MADAJET XL
MEDICAL PRESENTATION

MADA Medical
MADA Equipment
MADA International

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11/08

Contains

1- MadaJet XL Medical

1- Carrying case

1- MadaJet XL stand

1- Wrench for Extenda Tip

1- 32 oz. MadaCide-FD disinfectant solution

1- Stylet

2- Extra Pyrex fill chambers

1- Extra Extenda Tip with Sheath

CAUTION: Please do not test your MadaJet XL by injecting your fingers or hand. Injecting directly over the digital bones can produce periostitis or traumatize the underlying bones.
For special applications, please review all enclosed literature.

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MADAJET XL
MEDICAL PRESENTATION

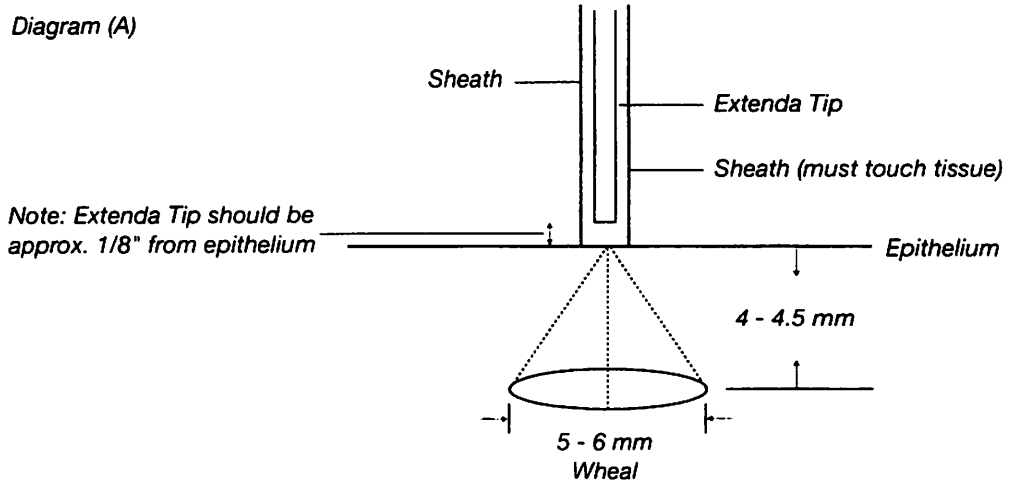
COMMENTS:

We fully realize that most physicians can frequently put a needle into a patient's tissue with minimal pain. However, it is not so much the **pain** from the needle that bothers the patient, **IT IS THE NEEDLE ITSELF** that patients fear.
PATIENTS HATE NEEDLES. "Needle Phobia" is something that all physicians have to deal with.

1. The MadaJet XL, a fine precision instrument, has the unique ability to function as an injection device for local anesthetic agents.
   It is also the ONLY jet injection device that allows the physician to inject through ALL BODY ORIFICES for deep tissue infiltration, i. e. oral cavity and laryngeal areas, the vagina and cervix, rectum, ear and nasal areas, open wounds and surgical openings.

   The physiological advantage of injections to the above areas is that the physician can provide excellent anesthesia levels using small volumes of local anesthetic agents, accomplishing this with **minimal patient discomfort** in contrast to the needle and syringe technique. Another interesting physiological advantage is that by jet injection technique, a very small amount by volume (0.1 cc of 2% anesthetic) will provide unusually high levels of tissue anesthesia. This advantage allows for the absence or **minimal blood levels** of any medication injected with the MadaJet XL.

   The controlled depth of anesthetics, or other aqueous medicaments into the intradermal tissue is seen in the diagram below. In contrast to "pooling" of medication by syringe/needle, the MadaJet XL disperses the medication into the tissue in tiny droplets, producing **immediate effect** and greater intensity of the drug used.



