

Benefits and Cost Savings from Using Cannuflow Extravastat™ Anti-extravasation Technology in Arthroscopy

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This paper describes the documented complications and hazards to patients from interstitial fluid extravasation (FEX) in patients undergoing arthroscopic shoulder and hip procedures, and the cost burden to the healthcare system, and how using Cannuflow access and fluid management devices with Extravastat™ technology results in lower costs, surgical efficiency, and improved patient outcomes, and helps support newer, advanced repair and augmentation therapies.

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Fluid extravasation in arthroscopy (FEX)

Fluid extravasation (FEX) is probably the most common complication of shoulder arthroscopy. FEX is the unintended migration of pressurized irrigation fluid into the interstitial tissue from the joint capsule and subacromial space. A typical arthroscopy leaves from 1-3 liters and more of fluid behind in the patient's interstitial tissue. This can interfere with surgery due to swelling and collapse of the working space and loss of instrument maneuverability. This swelling and tissue saturation can also lead to early termination of the procedure. A recent statistic states that only 25% of shoulder arthroscopies remain arthroscopic, and as many as 75% convert to open. FEX is an important cause of this, as it limits the amount of time the surgeon can spend in the shoulder arthroscopically. For those cases that convert to open, when extravasation occurs, the surgeon must deal with saturated, poor quality edematous tissue, and a more difficult closure, and potentially poorer cosmesis.

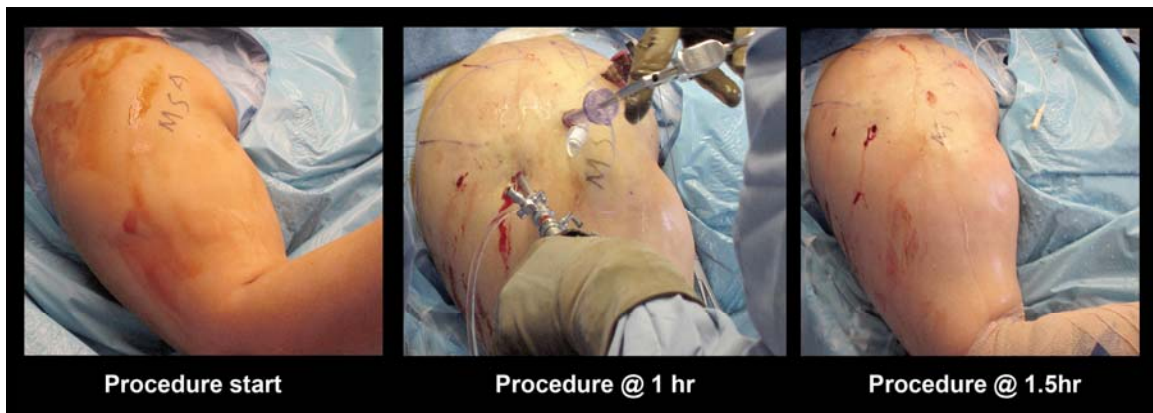


Figure 1 Typical extravasation, shoulder repair and ASAD, gravity irrigation. Note swelling and ischemic tissue blanching even after just 90 min using gravity inflow.

A recent Orthopedic Learning Center (Rosemont IL) Masters shoulder arthroscopy course states the following:

“Excessive fluid extravasation can have very serious consequences if it compromises the airway. In any case where there is excessive swelling the anesthesiologist should check for tracheal deviation before extubating the patient. If there is any concern the patient should be left intubated and started in some diuretics in the recovery room until it is safe to remove the tube. Premature extubation can necessitate an emergency tracheostomy.”¹

There have been field reports of problems such as neck swelling in older patients, as well as reports of fatalities where a surgical team lost the airway due to edema caused by FEX. Some hospitals will keep patients overnight for observation if neck swelling from extravasation of edema occurs.

The AAOS has also recently released *Complications in Orthopaedics: Shoulder Arthroscopy* by Xavier A. Duralde, MD, (Editor) extensively documenting the problems of fluid extravasation, such as edema, airway blockage and fluid overload complications.²

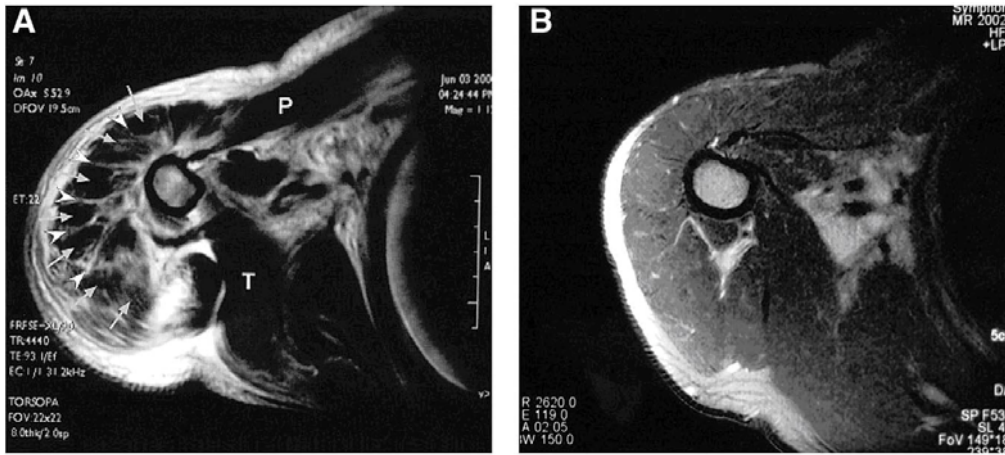


Figure 2 MRI of Extravasated Shoulder, Lim, et. al.³ By permission.

