In Vivo Arthroscopic Temperatures: A Comparison Between 2 Types of Radiofrequency Ablation Systems in Arthroscopic Anterior Cruciate Ligament Reconstruction—A Randomized Controlled Trial

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Purpose: To compare a plasma ablation device with a standard ablation device in anterior cruciate ligament (ACL) reconstruction to determine which system is superior in terms of intra-articular heat generation and diathermy efficiency. Methods: This was a prospective, randomized controlled trial. The inclusion criteria were adult patients undergoing primary ACL reconstruction. Patients were randomized preoperatively to the standard ablation group or the plasma ablation group. A thermometer was inserted into the inferior suprapatellar pouch, and the temperature, time, and duration of radiofrequency ablation were measured continually. **Results:** No significant differences were found between the standard ablation system and the plasma ablation system for maximum temperature (29.77°C and 29.34°C, respectively; P = .95), mean temperature (26.16°C and 26.99°C, respectively; P = .44), minimum temperature (22.66°C and 23.94°C, respectively; P = .54), and baseline temperature (26.80°C and 27.93°C, respectively; P = .35). Similarly, no significant differences were found for operative time (82.90 minutes and 80.50 minutes, respectively; P = .72) and mean diathermy activation times (2.6 minutes for both systems; P = .90). The between-system coefficient of variation for the measured parameters ranged from 0.12% to 3.69%. No intra-articular readings above the temperature likely to damage chondrocytes were recorded. The mean irrigation fluid temperature had a significant correlation with the maximum temperature reached during the procedure (Spearman rank correlation, r = 0.87; P < .01). Conclusions: No difference in temperature was observed between the standard ablation and plasma ablation probes during ACL reconstruction. Temperatures did not exceed critical temperatures associated with chondrocyte death. Level of Evidence: Level I, randomized controlled trial.

A retroscopic anterior cruciate ligament (ACL) reconstruction is a frequently performed surgical treatment for ACL rupture. During the procedure, radiofrequency (RF) ablation is used to debride the ACL remnant and to define anatomic landmarks. These landmarks are used to define the entry point for the

tibia and femoral tunnel positions for subsequent placement of a hamstring tendon graft.

As a byproduct of RF ablation, heat is produced, with the potential within the enclosed space of the knee joint for temperatures to increase to levels at which damage to sensitive tissues occurs. A temperature of 45° C can

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damage muscle and nerve cells, whereas a temperature of approximately 55°C has been shown to cause destruction of chondrocytes in vitro.¹

Both extra-articular RF ablation and intra-articular RF ablation are generally considered safe; however, case reports linking incidences of glenohumeral chondrolysis to RF ablation exist.² RF devices are developed and tested in simulated clinical environments, often using animal or cadaveric tissues. Although these modalities are reasonable surrogates, the characteristics of these environments differ from the environment of true, human intraoperative use. Recently, RF ablation instruments have incorporated the use of a plasma bubble to ablate tissue with the aim of more efficient diathermy and reduction of temperature transmission to surrounding tissue. We conducted a literature review using PubMed, Ovid, and Medline. No studies involving in vivo monitoring of joint fluid temperature during ACL reconstruction were identified. Furthermore, no robust data comparing intra-articular temperature differences between standard ablation and plasma ablation could be found.

The purpose of this study was to compare a plasma ablation device with a standard ablation device in ACL reconstruction to determine which system is superior in terms of intra-articular heat generation and diathermy efficiency. We hypothesized that the plasma ablation group would operate at a lower temperature and more efficiently, resulting in lower intra-articular temperatures and reduced diathermy times intraoperatively. We further hypothesized that by adhering to safe diathermy practices as defined by Zoric et al.,³ intraarticular temperatures would be maintained below 45°C for both systems.

Methods

Ethics committee approval was obtained from the health region ethics committee (MHS20130806-02) before commencement of the study, and the trial was registered with the country of origin's clinical trials registry (Australian Clinical Trials Registry, ACTRN12613000569707).

