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BASIC RESEARCH

Fenestrated Cannulae with Outflow Reduces Fluid Gain in Shoulder Arthroscopy

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Abstract Soft tissue fluid retention is a common problem after arthroscopy, with as much as 2% of patients having complications develop. A fenestrated outflow cannula has been introduced to reduce interstitial swelling. We tested the ability of this outflow cannula design to reduce fluid weight gain. We enrolled 28 patients undergoing shoulder arthroscopy and randomized them into two groups using fenestrated outflow versus conventional cannulae. The conventional group had greater weight gain as a function of the procedure duration than the fenestrated outflow group (slope = 0.542 ± 1.160 kg/hour versus 0.0144 ± 0.932 kg/hour). The conventional group also had greater weight gain as a function of fluid volume than the fenestrated outflow group (slope = 0.022 ± 0.038 kg/L versus 0.002 ± 0.341 kg/L). Compared with conventional nonoutflow cannulae, fenestrated outflow cannulae with negative pressure reduced weight gain associated with longer arthroscopic surgeries and increased arthroscopic fluid volume.

Level of Evidence: Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

Shoulder arthroscopy has become more common as surgical techniques continue to advance. More complex reconstructive procedures once considered feasible only through traditional open approaches are being attempted. As the complexity of the procedures increases, so does the soft tissue fluid retention seen postoperatively. Soft tissue fluid retention is relatively common after shoulder arthroscopy, with severe problems such as respiratory distress or cervical edema requiring respiratory monitoring reported in 2.8% of patients in one study [1]. Problems can range from relatively minor issues such as weight gain and soft tissue edema to major issues such as skin necrosis [12], neurapraxia [15], and intraoperative loss of airway [2]. Causes of fluid overload relate to factors such as duration of the procedure, complexity of the case, severity of the abnormality, increased fluid volume, number of procedures attempted, and surgeon proficiency [6].

Prior studies evaluating fluid weight gain during routine shoulder arthroscopy have noted average fluid weight gain was 1.3 to 2 kg per hour of arthroscopic surgery time and 0.06 to 0.3 kg per liter of irrigation fluid used [10, 16].

A fenestrated double-lumen outflow cannula has been introduced to reduce interstitial swelling seen during arthroscopic procedures. In addition to the conventional central portion through which instruments are inserted, this cannula has a separate outer fenestrated portion intended to be in contact with the soft tissue. The fenestrations are in continuity with the subcutaneous tissue and shoulder

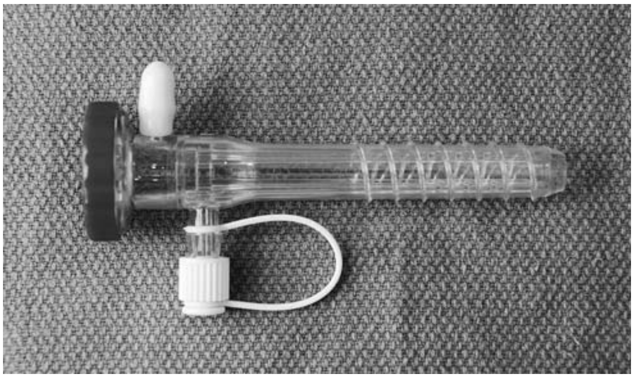

Fig. 1 The fenestrated outflow cannula we used in this study is shown. The fenestrations are along the threaded portion of the cannula.

musculature but do not communicate with the glenohumeral or subacromial spaces. Arthroscopic irrigation fluid typically escapes into the interstitial tissue adjacent to portal/cannula sites. The proposed reduction in soft tissue swelling occurs by drainage of the interstitial fluid at the fenestrated portal/tissue interface through an outflow port on the cannula through negative pressure (Fig. 1).

To confirm this, we posed two hypotheses: (1) the fluid weight gain as a function of procedure duration would be less in patients in whom a fenestrated cannula with outflow was used compared with patients in whom a conventional nonoutflow cannula was used; and (2) the fluid weight gain as a function of irrigation fluid would be less in patients in whom we used the fenestrated cannula with outflow compared with the conventional nonoutflow cannula.

Materials and Methods

During a 3-month period, all 28 patients undergoing shoulder arthroscopy by four fellowship-trained upper extremity surgeons were enrolled preoperatively into one of two randomized groups: a fenestrated outflow group (using EntreVu EX™; Cannuflow®, San Jose, CA) and the conventional nonoutflow group. The randomization sequence generation was obtained from an envelope containing an equal number of fenestrated outflow and conventional group allocation cards drawn in a blinded fashion yielding a 50:50 chance; we therefore had 14 patients in each group. Patients were blinded to their randomization. No selection criteria were applied to patients undergoing shoulder arthroscopy. Patients were recruited, gave consent, were randomized, and had their data collected all in the same setting. Institutional Review Board approval was obtained before the start of this study. The study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. All persons gave informed consent before inclusion in the study. All studies were performed in accordance with regulations of the US Health Insurance Portability and Accountability Act (HIPAA).