FEX Fluid Load and Procedure Length

Arthroscopy is considered a challenging skill to learn. In the earlier stages of an arthroscopist’s career cases take the longest, and fluid extravasation is especially problematic. It takes about 200 cases for an arthroscopist to become proficient. At 3 cases per week this is about 2 years’ experience. Earlier on the learning curve, 4 or more liters of fluid can build up in a typical case, an amount that can markedly interfere with surgery, may pose a particular risk to some patients, and cause significant post-operative pain. Figure 2 shows and MRI image of the typical extensive infiltration of fluid into the soft tissue from FEX. Once proficiency is attained, a relatively small number (estimated at 15%) of shoulder arthroscopy specialists can perform typical cases in one hour or less. However for the 85% of generalists, or meticulous specialists, or in technically challenging cases these cases routinely take longer (72-112 minutes) and extravasation and its complications are a chronic concern.

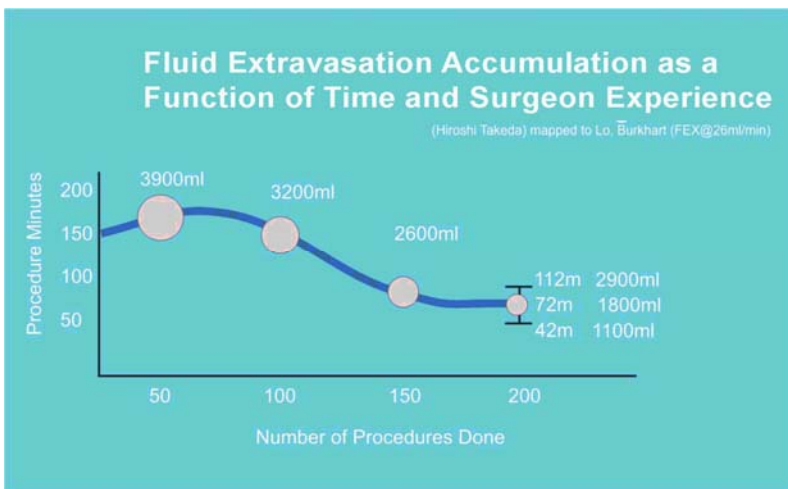


Figure 3 Extravasation as a function of time and surgeon experience⁴

Symptoms of Fluid Extravasation

In the paper *Fluid Absorption in Endoscopic Surgery*⁵, several perioperative and postoperative symptoms of fluid overload are presented, along with their rate of occurrence proportional to the amount of fluid retention. Typical fluid retention in arthroscopy is from 1000ml to 3000ml (Lo, Burkhart).

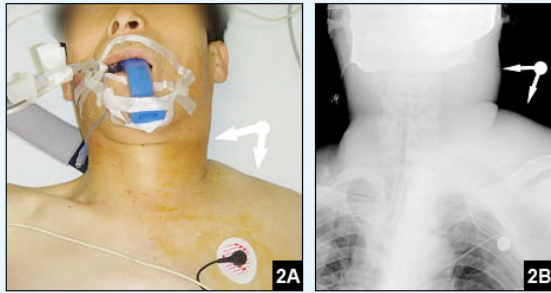


Figure 2: Photograph (A) and radiograph (B) showing the swollen and tense shoulder, neck, and face immediately following arthroscopic rotator cuff repair.

Figure 2 Neck swelling from extravasation after 45m procedure (Venkat, et.al)⁶ By permission.