Trial Design

This trial was conducted in a prospective, randomized manner, with 47 participants over the age of 18 years and of both male and female gender enrolled. Recruiting occurred between March 2014 and June 2015. The inclusion criteria were adult patients undergoing primary arthroscopic ACL reconstruction by a single bundle secured with double adjustable suspensory loop fixation to an anatomically referenced ACL footprint. Revision ACL reconstructions and/or ACL reconstructions using bone—patellar tendon—bone graft were not eligible for inclusion. The exclusion criteria were patients who were unable to provide informed

consent or unable to attend a 6-month follow-up visit. All surgical procedures were performed by 1 of 3 orthopaedic consultants (P.M., K.H., M.W.), in private practice, within a large regional hospital. All of the surgeons are current members of the Australian Orthopaedic Association and hold an F.R.A.C.S.(Ortho). They have 16, 9, and 6 years' experience since attaining fellowship. The 2 most experienced surgeons (P.M., K.H.) specialize in lower limb surgery, with the most senior (P.M.) specializing in surgery of the knee only. At the time of recruitment, patients were randomly assigned to either the standard ablation group, treated with the Stryker SERFAS probe (Kalamazoo, MI), or the plasma ablation group, treated with the ArthroCare RF Wand Super TurboVac 90 IFS system (Austin, TX), with a computer program used to generate a random number list. The device to be used was concealed from the surgeon until the time of surgery, when it was revealed by the nursing staff under the direction of the research assistant.

Intraoperatively, 1 or 2 medial portals and 1 lateral arthroscopic portal were placed, and a Luxtron 812 thermometer (LumaSense Technologies, Santa Clara, CA) connected to a LumaSense Technologies fiberoptic temperature probe (STB Probe [part No. SQ10939L]) was inserted into the inferior aspect of the suprapatellar pouch, percutaneously, independent of the ports. The probe was positioned so that it was as close to the working area of the RF ablation probe as possible without interfering with the arthroscopic instrumentation. The thermometer was connected to a computer running Luxtron TrueTemp (version 2.0.0; LumaSense Technologies), and the temperature was recorded in real time every 0.5 seconds. Subsequent analysis was performed with SPSS software (version 20; IBM, Armonk, NY).

The surgical technique consisted of ACL reconstruction with a single-bundle semitendinosus graft in a double adjustable suspensory configuration placed in the anatomic ACL footprint. Normal saline solution stored at room temperature was used for irrigation of the joint, with the operating room temperature set at 21°C. The fluid was delivered either by a gravity-fed system that used two 3-L bags elevated to 1.85 m and a hand pump or by a pressure-regulated electric pump. The pressure of the gravity-fed irrigation system was calculated by connecting the system to the arterial blood gas manometer and was zeroed at the level of the patient's knee. This process was repeated 3 times and returned an average reading of 80 mm Hg with both bags full and open to the circuit. This figure has been adopted in statistical calculations using this variable. The pump pressure setting varied according to the surgeon's preference and ranged from 35 to 90 mm Hg. An independent suprapatellar outflow portal was created and connected to free drainage in cases in which it was the surgeon's preference to do so.

The RF ablation probes were used intermittently. Suction was attached to the RF ablation wand when requested by the surgeon. When suction was not requested, free drainage was used.

We set a temperature of 45° C as the maximum acceptable temperature for the joint. The worthwhile differences in the maximum temperature were determined according to a nomogram for the estimation of the measurement repeatability error from the coefficient of variation (CV).⁴ The worthwhile differences for the current sample size (20 per group) and a hypothetical sample size of 10 per group were determined using linear regression equations (y = 0.7955x + 0.1284 and y = 1.1096x - 0.1132, respectively).⁵ On the basis of these calculations, the worthwhile differences of the current sample size of 20 per group and a hypothetical sample size of 10 per group were 0.93% and 1.32%, respectively.

The plasma ablation device has an inbuilt thermometer that was set to alarm at 45°C. On occasion, the inbuilt alarm would be triggered; however, there was no change to the intra-articular temperature as measured by the independent fiberoptic probe. When the RF ablation tool was activated by the surgeon, the time and duration of activation were measured with a stopwatch operated by the research assistant. Times were documented in Microsoft Excel. At the completion of the case, the probe was removed and inspected for damage before being sent to the institution's central sterilizing department for reprocessing.

The primary outcome measure was the intra-articular temperature recorded every 0.5 seconds for the duration of the operation that involved RF ablation. The secondary outcome measures were the duration of application of RF ablation for each system and the total operating time for each system.