Power analysis was performed using literature-based fluid weight gain as a function of procedure duration and irrigation volume used to assess the sample size needed for this study [16]. The magnitude of change for clinical importance was estimated based on previous work describing weight gain as a function of volume and surgical duration [16]. Although the weight gain per volume irrigated was estimated to be 0.25 ± 0.5 kg/L, we chose a slope reflecting no weight gain per increasing irrigation volume as being significantly different clinically from the conventional nonoutflow cannulae. Therefore, for weight gain as a function of fluid volume assuming the slope for the conventional cannula is 0.25 ± 0.5 kg/L and the fenestrated cannula was 0.0 ± 0.05 kg/L with $p = 0.05$ and power at 0.8, the required sample size for each group was five patients, making a total of 10 patients. Similarly, the weight gain per time was estimated to be 2 ± 4 kg/hour; using data from Smith and Shah [16], we assumed a slope reflecting no weight gain per increasing surgical duration would be clinically different from conventional cannulae. Thus, for weight gain as a function of time, assuming the slope for the conventional cannula is 2 ± 4 kg/hour and the fenestrated cannula was 0.0 ± 4 kg/hour with $p = 0.05$ and power at 0.8, the required sample size for each group was five patients, making a total of 10 patients. We chose at least twice that number to be conservative.

There were no differences in age, gender, BMI, number of arthroscopic portals, and patient positioning between the two groups (Table 1). The number of portals were not case-matched between the groups but were comparable (Table 2). The surgical procedures and shoulder diagnoses were comparable in both groups. The most common condition treated in both groups was subacromial impingement (Table 2). Furthermore, arthroscopic times were comparable ($p = 0.432$) between the two groups (fenestrated outflow mean, 60 ± 28 minutes; conventional mean, 69 ± 42 minutes).

The designated data collectors performed the sequence and enrollment process. One 8.25-mm EntreVu EX™ cannula was used in each patient consistently. Additional

Table 1. Patient demographic data

Demographic	Conventional	Fenestrated	p Value
Age (years)*	49 ± 17	52 ± 17	0.7248
Body mass index (kg/m^2)*	29 ± 5	30 ± 5	0.6511
Gender (male:female)	10:4	11:3	0.6625

* Values expressed as mean ± standard deviation.

cannulae used were traditional nonfenestrated, nonoutflow type. The only difference between the conventional nonoutflow and fenestrated outflow groups was that in the conventional group, the outflow port on the cannula remained capped throughout surgery to simulate a traditional cannula where there is no outflow, whereas in the fenestrated outflow group, the outflow port was attached to low wall suction through tubing.

The patient's weight was measured by the same person and using the same scale with the patient wearing a hospital gown and socks before and after surgery. The postoperative weight was taken before oral intake or voiding. For each patient, we recorded the type of dressings and sling used, total intravenous fluids received (including intravenous medications), and any interval urine produced. The combined weight of the dressings, sling, intravenous fluids, and preoperative weight was subtracted and urine output was added to the postoperative weight to arrive at the net weight gain attributable to arthroscopy irrigation. Patient data collected included age, gender, preoperative body mass index (BMI), shoulder diagnosis, and type of procedure performed. Surgical factors recorded included patient positioning (beach chair versus lateral), duration of case (defined as arthroscopy pump start and stop times), and amount of arthroscopy irrigation fluid used. A Smith-Nephew® Access-15 pump (Memphis, TN) was used for all cases and pump pressure was standardized to 60 mmHg.

We compared the patient and surgical factors of the two groups using the Student's t test (age, BMI, portals) or chi square analysis (gender, surgical positioning, shoulder disorder, procedure). Linear regression was performed for the fenestrated outflow and conventional groups to assess the fluid weight gained based on duration of the procedure. The regression slope with its standard error was obtained. We then constructed a t distribution based on pooled standard deviations to arrive at a p value. Fluid weight gain versus amount of arthroscopy irrigation fluid used was similarly calculated for the two groups.

Table 2. Surgical data

Surgical parameter	Conventional	Fenestrated	p Value
Arthroscopic portals*	2.86 ± 0.86	3.00 ± 0.68	0.6309
Positioning (beach chair:lateral)	9:5	7:7	0.4450
Shoulder diagnoses			0.7402
Labral	3	2	
Rotator cuff tear	5	4	
Adhesive capsulitis	4	3	
Impingement/bursitis	5	6	
Instability	0	1	
Procedure			0.7402
Labral repair	3	2	
Rotator cuff repair	5	4	
Lysis of adhesions	4	3	
Subacromial decompression	5	6	
Capsulorrhaphy	0	1	

* Values expressed as mean ± standard deviation.