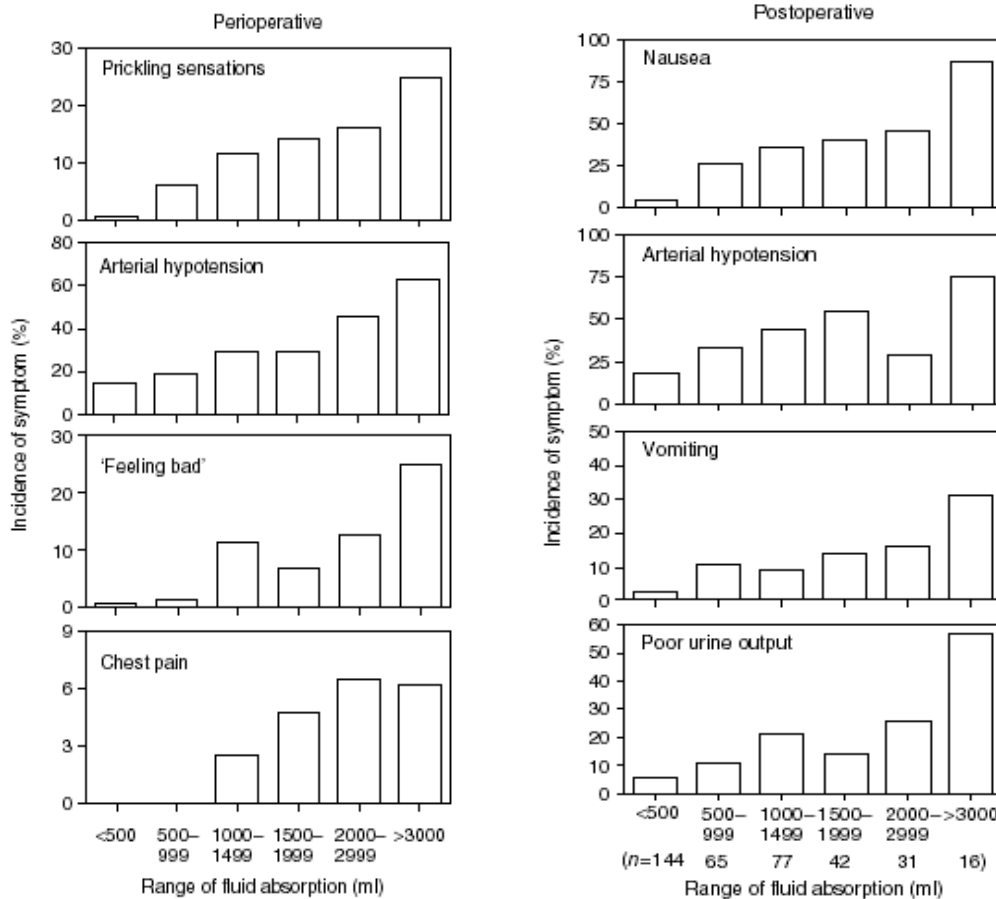


Figure 5: Fluid absorption symptoms: Hahn, RG *British Journal of Anaesthesia* 96 (1): 8-20 (2006) by permission.

Documented Efficacy of Extravastat™ Technology

Cannuflow Extravastat technology is proven to be effective in significantly reducing rate of accumulation of extravasated fluid during arthroscopic surgery and significantly reducing the overall amount of extravasated fluid retained. This was clearly demonstrated⁷ in a recent randomized, prospective clinical study at Loma Linda University Hospital: “Fenestrated Cannulae with Outflow Reduces Fluid Gain in Shoulder Arthroscopy” published in the journal *Clinical Orthopedics and Related Research (CORR)*⁸

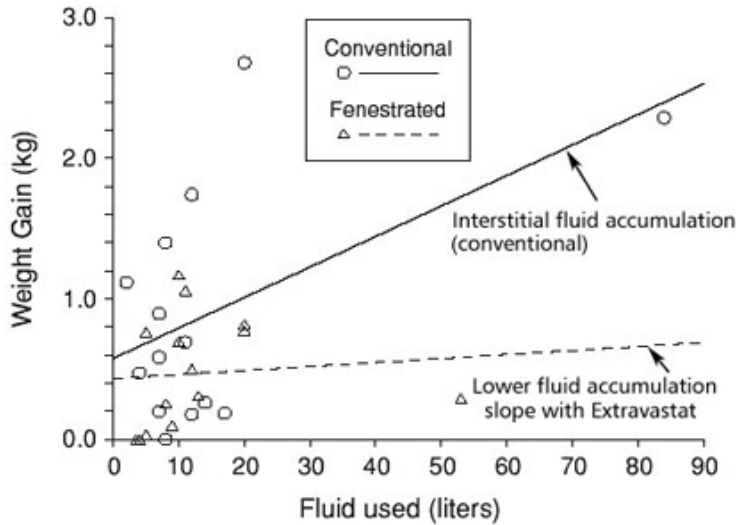


Figure 6 Conventional vs Extravastat fluid accumulation rate slope. By permission.

How Extravastat™ Technology Works

Extravastat™ is a patented interstitial tissue drainage technology that suctions out extravasated fluids from the interstitial tissue. This significantly lowers the rate of extravasation and prevents fluid overload. Extravastat technology is very easy to use, is incorporated into instruments the surgeon already uses (portal cannulas, scope sheaths, portal plugs) and requires no capital equipment expenditure or change in procedure.