As reported in the Results section, the total diathermy time is defined as the total duration of the active RF ablation within the intra-articular space during the procedure, calculated by the sum of all individual diathermy applications. The total temperature time is defined as the total duration for which the temperature probe was actively recording temperature during the procedure. The temperature probe was removed during the case once no further RF ablation was required to mitigate the risk of probe damage or entanglement during the passage of the graft. The total surgery time is defined as the time from knife to skin until completion of wound closure. A port is defined as a stab incision to the skin for the passage of instruments, an accessory outflow portal, or the arthroscope; the probe was inserted using a cannulated needle and is not classified as a port. Pressure, as reported in the Results section, is as measured by a manometer at the end of the irrigation tubing at knee-high level for the manual pressure-fed system or the setting for pressure control

pumps. The baseline mean temperature is defined as the average temperature for the first 5 seconds after probe insertion into the knee. The mean temperature is defined as the average temperature of all readings recorded during the procedure, and the maximum temperature is the highest single reading recorded during the case.

Statistics

All statistical analyses were conducted with SPSS software (version 20). An a priori calculation was conducted with an anticipated effect size of 0.8, an α level of .05, and a power of 0.8 (G*Power 3.1.9.2, Heinrich-Heine-Universität, Düsseldorf, Germany) for differences between 2 independent measures. The sample size was based on 2 groups (standard ablation and plasma ablation). According to these effects, a total sample size of 40 was required.

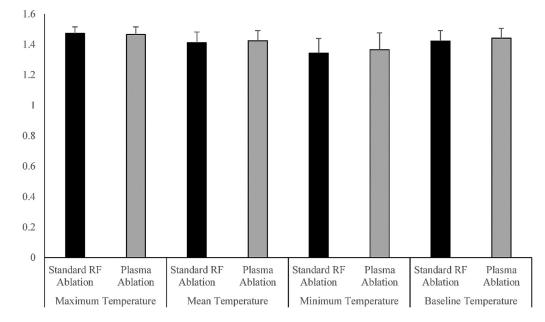
On the basis of the Shapiro-Wilk test, the dependent variables were not normally distributed and thus all measures were log transformed $(\log_{10}[x])$ before analyses. The measures of central tendency and dispersion are reported as mean \pm standard deviation. By use of the $\log 10[x]$ data, the intersystem CV (% CV = Standard deviation \times 100/Mean) of the dependent variables was calculated. Furthermore, differences in the dependent variables between the Stryker and Arthro-Care systems were determined using analysis of covariance with 3 separate surgeons treated as a covariate. The correlations between dependent variables were examined by use of the Pearson correlation coefficient for pooled data, as well as the correlations for the Stryker and ArthroCare systems. The level of significance was established at .05.

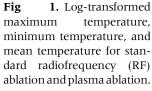
Results

A total of 47 patients were recruited into the study; 7 of these were excluded. Two participants withdrew consent to have their temperatures recorded after randomization but before surgery, and 1 patient was deemed medically unfit for the procedure in the anes-thetic holding bay and the procedure was cancelled. The remaining 4 were withdrawn because of equipment issues (laptop hardware or software failure) at the time of data collection that resulted in incomplete data collection during the procedure.

Of the remaining 40 patients, 19 were randomized to the plasma ablation group and 21 to the standard ablation group. ACL reconstruction was performed in 18 right and 22 left knees. Eight patients had an accessory suprapatellar portal under free drainage; of these, 4 were in the standard ablation group and 4 were in the plasma ablation group. Twenty-three patients had 2 medial portals and no suction attached to the diathermy device; of these, 12 were in the standard RF group and 11 were in the plasma ablation group.

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During the course of the study, 3 temperature probes required replacement as a result of the fiberoptic filament being kinked intraoperatively; this occurred at the time the probe was removed through the skin. The fiberoptic probe was noted to be particularly prone to damage when not withdrawn directly perpendicular to the skin surface.

The patient's irrigation pressure was determined intraoperatively by the surgeon. The pressure was 35 mm Hg in 5 patients, 40 mm Hg in 4 patients, 45 mm Hg in 2 patients, 50 mm Hg in 1 patient, 55 mm Hg in 1 patient, 60 mm Hg in 1 patient, 70 mm Hg in twelve patients, 75 mm Hg in 1 patient, 80 mm Hg in 11 patients, and 90 mm Hg in 2 patients.