Unique Feature of the MadaJet XL

MadaJet XL Extenda Tips are removable and interchangeable between patient use. They can be sterilized by autoclaving, cold sterilization and other normal sterilizing procedures. Each Extenda Tip comes with a **protective sheath** which is normally placed gently on the tissues to be injected. The sheath should be left on the Extenda Tips at all times.

General Information regarding Medical Specialties

A. Plastic/Reconstructive Surgeons
B. Dermatologists
C. Otolaryngologists
D. Colorectal Surgeons
E. Anesthesiologists
F. OB/GYN
G. Emergency Room Physicians
H. Orthopedic Surgeons
I. Urologists

Plastic Surgeons/Reconstructive Surgeons:

a. Local anesthetics into skin tissue for biopsies, keloids, minor surgical procedures, hair transplants.

b. Capabilities of injecting into the inner nasal and ear (otic) tissues.

c. Pinpointing tissues around the eyes.

d. Suturing or removal of sutures.

e. Infiltration of steroids into tissue to reduce inflammation and pain which frequently occurs where simple non-infectious inflammatory conditions can exist.

NOTE: The MadaJet XL has the unique capability of producing excellent tissue anesthesia without the "ballooning" effect caused by syringe and needle technique. This is of great value in allowing the surgeon to suture the proximal edges of a wound or incision without distortion of the tissue, thereby minimizing scar tissue and tissue artifacts (abnormal histological tissue changes) while performing biopsies, etc.

Dermatologists:

The longest history of use has been with this specialty. The MadaJet XL with the 3/4" Extenda Tip provided, is an excellent instrument to inject dermatological lesions with great advantages for the patient:

a. Far less painful than the use of a needle and syringe.

b. Allows for minimal volumes of steroids to be used while producing much better control and treatment of dermatological lesions.

c. Greatly reduces the possibility of causing blood levels (titers) of the steroids used.

d. Greater control of depth of penetration (4-4.5 mm) below the epithelium in the intradermal areas.

e. Allows physician to mix the steroid to be used in much smaller volumes, with 2% Lidocaine as the diluent. This procedure provides much better patient acceptability by reducing the ache or pain from the steroids hours after treatment.

NOTE: Always keep steroids cold before treatment to prevent crystal growth in the vial and always keep the anesthetic at body temperature to prevent burning sensation and discomfort from use of cold anesthetic agents.

A suggestion regarding the dilution mixture of the steroid with 2% Lidocaine is to initially use 1/3 part by volume of the anesthetic and 2/3 parts by volume of the steroid. The concentration of the steroid can be increased after the first or second treatment. The steroid often successfully used is Celestone Soluspan by the Schering Company.

See Medical Applications brochure for general dermatological uses.

Otolaryngologists:

In this specialty, there is no other instrument available that can perform local injections of anesthetics or steroids like the MadaJet XL.

a. Injections into tissues of the anterior and posterior portions of the aural and nasopharyngeal areas are easily done with much less pain for the patient. If larger volumes of anesthetics are needed by using a needle and syringe, the patient will have minimal discomfort from this procedure, although this is often not necessary.

b. Many otolaryngologists are also involved in facial plastic and reconstructive surgery including installation of adipose (fat) tissue from other parts of the body as well as the infiltration of collagen materials or similar medicaments for facial wrinkles. The MadaJet XL has been clinically used for this procedure.

NOTE: A 6.5" (165.1 mm) Extenda Tip is available for reaching the pharyngeal areas.

Colorectal (Proctology):

The areas around the anal sphincter are often injected, as are the tissues internally and adjacent to the sphincter tissues. This is normally a quite painful procedure and the MadaJet XL can be an excellent and a far less painful method of providing adequate anesthetics (2% Lidocaine). It has been reported that the injections directly into hemorrhoidal tissues have been successfully done.