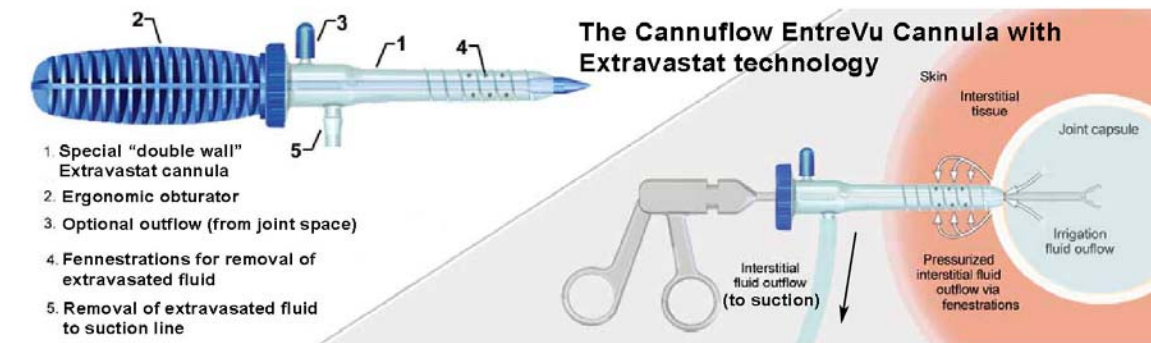


Figure 7 EntreVu cannula, principle of operation

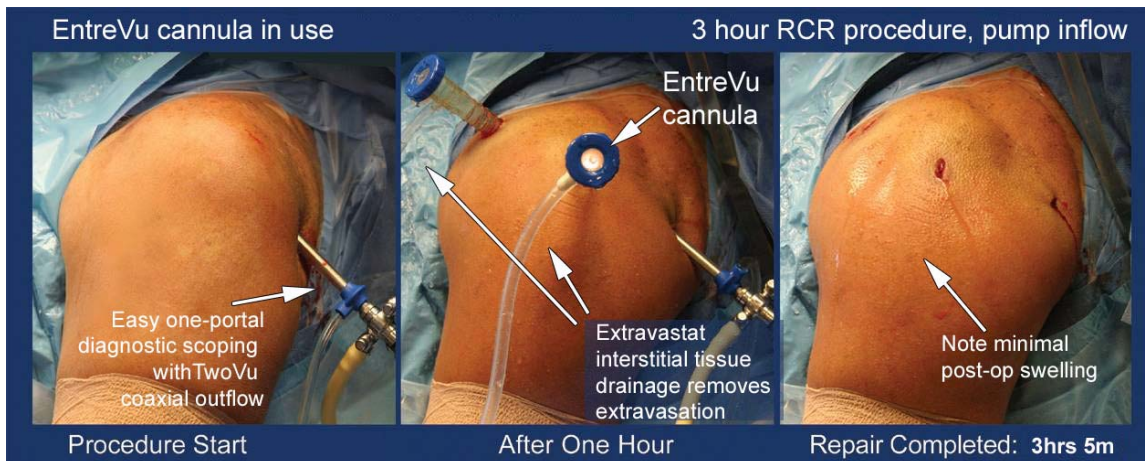


Figure 8 Shoulder rotator cuff repair, using EntreVu cannula, 3 hours, showing minimal swelling from extravasation

How Extravastat technology Helps Meet Patient Demand for Minimally-Invasive Procedures

Patients are increasingly unwilling to undergo more invasive procedures when there is a minimally invasive alternative. A Mayo Clinic study by Sperling, et.al.⁹ revealed a 92% patient preference for arthroscopy vs. open surgery and a 19.5% of patients would choose to avoid shoulder repair surgery altogether if an open surgery were the only available option.

Arthroscopy has the reputation, of generating less morbidity, scarring, and less post-operative pain that open shoulder repair.¹⁰ Yet, it is estimated that only 25% of shoulder repairs are done fully arthroscopic, and 75% convert to open. There are two potential reasons for this: one, the difficulty in mastering the technically challenging art of arthroscopic tissue repair, and two, fluid extravasation that limits the amount of time a surgeon can spend in a shoulder, which contributes to the difficulty in mastering arthroscopy.

Control of extravasation may greatly reduce the need for many procedures to “go open.” Active control of extravasation with active interstitial tissue drainage such as the EntreVu Cannula with Extravastat technology can enable this, and help keep more shoulder cases closed, which results in higher patient satisfaction and faster return to activity.

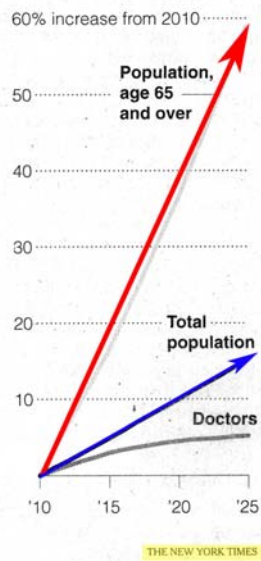
Additionally, in cases that convert to open procedures, the use of Extravastat anti-extravasation technology can help preserve tissue quality, resulting in a more efficient open procedure, easier closure, and potentially better post operative healing due to less tissue edema.

Categories of Patients at Particular Risk for FEX Complications

There are other categories of patient where FEX is especially problematic. Important ones are:

Older Patients

“Orthopedics (for older) and geriatric patients is the fastest growing and most neglected segment of the orthopedic market.”¹¹ Older patients need (and demand) minimally invasive arthroscopic surgery. These patients may also be at risk for serious, and potentially life-threatening complications from FEX due to underlying cardiopulmonary and renal conditions.