For comparisons between the standard RF ablation and plasma RF ablation systems, no significant differences were found for any of the variables examined (P > .05, Figs 1-3). The mean values $(\log_{10}[x])$ for the maximum temperature in the standard ablation and plasma ablation groups were 29.77°C and 29.34°C, respectively (CV, 1.01%); the mean temperature was 26.16°C and 26.99°C, respectively (CV, 0.96%). The operative times for the standard and plasma ablation groups were 82.90 minutes and 80.50 minutes,

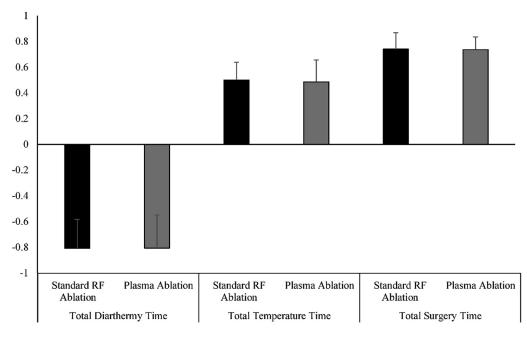


Fig 2. Log-transformed total diathermy time, total temperature time, and total surgery time for standard radiofrequency (RF) ablation and plasma ablation.

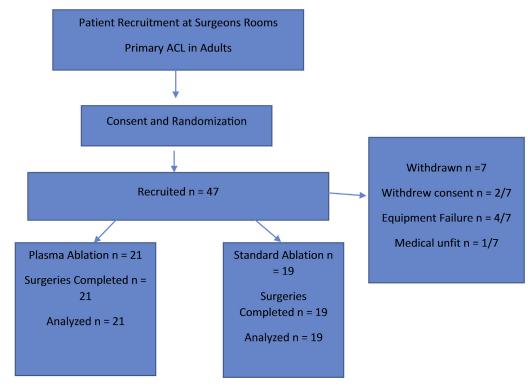


Fig 3. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. (ACL, anterior cruciate ligament.)

respectively (CV, 2.08%). The mean diathermy activation time was 2.6 minutes for each group (CV, 1.91%).

No interaction effect was found between any of the dependent variables with different surgeons as a covariate (P > .05). The intersystem CVs ranged from 1.2% to 3.6% (Table 1). For the correlation analyses of the pooled data (i.e., standard RF and plasma RF systems combined), significant correlations were found between a number of dependent variables (P < .05, Table 2). The minimum temperature had a strong correlation (r = 0.74, P < .001) with the maximum temperature recorded for both systems combined. This correlation was also seen when the 2 systems were analyzed independently: r = 0.63 and P = .005 for

standard ablation and r = 0.86 and P < .001 for plasma ablation (Tables 3 and 4). The mean temperature for both systems correlated with the maximum temperature (r = 0.86, P < .001); again, this was also seen when both systems were analyzed independently: r = 0.85 and P < .001 for standard ablation and r = 0.91 and P < .001 for plasma ablation.

At no time when the plasma RF probe's inbuilt thermometer alarmed at 45°C was a temperature change detected in the joint. All patients attended 6-month follow-up visits. Although not a defined outcome measure, there were no presentations consistent with chondrolysis, defined as complete cartilage loss in 1 or more compartments, in any of the patients. Because no patients had clinical symptoms

Table 1. Coefficients of Variation and Percentage Differences of Log-Transformed (log₁₀[*x*]) Means of Dependent Variables

	Mean (log	$_{10}[x])$			P Value [*]
Parameter	Standard RF Ablation	Plasma Ablation	CV, %	PD, %	
No. of ports	2.95 (0.47)	2.95 (0.47)	0.12	0	.97
Pressure, mm Hg	65.71 (1.82)	62.37 (1.79)	3.69	1.25	.34
Surgery, min	82.90 (1.92)	80.50 (1.91)	2.08	0.67	.72
Temperature, min	47.9 (1.68)	47.6 (1.68)	0.44	0.16	.74
Diathermy, min	2.60 (0.41)	2.60 (0.41)	1.91	2.81	.90
Mean temperature, °C	26.16 (1.42)	26.99 (1.43)	2.22	0.96	.44
Minimum temperature, °C	22.66 (1.36)	23.94 (1.38)	2.89	1.73	.54
Maximum temperature, °C	29.77 (1.47)	29.34 (1.47)	1.01	0.42	.95
Baseline temperature, °C	26.80 (1.42)	27.93 (1.44)	2.93	4.1	.35

CV, coefficient of variation; PD, percentage difference; RF, radiofrequency.

*The level of significance was set at P < .05.