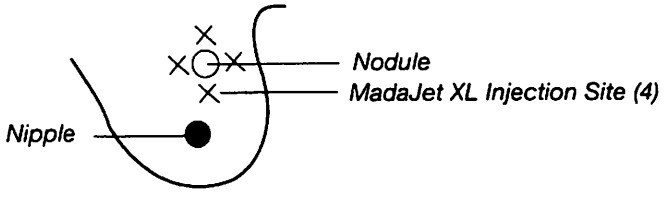
NOTE: Various lengths of Extenda Tips are available to reach deeper areas up to 6.5" posteriorly to the sphincter area.

OB/GYN:

A common procedure in this specialty is cervical biopsies. This often painful procedure is an excellent place where the simple injection of local anesthetic (2% Lidocaine) with the MadaJet XL will facilitate the physicians test, and most certainly add to the patients comfort.

Breast tissue biopsy - as previously discussed, injections with the MadaJet XL of 2% Lidocaine adjacent to the tissues to be biopsied is an excellent method of anesthetizing these tender tissues. From 1-4 injections should be made at 90 degree angles to the area involved.

Diagram (B)



Each of the injections should be approximately 1/4" away from the periphery of the nodule. The depth of injection will be 4.5 mm below the epithelium, and will produce a 6 mm wheal at the base of each MadaJet XL injection (see page 1 diagram A). The MadaJet XL can be autoclaved if it is to be used in the delivery room for use during episiotomy procedures.

Emergency Room Physicians:

Lacerations of the face and other parts of the body, especially with children, often require painful injections of local anesthetics causing the psychological trauma of "needle phobia". The MadaJet XL provides two (2) major advantages:

a. Eliminates the use of the needle and syringe.

b. Will not balloon the tissues. This makes it easier to suture the proximal edges, and also prevents undue amounts of scar tissue forming from the suture line.

Venipuncture or arterial punctures for blood sampling can be painlessly done by injecting 2% Lidocaine adjacent to the vessel or where needle penetration is done.

When attempting to do this directly over the blood vessel, simply "hump" the skin tissue between the first finger and thumb and inject into this area.

NOTE: If injections of anesthetics are required into deeper tissue areas, this can easily be done by injections with the MadaJet XL and using a 4 x 4 gauze pad to prevent splattering of blood or fluids from the wound.

Orthopedic Surgeons:

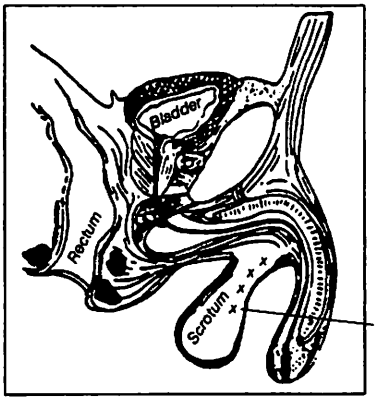
a. Arthroscopy procedures requiring injections of local anesthetics into the knee can be greatly facilitated by using the MadaJet XL. Several prominent Sports Physicians employ the use of the MadaJet XL. Injections at the site where the scope is to be inserted with the MadaJet XL is recommended using 2% Lidocaine/1:1,000,000 epi.

b. Bursal infiltrations - This frequently painful procedure can be greatly helped by first injecting 2% Lidocaine at the site where "deep needle" insertion is to be made.

Urologists:

a. Injections in the upper and lateral areas of the scrotum with 2% Lidocaine for vasectomies has been successfully performed. 2-3 injections spaced approximately 1/4" apart in a descending line on each lateral surface of the scrotal sac is recommended.

Diagram C.



Approximate site of injections 1/4" between each injection.

Note:
Please see Page 6 describing "No Scalpel Vasectomy Procedure". Clinical Report Available.

b. Bent Spike Syndrome (Pyronees Disease).
Injections directly intraurethral through the head of the penis using a mixture of steroids and 2% Lidocaine can be done. Various size Extenda Tips are available up to 6.5" in length. This allows the physician to inject directly into the Keloids or scar tissue of the patients urethral tissue.

Anesthesiologist:

a. Anesthetizing the site for spinal injections.
b. Anesthetizing the site for arterial or venous punctures.
c. Similarly for insertion of catheters.
d. Biopsies, see diagram B.