“The number of patients over 65 years of age is increasing 10 times faster than those under 65... The average geriatric patient has 1.8x the complications of the non-geriatric patient.”¹²

As muscle and skin ages, collagen begins to break down, and the tissue becomes less elastic. Some of these patients, such as older, higher BMI female patients with reduced muscle tone are at particular risk for neck swelling and tracheal deviation, airway blockage, and fluid overload complications. Older patients extravasate more quickly, as the pressurized fluid dissects the tissue planes. Older patients are also at increasing risk statistically for underlying cardiac, pulmonary and renal insufficiency, putting these patients at particular risk for complications from fluid overload from FEX. The risks of fluid overload to the older patient has been extensively documented in the urology literature, and is commonly referred to as “TUR (Trans-urethral resection) Syndrome.”

Obese Patients

Obese patients tend to have less muscle tone and poorer tissue quality due to subcutaneous fat which allows fluid to dissect the tissue planes more easily, and forms less of a seal at the tissue tract and cannula interface, causing excessive extravasation. Subcutaneous adipose tissue (fat) is also more easily susceptible to pressurized irrigation fluid absorption. Obese patients are documented to have more surgical complications overall, and tend to heal more slowly. FEX is of particular concern in this growing population of patients.

Smokers

Smoking is a risk factor for fluid extravasation, as documented in the urology literature. This is possible due to tissue ischemia and lower oxygen transport.

Larger, Muscular Patients

The large muscular patient, such as football players or laborers with significant deltoid muscle mass the absorption of irrigation fluid in a FEX particular problem. It is common that this category of patient will swell, requiring the use of a second, longer cannula to reach the joint space. This doubles the cost of disposables. EntreVu helps prevents this swelling and loss of cannula length, and allows the procedure to be done without opening additional cannulae.

Diabetic Patients

The diabetic patient whose less elastic tissue quality leads to cannula leakage at the tissue tract, fluid absorption into the soft tissue and significant FEX. Devices with Cannuflow Extravastat technology can help mitigate this problem.

Categories of Documented Complications from FEX

Post-operative Pain

Post-operative pain is possibly the most common complication of FEX. The stretching of the tissue caused by extravasation is suspected by surgeons to be an important contributing cause of post-operative pain. It can also cause neuropraxia and nerve damage as the swelling puts traction on nerves.

Patient discomfort can be quite burdensome to the healthcare system in terms of increased patient management, patient contacts to the on-call surgeon, lower patient satisfaction, and the costs of increased use of analgesics. Field reports have shown that FEX can also be a contributing factor to PONV (post-operative nausea and vomiting)

Compartment Syndrome

Compartment syndrome is a feared complication of fluid extravasation:

“Compartment syndrome is a painful condition that results when pressure within the muscles builds to dangerous levels. If pressure within the compartment gets too high, it can damage blood vessels and nerve and muscle cells. Acute compartment syndrome is a medical emergency. Without treatment, it can lead to paralysis, loss of limb or death.”¹³

Compartment syndrome may often require painful and invasive fasciotomy to resolve, result in scarring and disfigurement, and painful recovery. FEX is a well documented cause of compartment syndrome. It is relatively rare in shoulder arthroscopy, and more common in elbow, ankle, and hip arthroscopy.^{14 15}

Infection Risk¹⁶

Fluid load in wounds has been documented to inhibit healing¹⁷, and fluid extravasation has been documented to increase the risk of infection.

FEX has been shown in clinical studies to raise risk of infection in shoulder arthroscopy due to the dilution of the surgical sterile preparation and dressing strike-through due to irrigation fluid leaking from the surgical wounds post-operatively.

Neck Swelling and Airway Blockage

Life-threatening airway blockage during shoulder arthroscopy has been extensively documented in the anesthesia literature. Most of these potential catastrophic events have been averted only by immediate procedure termination and skillful emergency airway management. At least one fatality and several emergencies have been reported in the literature.^{18 19 20} The following citation is especially relevant:

“Several earlier reports have described life-threatening airway obstruction during arthroscopic shoulder surgery performed under regional anesthesia, caused by the leakage of irrigation fluid out of the shoulder joint space into the surrounding soft tissues and then the neck and the pharynx. Here, we present a case of airway obstruction that occurred in a patient under general anesthesia. A 77-year-old woman with a rotator cuff rupture who was to undergo right-shoulder arthroscopic surgery was anesthetized with fentanyl and propofol. Her airway was secured with a flexible laryngeal mask airway (LMA). During surgery, the compliance of her breathing bag became gradually poorer, and finally we were not able to ventilate her at an airway pressure of 60 cmH₂O. We found that her chest wall, neck, and face were swollen and tense. Laryngoscopy revealed massive swelling of the pharyngeal soft tissues. The vocal cords were not visible. Her trachea was intubated blindly, and adequate ventilation was re-established. ... We recommend that physicians should periodically examine the neck of any patient undergoing arthroscopic shoulder surgery, especially when general anesthesia is used, because anesthetized patients cannot complain of breathing difficulty and the airway swelling may progress until it becomes life-threatening.”²¹

Reduction of fluid load from extravasation with Extravastat interstitial tissue drainage technology can help mitigate this risk, especially in older patients such as the one mentioned in this paper.

