from debris (a typical event in arthroscopic surgery), the risk of joint fluid temperatures rising rapidly becomes even greater. With no automatic protection mechanism, temperatures can quickly climb to dangerous levels without a surgeon being aware of it. Therefore, it is essential to maintain reliable fluid flow to ensure safe joint fluid temperatures.[7] To demonstrate the advantages of using the Cannuflow TwoVu ST to safely and effectively manage fluid temperatures when

utilizing an RF device, Cannuflow conducted a pre-clinical study to evaluate and measure glenohumeral fluid temperature changes in a simulated shoulder when using no flow, device built-in flow, and a TwoVu ST-5 Outflow Sheath. To establish a controlled environment for the study that would mimic an adult human shoulder, Cannuflow was provided with the same validated, custom-built simulated shoulder chamber* (see Fig 1) used in the *Effect of Simulated Shoulder Thermal Capsulorrhaphy Using Radiofrequency Energy on Glenohumeral Fluid Temperature* study and followed a similar procedure for measuring temperatures.

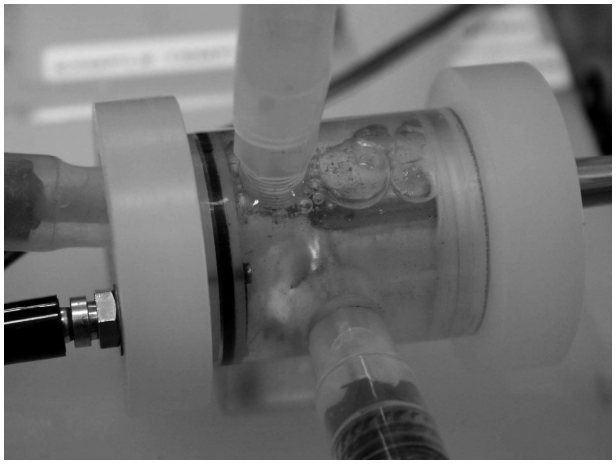


Fig 1—Custom-built ablative figure jig from the University of Wisconsin-Madison

Method and materials

The irrigation fluid used in the study was a normal .9% saline solution and the starting fluid temperature between 21 to 25ºC. Tissue used was fresh porcine joint, cut to 2cm x 1cm x .5cm. Leading industry RF devices were employed – the Mitek Vapr and End Effects probe 2.3 Vapr Wedge; the Smith & Nephew Vulcan /Saphyre probe; and the ArthroCare System 2000/Turbovac 90 probe. The Smith & Nephew probe was operated at the default setting, the other probes were operated at their full power settings. All RF instruments were new and taken from sealed packages. Chamber fluid temperatures were taken at 30-second intervals during three minutes of continuous ablation. Temperature measurements were made using the built-in thermocouple probe of a Smith & Nephew TAC-II probe (operated at its default setting). Temperatures represent typical values over three (3) runs. Temperature measurements were recorded manually.

OBSERVATIONS

Without the use of outflow (Fig 2) temperatures within the simulated joint capsule rapidly increased to unsafe levels (well over 45°C) with all RF devices. When the built-in outflow feature was introduced (Fig 3) with the ArthroCare and Mitek probes temperatures rose 10° - 15° C or more during the treatment but did not exceed 40°C. It was immediately clear that using the TwoVu ST (Fig 4) during RFE treatment dramatically reduced the potential for dangerous temperature increases. The continuous flow capability of the device allowed consistent and safe temperature levels to be maintained no matter the duration of the RFE exposure.

ABLATION SYSTEM (generator/probe)	Start temp (℃)	30sec	1min	1:30min	2min	2:30min	3min
ArthroCare System 2000/ Turbovac 90 probe	25	**45**	**58**	**70**	**79**	**85**	**89**
Smith & Nephew Vulcan / Saphyre probe	22	25	33	42	**49**	**59**	**70**
Mitek Vapr/End Effects probe 2.3 Vapr Wedge	22 23	36 32	**47** **40**	**56** **46**	**64** **54**	**71** **59**	**77** **63**

Fig 2—Continuous ablation of 3 minutes with no outflow. Temperatures rapidly exceeded safe levels

ABLATION SYSTEM (generator/probe)	Start temp (℃)	30sec	1min	1:30min	2min	2:30min	3min
ArthroCare System 2000/ Turbovac 90 probe	20	21	23	25	26	33	**37**
Smith & Nephew Vulcan / Saphyre probe	21	27	32	35	32	**37**	**38**

Fig 3—Continuous ablation for 3 minutes with device built-in outflow. Temperatures still rise but remain just below danger levels

ABLATION SYSTEM (generator/probe)	Start temp (℃)	30sec	1min	1:30min	2min	2:30min	3min
ArthroCare System 2000/ Turbovac 90 probe	20	21	21	21	21	21	21
Smith & Nephew Vulcan / Saphyre probe	21	20	20	20	20	20	20
Mitek Vapr/End Effects probe 2.3 Vapr Wedge	20	20	20	20	20	20	20

Fig 4—Continuous ablation for 3 minutes with only the Cannuflow TwoVu ST. Temperature levels do not rise but remain consistently at safe levels.

CONCLUSIONS

Damage to articular surfaces due to chondrocyte death often causes a delayed loss of mechanical integrity in a joint that is not always immediately observable[8] after surgery. This loss of integrity can be a root cause to the future onset of osteoarthritis[9] and joint capsule deterioration. If joint fluid temperatures can be easily and consistently controlled when using RFE treatments, the opportunity for collateral tissue damage can be reduced, significantly improving the safety margin for using RFE in clinical applications.[10]

Although built-in outflow features on RFE probes can provide sufficient fluid flow to keep joint fluid from reaching unsafe levels, fluid temperatures can still rise close to the during an actual procedure due to repositioning or to clogging from debris (a common occurrence), temperatures could quickly exceed safe levels. In addition, the cumulative effect on temperature buildup even in an interrupted technique can exceed safe levels; and once an RFE wand is removed, any outflow it provided is terminated leaving high joint fluid temperatures still a problem.

The ConstantFlow™ design of the TwoVu ST Outflow Sheath ensures that fluid flow is *continuous*; helping fluid clarity. Large fenestrations at the distal tip of the device allow for the evacuation of sizable particulate matter to provide uninterrupted flow throughout a procedure. Simple to use, compati-

ble with current equipment and techniques, the TwoVu ST Outflow Sheath delivers an automatic mechanism for effectively controlling and maintaining fluid temperatures during RF treatments to ensure greater joint protection during arthroscopic procedures.

*ACKNOWLEDGEMENTS

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Cannuflow Incorporated
1190 Coleman Ave, Suite 250
San Jose, California 95110

408.764.0220
866.484.5400 toll free
408.280.0323 fax

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