THE JOURNAL OF UROLOGY®
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Vol. 173, 1677–1680, May 2005
Printed in U.S.A.

NO-NEEDLE JET ANESTHETIC TECHNIQUE FOR NO-SCALPEL VASECTOMY

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ABSTRACT

Purpose: We describe a new, modified jet injection technique for local anesthesia for no-scalpel vasectomy without the use of a needle, which may minimize the fear of vasectomy in men due to the needle involved in local anesthesia.

Materials and Methods: A MadaJet Medical Injector (MADA Medical Products, Carlstadt, New Jersey) was used in this study to deliver a high pressure spray of 0.1 cc local anesthetic solution directly through the scrotal skin down onto the tissue around the vas. Two or 3 jet injections are delivered to each vas and a total of 4 to 6 suffice for the entire vasectomy.

Results: No-needle jet injection is remarkably effective for local anesthesia for no-scalpel vasectomy. The average volume of anesthetic solution per jet injection is 0.1 cc with 0.2 to 0.3 cc for each vas. Onset is almost immediate, within 10 to 20 seconds after injection. About 465 patients were anesthetized by the jet injection technique with great satisfaction. The average visual analog scale score for the pain of the jet injection itself was 1.71 of 10. The average visual analog scale score for the pain of subsequent vasectomy during the surgical procedure was 0.66 of 10 (median 0.2). No hematomas were noted. Patients experience the mild discomfort of a pinch, not unlike a rubber band, with the first injection.

Conclusions: No-needle anesthesia with jet injection is a new technique to deliver rapid onset of profound local anesthesia to the patient undergoing vasectomy. It is a simple and safe approach with high patient satisfaction, as reflected in low pain scores. The benefit of this technique without a needle is that it may decrease the fear of pain in men and enhance the popularity of vasectomy worldwide.

KEY WORDS: vasectomy; anesthesia; injections, jet; scrotum; needles

Vasectomy is a safe and effective method of permanent male contraception. In the United States it is used by almost 7% of all married couples and performed in approximately a half million men yearly, more than any other urological surgical procedure. Historically some men have shied away from vasectomy because they fear pain and the possible complications. However, in clinical practice one of the commonest voiced concerns is that of the needle for the injection of local anesthesia into and through the scrotal skin. Efforts to enhance the popularity of vasectomy have led groups in China to develop refined methods of no-scalpel vasectomy that minimize trauma, pain and complications.[1–5] While the introduction of no-scalpel vasectomy has successfully allayed the fear of many men with regard to the scalpel, the success of Chinese groups in attaining these goals is evidenced by a complete reversal of the ratio of male-to-female sterilizations (now 3:1) in favor of vasectomy in the Sichuan province of China.[6]

The option of receiving local anesthesia without a needle is particularly welcome in many men, which may have some significant advantages for the popularity of vasectomy, especially in developing countries. Conventional vasal block needle anesthesia for no-scalpel vasectomy involves a 25 or 27 gauge 1½-inch needle, which is used to raise a wheal at the median raphe at the junction of the upper third and lower two-thirds of the scrotum. It is then advanced its full length toward the external inguinal ring on each side, where further anesthetic solution is deposited (fig. 1, *A*).[7] In 2001 Wilson initially described no-needle jet injection as an anesthetic technique using the MadaJet system for vasectomy.[8] One of us (RSW) modified and refined the jet injection technique for vasectomy discussed in this report (fig. 1, *B*). The goal of this modified, no-needle jet anesthetic approach is to simplify the surgical technique and decrease the fear of vasectomy in men.

Submitted for publication August 18, 2004.

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MATERIALS AND METHODS

General preparation. A warm room temperature (20C to 25C) is set up in advance to facilitate relaxation of the scrotal skin. The scrotal skin is shaved, preferably in advance, and the penis is retracted by a rubber band placed around the glans and secured with a clamp to the shirt of the patient.