Cardiovascular Risk²²

Congestive Heart Failure (CHF) is the progressive loss of heart function usually due to hypertension, affecting 5 million patients with 500,000 new cases reported per year, and 300,000 deaths.²³ The congestive component is due to the accumulation of fluids in the tissues of the lung, leading to difficulties in breathing. This is due to the pulmonary edema resulting from decreased cardiac output. The mechanisms of this are only beginning to be accurately understood.²⁴

The dumping of excess fluid via FEX into a patient already suffering from underlying CHF can be especially risky. A leading cardiologist, states this is “absolutely a reasonable concern for any patient with congestive heart failure”²⁵ This concern was also expressed by a past president of AANA (the Arthroscopy Association of North America) The following citation from the *Arthroscopy Journal* documents the complication rates in arthroscopic surgery attributable to FEX:

“Weber et al. documented overall complication rates of between 5.8% and 9.5%. These authors emphasized that potentially serious general surgical complications may occur in shoulder arthroscopy, and in this earlier study, irrigation pumps were implicated in fluid extravasation... and the development of pulmonary problems.”²⁶

How Cannuflow Extravastat Technology Can Help Support Advanced Arthroscopic Procedures

The practice of arthroscopy is an ever-evolving field. The trend is toward doing more and more “through the scope” and less and less as open procedures. Challenging procedures such as complex multi-tendon repairs and shoulder stabilizations once thought difficult or impossible arthroscopically are now considered more or less routine.

The more work that is done “through the scope” the more time the surgeon will need in the shoulder arthroscopically. Extravasation build up as a function of time, with 70 minutes considered the maximum safe time limit in the shoulder. For the typical surgeon this is right at the edge of where a proficient arthroscopist with about 200 cases of experience operates before extravasation begins to seriously interfere with the procedure. This also limits the range of therapeutic procedures that may be done arthroscopically.

Two advanced repair therapies that are beginning to make their way into practice are platelet therapy implants to improve tendon to bone healing, and graft matrix repair implants.

Graft matrix implant for cuff repair is a technically demanding procedure, adding at least one hour to an arthroscopy even in the hands of a highly experienced surgeon. Even experienced surgeons find that they are “shut out” by extravasation and either have to

abandon the procedure, or deliver the implant through a mini-open procedure, and now having to fight with swollen, saturated, edematous tissue.

Because the Cannuflow EntreVu portal cannula with easy to use Extravastat technology significantly reduces the rate of interstitial fluid accumulation, these more time-consuming and complex procedures now become practical arthroscopically.

How Cannuflow Extravastat Technology May Help Prevent FEX Complications

The root cause for the previously mentioned complications is excess interstitial fluid load, sometimes up to several liters, on the patient from extravasation. Until now, there have been no solutions available to address this chronic problem, except for surgeons to work faster, or to avoid arthroscopic cuff repairs entirely with more-invasive mini-open procedures.

Cannuflow Extravastat technology is a ground-breaking yet simple and easy to use system that has been shown to significantly reduce the amount of extravasated fluid retained by the patient. It is inexpensive, and requires no change in surgeon procedure. It is the first and only system for actively removing extravasated fluids during arthroscopic procedures.

The High Costs of FEX Complications

Costs of FEX in Extra Hospital Day Stays

Numerous studies document the complications associated with this excessive fluid in shoulder arthroscopy such as airway blockage, neuropraxia, delayed resolution of swelling, tissue ischemia and increased infection risk.²⁷ Reported complication rates can run from 1.4-3.2% for all joints and up to 11.6% for subacromial procedures²⁸ for an average of 5.5%. Assuming 800,000+ shoulder procedures per year (USA) the number of complications from FEX is over 44,000. If these result, for example, in an additional one day hospital stay at a cost of \$3000 per day²⁹, and the cost of extravasation in the growing number of hip arthroscopy cases is considered, this extra cost burden to the healthcare system due to FEX may be as much as \$132,000,000M per year.

Malpractice Cost Burden of FEX

Malpractice awards can be exceptionally costly and burdensome to the healthcare system, and to the individual surgeon. According to the Physicians Insurance Association of America (PIAA) the average malpractice claim is \$314,000³⁰. A fatal complication can run \$1M per occurrence or more.^{31 32} A specific case of chest pain and heart failure in an

arthroscopic sub-acromial impingement case in Florida resulted in the death of the patient and a \$1,300,000 settlement.³³ Assuming that Florida accounts for 10% of all arthroscopies, this settlement alone added a \$16.25 cost burden to every Florida shoulder case.

Assuming one percent of complications of FEX generating the average claim of \$314,000, this adds an estimated additional financial burden on the health care system for FEX of over \$138,160,000. This does not take into account the lost productivity on the part of the surgeon, defense costs, and higher malpractice insurance premiums.