Results

For weight gain as a function of procedure duration (Fig. 2), the conventional group had a greater weight gain ($p = 0.049$) than the fenestrated outflow group (slope = 0.542 ± 1.160 kg/hour versus 0. 0144 ± 0.932 kg/hour).

For weight gain as a function of fluid volume (Fig. 3), the conventional group also had a greater weight gain

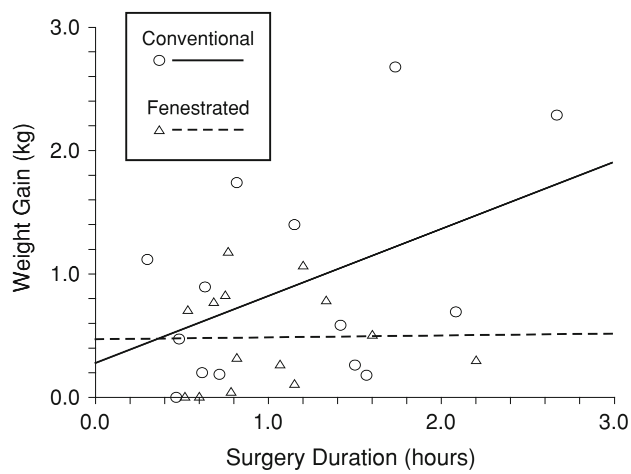

Fig. 2 The plot of weight gain as a function of surgery duration shows a difference between the conventional group (positive slope) and the fenestrated outflow group (flat slope).

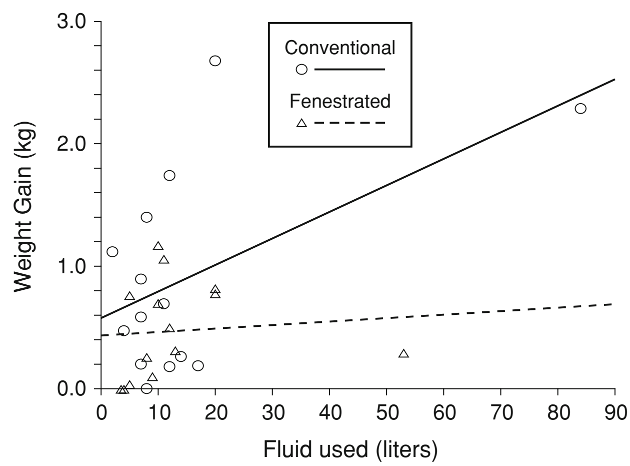

Fig. 3 The plot of weight gain as a function of fluid used for conventional and fenestrated outflow groups shows a difference with a more positive slope seen in the conventional group.

($p = 0.041$) than the fenestrated outflow group (slope = 0.022 ± 0.038 kg/L versus 0.002 ± 0.341 kg/L).

There were no adverse events or side effects in either interventional group.

Discussion

As the diagnostic and therapeutic potential of shoulder arthroscopy continues to advance, the length of procedure and the amount of arthroscopy fluid infused also will increase. As a consequence, soft tissue fluid retention will become a more prominent issue. Prior studies have shown that the weight gain attributable to arthroscopy irrigation fluid is 0.9 to 1.9 kg with associated surgical times ranging from 27.4 to 91.2 minutes [10, 16]. Although soft tissue fluid retention is a relatively common issue after shoulder arthroscopy, complications such as postoperative pain, skin necrosis, neurapraxias, and respiratory compromise fortunately are much less common [1, 4, 8, 11, 12, 15, 17]. We asked whether the fenestrated outflow cannula design could reduce fluid weight gain as a function of procedure duration and irrigation fluid used.