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Table 2. Spearman ρ Correlation Between Selected Parameters for Pooled Data (i.e., Standard and Plasma Ablation Systems Combined)

Parameter	Pressure	Surgery	Temperature	Diathermy	Mean Temperature	Minimum Temperature	Maximum Temperature	Baseline Temperature
Ports	r = -0.08	r = 0.40	r = 0.38	r = -0.01	r = -0.24	r = -0.12	r = -0.14	r = 0.21
	P = .61	P = .01	P = .02	P = .95	P = .14	P = .45	P = .40	P = .21
Pressure	_	r = 0.34	r = 0.21	r = -0.02	r = -0.32	r = -0.47	r = -0.25	r = 0.06
		P = .03	P = .19	P = .90	P = .046	P = .006	P = .12	P = .72
Surgery	_	_	r = 0.75	r = -0.009	r = -0.25	r = -0.30	r = -0.16	r = 0.13
			P < .001	P = .96	P = .13	P = .06	P = .33	P = .45
Temperature	_	—	—	r = 0.13	r = -0.30	r = -0.32	r = -0.28	r = 0.19
				P = .43	P = .06	P = .047	P = .08	P = .27
Diathermy	_	—	—	—	r = 0.19	r = 0.05	r = -0.02	r = 0.18
					P = .26	P = .76	P = .93	P = .31
Mean	_	—	—	—	—	r = 0.88	r = 0.86	r = -0.04
temperature						P < .0001	P < .001	P = .83
Minimum		_	—	_	—	—	r = 0.74	r = -0.03
temperature							P < .001	P = .92
Maximum	—		—	—	—	—	—	r = 0.02
temperature								P = .92

NOTE. Pressure was measured in millimeters of mercury; surgery, temperature, and diathermy were measured in seconds; and mean, minimum, maximum, and baseline temperatures were measured in degrees Celsius.

that warranted further investigation, no further radiographs or magnetic resonance imaging scans were performed to confirm this.

Discussion

Our study confirmed the safety of the 2 aforementioned types of RF ablation systems and showed no difference in operative time or temperature generation between standard RF ablation and plasma ablation in ACL reconstruction. Furthermore, we found that the mean intra-articular temperature correlated closely with the maximum temperature reached in the joint, a similar finding to that observed by Barker et al.⁶

The use of appropriate-temperature irrigation fluid is a key factor because it closely correlates with mean temperature and maximum temperature intraarticularly. Cheng et al.⁷ showed in a rat model that the intra-articular temperature changes according to the temperature of the irrigation fluid and that the magnitude of this change is related to the initial irrigation fluid temperature.

At no point in our study did the use of the standard RF ablation device or the plasma RF ablation device result in a temperature that exceeded the safe working limit of 45°C. These findings replicate those of Barker et al.,⁶ who examined intra-articular temperatures during subacromial decompression. Barker et al. confirmed that the heat generated by the probe escapes through its drainage tube; at no time when the ArthroCare system's temperature probe alarmed at

Table 3. Spearman ρ Correlation Between Selected Parameters for Standard Radiofrequency Ablation System

Parameter	Pressure	Surgery	Temperature	Diathermy	Mean Temperature	Minimum Temperature	Maximum Temperature	Baseline Temperature
Ports	r = -0.313	r = 0.19	<i>r</i> = 0.23	r = -0.30	r = -0.18	r = -0.01	r = -0.09	r = 0.20
	P = .17	P = .42	P = .33	P = .22	P = .43	P = .98	P = .70	P = .39
Pressure	_	<i>r</i> = 0.23	r = 0.09	r = -0.01	r = -0.05	r = -0.23	r = -0.01	r = 0.14
		P = .31	P = .70	P = .96	P = .84	P = .31	P = .96	P = .55
Surgery	_	_	r = 0.71	r = -0.04	r = -0.24	r = -0.37	r = -0.22	r = 0.04
			P < .001	P = .87	P = .29	P = .10	P = .34	P = .22
Temperature	_	_	—	r = 0.12	r = -0.47	r = -0.48	r = -0.39	r = -0.21
				P = .63	P = .03	P = .03	P = .08	P = .35
Diathermy	—	—	—	_	r = 0.39	r = 0.29	r = 0.05	r = 0.10
					P = .10	P = .25	P = .84	P = .71
Mean temperature	_	_	_	_	_	r = 0.85	r = 0.82	r = -0.15
						P < .001	P < .001	P = .53
Minimum temperature	—		—	—	—	—	r = 0.63	r = -0.08
							P = .005	P = .75
Maximum temperature	—		—	—	—	—	—	r = -0.13
								P = .57

NOTE. Pressure was measured in millimeters of mercury; surgery, temperature, and diathermy were measured in seconds; and mean, minimum, maximum, and baseline temperatures were measured in degrees Celsius.