Estimated Cost Burden of FEX

Adding the potential costs of extra hospitalization, and the potential cost of malpractice burden, the total may easily exceed \$270M per year. This adds a global cost to all shoulder arthroscopies of \$165 per procedure in terms of hospital stays, and \$172 per procedure in terms of malpractice costs for a total cost of potential complications of \$337 per procedure. The use of extravasation control technology such as the Extravastat interstitial tissue drainage by Cannuflow may help avoid these risks and costs.

Table 1 Cost Burden of FEX

Category of Cost	Cost to System (USA)	Cost Per Procedure (USA)
Hospital Stay Costs	\$132,000,000	\$165.00
Malpractice Costs	\$138,160,000	\$172.70
Combined Costs	\$270,160,000	\$337.70

Table 2 Projected Cost Savings using Extravastat Technology in Arthroscopic Rotator Cuff Repair Cases

Line Item	Cost Per Case	500 cases (@10 cases/week x 50 weeks/yr)
Average cost of generic cannula (\$25-\$40)	\$32.50	\$16,250
Retail price of Cannuflow EntreVu Cannula	\$45.00	\$22,500
EntreVu cost per procedure after replacement	\$12.50	\$6250
Averaged FEX cost burden	\$337.70	\$168,850
Averaged savings using Cannuflow EntreVu	\$325.20	\$162,600

Based on these numbers, an investment of \$6250 per year for the additional cost of Extravastat technology can yield a 13x ROI on \$82,000 in avoided costs from prevention of complications and a 14x ROI on \$86,350 in avoided malpractice costs.

Conclusion

Solutions to the growing problem of FEX complications in all arthroscopic procedures are urgently needed. Cannuflow Extravastat technology offers the only solution to actively drain extravasation on the market today.

Fluid extravasation has been clearly implicated in the scientific literature in numerous complications such as airway blockage, post-operative pain, compartment syndrome, and increased infection risk. There is also a potential risk with FEX and older patients with underlying cardiovascular disease, and the number of these patients at risk is growing rapidly.

This problem of fluid extravasation complications has several drivers. These include an aging and active population, as well as a growing population of all ages of the obese and sedentary. All of these growing populations are at risk for complications caused by fluid extravasation in shoulder and hip and small joint arthroscopic surgery, and these complications place a significant global cost burden on the healthcare system. Cannuflow Extravastat technology helps avoid these costs.

A new standard of care is required for arthroscopic fluid management. Prevention of FEX during arthroscopy of at-risk patients may help improve outcomes, increase patient satisfaction, prevent costly hospital admission and re-admissions, hospital acquired infections (HAI's) as well as help prevent liability exposure. Prevention of FEX may be potentially life-saving as well.

Cannuflow is leading the way with the world's first and only comprehensive line of active anti-extravasation products for arthroscopic fluid management.

For more information, or to order Cannuflow devices for arthroscopy, contact Cannuflow 1190 Coleman Avenue, #250, San Jose CA 95110, 408-764-0220 or visit www.cannuflow.com

¹ Orthopedic Learning Center Masters Course in Shoulder Arthroscopy course syllabus February 15-17 2008 page 162, presentation by J. Emory Chapman, MD

² http://www4.aaos.org/product/details_page.cfm?code=02957&dlink=02957Duralde.cfm

³ ³ Rhabdomyolysis Following Shoulder Arthroscopy, 12 September 2006 Lim JK, Ang KC, Wang SC, Kumar VP pages 1366.e1-1366.e5

⁴ See also Arthroscopic Rotator Cuff Repair: The Learning Curve, Guttman et.al. Arthroscopy 21:4 pp 394-399

⁵ *Fluid Absorption in Endoscopic Surgery* British Journal of Anaesthesia 96 (1): 8-20 (2006) R. G. Hahn Department of Anaesthesia, Karolinska Institute, South Hospital, SE-118 83, Stockholm, Sweden, on-line at: <http://bj.oxfordjournals.org/cgi/content/full/96/1/8>

⁶ Upper Airway Compromise by Extravasated Fluid: A Rare Complication After Arthroscopic Repair of Atrophic Cuff Tear By Gorthi Venkat, MS; Young Lae Moon, MD; Woong Chae Na, MD; Keum Young So, MD ORTHOPEDICS 2009; 32:1, <http://www.orthosupersite.com/print.asp?rID=43785>

⁷ Clin Orthop Relat Res. 2009 Jun 26. [Epub ahead of print] Fenestrated Cannulae with Outflow Reduces Fluid Gain in Shoulder Arthroscopy. Syed HM, Gillham SB, Jobe CM, Phipatanakul WP, Wongworawat MD.

⁸ Fenestrated Cannulae with Outflow Reduces Fluid Gain in Shoulder Arthroscopy (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.

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⁹ Patient Perceptions of Open and Arthroscopic Shoulder Surgery John W. Sperling, M.D., M.B.A., Adam M. Smith, M.D., Robert H. Cofield, M.D., and Sunni Barnes, Ph.D. Arthroscopy. 2007 April; 23;(4):361-6

¹⁰ Ibid.