There were several limitations to our investigation. First, although those assessing the outcomes were blinded, we were unable to blind the surgeons regarding the group given the presence or absence of the associated suction tubing attached to the outflow drainage port on the cannula. We considered placing suction tubing on the cannulae of both groups and only placing negative pressure to the experimental arm. However, attachment of a tube to the outflow port without suction still would provide an open cavity for fluid to flow into it from the higher-pressure environment of the soft tissues. In addition, transmission of fluid through the suction tubing would reveal the identity of the experimental arm. Second, although graphic comparison of the fluid gain versus arthroscopic duration and irrigation used generated different slopes in the fenestrated outflow and conventional groups, there was a fair amount of scatter in the data. However, the control slopes of fluid weight gain versus duration and arthroscopic irrigation showed the same trend seen in the study by Smith and Shah [16]. Third, shoulder diagnoses were compared in both groups directly to show equivalency (Table 2), but weight gain was plotted only against irrigation volume and duration. Carr and Murphy [5] also observed soft tissue fluid retention was not necessarily directly related to the type of procedure being performed. Fourth, in calculating net weight gain postoperatively, we did not include the weight of implants when used. However, the weight of the implants was considered negligible compared with the magnitude of weight change we were measuring for (on the order of kilograms). Fifth, we did not quantify the degree of severity of the abnormality being treated. We chose to use the duration of the procedure to reflect the complexity/severity because time is a measurable variable. Degree of severity reporting introduces intraobserver/interobserver variability and further confounds the data. Finally, difference in mean interstitial fluid pressure, as measured by a side port needle or slit catheter [3], could influence the soft tissue swelling generated by intraarticular hydrostatic forces. This also may be true regarding shaver time and the type of blade used. Although the shaver blade creates soft tissue trauma possibly leading to increased swelling, the shaver also removes fluid through its suction mechanism. Thus, there was no reliable way to account for these opposite effects, and we limited our analysis to surgical duration and fluid volume input.

Although the focus of this study was not on the economics of using the fenestrated outflow cannula, the cost-benefit ratio should be considered. At our institution, a fenestrated double-walled outflow cannula is approximately $10 more than a conventional cannula. For the past 2 years, this translates to an additional cost of $3000. During that period, we also had one patient admitted for respiratory compromise attributable to tracheal shift after shoulder arthroscopy. If one such admission could have been avoided, the cost would be offset. Furthermore, this is not taking into account other potential benefits of less tissue edema. However, our study was not designed to address cost issues or postoperative pain related to swelling; these may be topics for future investigations.

We made several general assumptions at the outset of this investigation. First, we selected weight as a measure of fluid weight gain based on prior work by Lo and Burkhart [10] and Smith and Shah [16]. Insensate fluid losses through respiration or perspiration were not measured in the study patients. We assumed capping the interstitial outflow drainage port on the fenestrated outflow cannula in the conventional group would allow it to function as a traditional arthroscopic cannula without having to account for different cannular geometries. The length of each case and the amount of arthroscopic irrigation were selected as independent variables because they reflect surgical complexity. Using the prior fluid weight gain model established by Smith and Shah [16], we calculated the slopes of fluid weight gain as functions of procedure duration and amount of arthroscopic irrigation fluid used.

Longer surgical duration did not correlate with an increase in fluid weight gain when using the outflow mechanism in the fenestrated cannula. Although compartment syndrome of the shoulder resulting from arthroscopy has not been reported, patients undergoing subacromial decompression using an infusion pump have been reported to have intramuscular deltoid pressures exceeding 70 mmHg [9, 13]. Complete and severe airway obstruction have been reported after 105 to 110 minutes during shoulder arthroscopy [2, 7]. Our data suggested less fluid weight gain with longer case duration when using the fenestrated outflow cannulae with continuous interstitial drainage than when using conventional non-outflow cannulae. Although we did not directly measure these parameters in this study, it seems logical excess fluid retention would have an adverse effect on muscle pressure.

An increased amount of arthroscopy irrigation fluid did not correlate with an increase in fluid weight gain using the outflow mechanism in the fenestrated cannula. Worrisome complications such as skin necrosis have been reported secondary to tense soft tissue swelling [12]. In addition to cutaneous lesions, neuropathies and neurapraxias have been described from fluid extravasation. In a prospective study of 20 shoulder arthroscopies evaluating neurapraxia using somatosensory-evoked potentials, one of the two clinical neurapraxias in the series involved the loss of somatosensory-evoked potentials in the musculocutaneous, median, and ulnar nerves corresponding to an area of massive soft tissue edema over the anterior aspect of the shoulder [14]. In another study of 24 patients undergoing shoulder arthroscopy, the investigators found deltoid and supraspinatus pressure elevations were correlated more directly with the amount of arthroscopy irrigation used than with the type of procedure being performed [5]. Using the outflow mechanism in the fenestrated cannula in our study appeared to decrease the fluid weight gain associated with arthroscopic irrigation. Interestingly, fluid volumes did not appear more for the fenestrated outflow group (Fig. 3). We mainly compared slopes instead of absolute volumes. Considering the difference in fluid weight gain between the two groups and clinical observation during the study period, which anecdotally included better observation and maneuverability, we elected to end data collection.

We evaluated the ability of a new cannula design to reduce fluid weight gain in patients having shoulder arthroscopy by continuously removing interstitial fluid through negative pressure at its outer lumen fenestration sites. Compared with conventional nonoutflow cannulae, fenestrated outflow cannulae with negative pressure reduced weight gain associated with longer arthroscopic surgeries and increased arthroscopic fluid volume.

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