Parameter	Pressure	Surgery	Temperature	Diathermy	Mean Temperature	Minimum Temperature	Maximum Temperature	Baseline Temperature
Ports	r = 0.13	r = 0.71	r = 0.58	r = 0.29	r = -0.29	r = -0.23	r = -0.18	r = 0.23
Forts								
	P = .59	P < .001	P = .01	P = .22	P = .21	P = .34	P = .46	P = .41
Pressure	_	r = 0.49	r = 0.30	r = 0.01	r = -0.56	r = -0.63	r = -0.50	r = -0.10
		P = .04	P = .22	P = .96	P = .01	P = .008	P = .03	P = .72
Surgery	_	—	r = 0.76	r = 0.04	r = -0.21	r = -0.18	r = -0.13	r = 0.32
			P < .001	P = .89	P = .39	P = .45	P = .59	P = .25
Temperature	—	_	_	r = 0.14	r = -0.13	r = -0.19	r = -0.13	r = 0.61
-				P = .57	P = .61	P = .44	P = .61	P = .02
Diathermy	_	_	_	_	r = -0.05	r = -0.12	r = -0.11	r = 0.27
-					P = .83	P = .64	P = .64	P = .34
Mean temperature	_	_	_	_	_	r = 0.91	r = 0.95	r = 0.14
						P < .001	P < .01	P = .61
Minimum temperature	—	_	—	_	—	—	r = 0.86	r = 0.04
_							P < .001	P = .90
Maximum temperature	_	_	_	_	_	_	_	r = 0.28
-								P = .30

Table 4. Spearman ρ Correlation Between Selected Parameters for Plasma Radiofrequency Ablation System

NOTE. Pressure was measured in millimeters of mercury; surgery, temperature, and diathermy were measured in seconds; and mean, minimum, maximum, and baseline temperatures were measured in degrees Celsius.

45°C did we detect a change in the temperature of the joint fluid being measured independently.

A cadaveric study by Zoric et al.³ identified 3 primary factors that influence the quantity and effect of heat generated during RF ablation in arthroscopic shoulder surgery. These are defined as follows: (1) the flow rate of the irrigation fluid, (2) the duration of application of RF ablation, and (3) the distance between the probe tip and target tissue.³ In their discussion Zoric et al. recommended that suction be applied to the RF ablation device, that adequate irrigation fluid flow be maintained, that RF ablation be activated only intermittently, and that the arthroscope be focused on the RF probe tip at the time of application.

Flow is proportional to pressure and can be calculated through the Hagen-Poiseuille relation. Variable pressure was used in our study, ranging from a minimum of 35 mm Hg up to a maximum of 90 mm Hg. No significant correlation was found between inflow pressure and intra-articular temperature; we assume that this is because inflow pressure of 35 mm Hg is above the threshold required to prevent heat build-up when ablation is used.

Good et al.² were able to show temperatures of greater than 45°C in all arms of their cadaveric trial, in which temperatures were recorded by a probe positioned 1 cm from the active diathermy area. High temperatures in vicinity to the probe were, however, not replicated in regions of the glenoid distant to the site of diathermy activation. By design, RF ablation, whether plasma based or non-plasma based, is the controlled application of heat; it is therefore reasonable to expect a transient temperature increase in proximity to the target field. The theoretical advantage of plasma ablation technology is that surrounding tissue is protected from heat, which is contained by the plasma

field. The amount of heat generated by RF ablation is a function of the power output of the device, the design of the electrode, and the duration of application; this has been extensively examined in the field of tumor ablation.⁸

Nonetheless, thermal injury and, by association, the use of RF frequency or intra-articular electrocautery devices have the potential to cause intra-articular temperatures that may lead to chondrolysis. A strong association of chondrolysis of the knee with RF ablation has not been established in the literature; it has only been implicated in knee chondrolysis in 3 of the 24 international studies examined by Provencher et al.⁹

Limitations

Our study examined only 2 different manufacturers' RF ablation systems. Given that we examined the RF probes only in the knee joint, which is a larger joint with higher fluid capacity than other joints, our findings cannot be extrapolated to other joints. We concede that we did not control the irrigation pressure, application of suction, and number of arthroscopic ports between the 2 groups. The potential bias from these variables is minimized by randomization, and the study design reflects the variability seen in orthopaedic practice. In addition, the study was not designed or powered to determine the effects of the different variables (use of suction, differences in inflow temperature, or number of portals) on intra-articular temperature. We did not measure the irrigation fluid temperature before its infusion into the knee.

Conclusions

No difference in temperature was observed between the standard ablation and plasma ablation probes during ACL reconstruction. Temperatures did not exceed critical temperatures associated with chondrocyte death.

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