¹¹ Billie Young Interview with Julia Switzer, MD Orthopedics This Week “Geriatric Orthopedic Surgery: It’s the Future Baby!” April 8, 2008

¹² Ibid

¹³ http://orthoinfo.aaos.org/fact/thr_report.cfm?thread_id=287&topcategory=General%20Information

¹⁴ Abdominal Compartment Syndrome During Hip Arthroscopy. Sharma A, Sachdev H, Gomillion M. Department of Anesthesiology, New York Presbyterian Hospital, Weill Cornell Medical Center, NY, NY Anaesthesia. 2009 May; 64 (5):567-9.

¹⁵ Arthroscopy. 2009 Feb;25(2):215-8. Epub 2007 Nov 9. Related Articles, Links

Leg anterior compartment syndrome following ankle arthroscopy after Maisonneuve fracture.

Imade S, Takao M, Miyamoto W, Nishi H, Uchio Y. Department of Orthopaedic Surgery, Shimane University School of Medicine, Shimane, Japan. imades@med.shimane-u.ac.jp

¹⁶ INFECTION AFTER MINI-OPEN ROTATOR CUFF REPAIR (Poster Presentation AOSSM 2001, www.sportsmed.org/tabs/education/downloads/Annual_2001_Posters.pdf -) Mauricio Herrera, MD (Queens, NY, NJ), Fletcher Reynolds, (NY, NJ), Richard Wilkes, (NY, NJ), Michael Freehill, (NY, NJ), Greg Bauer, (NY, NJ), Louis Bigliani, (NY, NJ), William Levine, (NY, NJ)

¹⁷ Inhibition of cell proliferation by chronic wound fluid. Bucalo B, Eaglstein WH, Falanga V. University of Miami School of Medicine, Department of Dermatology, Miami, Fla., USA.

¹⁸ Life Threatening Airway Edema Resulting From Prolonged Shoulder Arthroscopy Steven L. Orebaugh, M.D. Anesthesiology, V 99, No. 6, Dec. 2003.

¹⁹ Severe Airway Obstruction During Arthroscopic Shoulder Surgery Stephan Blumenthal, M.D., Marco Nadig, M.D., Christian Gerber, M.D., Alain Borgeat, M.D. Source: Anesthesiology, V 99, No. 6, Dec. 2003.

²⁰ Complete Airway Obstruction During Shoulder Arthroscopy Hynson JM, Tung A, Guevara JE et al. Anesthesiology Analg, 76 : 875-878, 1993.

²¹ Airway obstruction involving a laryngeal mask airway during arthroscopic shoulder surgery. Yoshimura E, Yano T, Ichinose K, Ushijima K. Department of Anesthesiology, Kumamoto University Hospital, 1-1-1 Honjo, Kumamoto 860-8556, Japan.

²² Five million Americans have Congestive Heart Failure (CHF), a chronic and often undiagnosed condition in which the heart cannot pump oxygen-rich blood to the body’s cells or is unable to prevent blood leakage into the lungs. People with heart failure experience shortness of breath and fluid retention that results in swelling of the feet and legs. <http://www.massgeneral.org/cardiology/cardiology/failure.html>

²³ *Advanced Treatment of Congestive Heart Failure*, Keith Wesley, MD Wisconsin State EMS Medical Director www.tdh.state.tx.us/hcqs/ems/Wesley_CHF.pdf

²⁴ In areas of the lungs that are adjacent to the pleura, this pressure gradient results in movement of fluid from the interstitial space across the visceral pleura into the pleural space. This movement of fluid, coupled with impaired lymphatic drainage due to elevated systemic venous pressures in left ventricular failure, results in a pleural effusion. John L. Johnson, MD *VOL 107 / NO 4 / APRIL 2000 / POSTGRADUATE MEDICINE*

²⁵ Correspondence with author

²⁶ Rhabdomyolysis Following Shoulder Arthroscopy, 12 September 2006 Lim JK, Ang KC, Wang SC, Kumar VP pages 1366.e1-1366.e5

²⁷ See http://www.cannuflow.com/research_archive.html#extravasation

²⁸ Complications of Subacromial Surgery Wesley M. Nottage, M.D. The Sports Clinic Orthopaedic Medical Associates Laguna Hills, California

²⁹ Sean Candrilli MS and Josephine Mauskopf Ph.D. "How Much Does a Hospital Day Cost" Meeting of the International Society for Pharmacoeconomics and Outcomes Research, 2006

³⁰ PIAA Warns That Without Tort Reform, Medical Malpractice Insurance Industry Return to Profitability Likely To Be Short Lived http://www.insurancenewsnet.com/article.asp?a=top_news&id=68294

³¹ Dr. Robert Hahn, Karolinska Institute, Sweden. Correspondence with author.

³² Tdcinjurylaw.com

³³ Vidmar, Neil, *Million Dollar Medical Malpractice Cases in Florida: Post-Verdict and Pre-Suit Settlements* Duke Law School Faculty Scholarship Series, Duke Law School 2006