Jet injector preparation. The MadaJet has been widely used in the fields of dermatology, cosmetic and plastic surgery, gynecology, dentistry and podiatry as well as for immunization (fig. 2, *A*).[9–14] The injector is fully autoclavable for instrumental sterilization. A drop of lidocaine solution is placed over the seal on the injector head to promote a good seal with the filling chamber (fig. 2, *B*). The filling chamber is filled with approximately 4.5 cc anesthetic solution, that is 2% lidocaine without epinephrine (fig. 3, *A*). The jet injector assembly is then attached to the filling chamber (fig. 3, *B*). The main injector assembly is affixed and pumped back and forth, and fired several times to prime the mechanism and clear any potential debris or contaminants from the tip prior to the first use after filling (fig. 4, *A*). The spacer can be modified by carving out a 3 to 4 mm diameter notch to fit

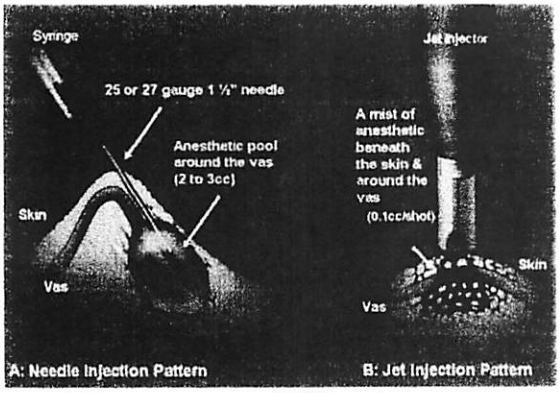

FIG. 1. Anesthetic dispersal patterns of jet vs needle injection. In needle injection pattern anesthesia is delivered by 25 or 27 gauge 1½-inch needle along vas, creating anesthetic pool around vas to block vasal nerve (*A*). In jet injection pattern mist of lidocaine solution without epinephrine is delivered via high pressure injector through tiny head to beneath skin and throughout tissue around vas, resulting in more rapid absorption and less pain (*B*).

snugly over the vas while administering jet anesthesia (fig. 4, *B* and *C*)

Surgical preparation. With the surgeon standing on the right side of the patient the right vas deferens is fixed and separated from the spermatic cord vessels and manipulated to a superficial position under the scrotal skin. The vas is firmly trapped between the middle finger, index finger and thumb of the left hand (fig. 5, *A*). To ensure that the jet injector functions well the preloaded injector is fired once immediately before each use. After the scrotal skin is swabbed with alcohol the spacer covered tip of the injector is placed over the vas with gentle pressure just to the left lateral aspect of the median raphe at the junction of the upper third and lower two-thirds of the scrotum. Two or 3 injections are administered sequentially, proceeding from proximal to distal, 2 to 3 mm apart along the left lateral aspect of the median raphe. The left vas deferens is grasped in similar fashion with 2 or 3 sequential injections, proceeding from proximal to distal, at 2 to 3 mm apart along the right lateral aspect of the median raphe at the junction of the upper third and lower two-thirds of the scrotum, and adjacent to the previous 3 injections (fig. 5, *B* to *D*). Unlike a conventional vasal block with needle injection for no-scalpel vasectomy there is no skin wheal or local edema to cause a pinch following anesthetic administration. Moreover, jet injection has completely different dispersal patterns. It delivers a mist of lidocaine solution without epinephrine via a high pressure injector through a tiny opening on the head to beneath the skin. The anesthetic mist is rapidly absorbed throughout tissue around the vas with much less trauma (fig. 1). Therefore, jet injection is less painful than the needle. Finally, the injection sites are identified by a pinpoint area of blanching. The jet injector should be disinfected appropriately (eg with soaking in glutaraldehyde) prior to the next use.

Injections are placed such that the right vas is brought up and injected just under the left lateral aspect of the median raphe and the left vas is brought up and injected just under

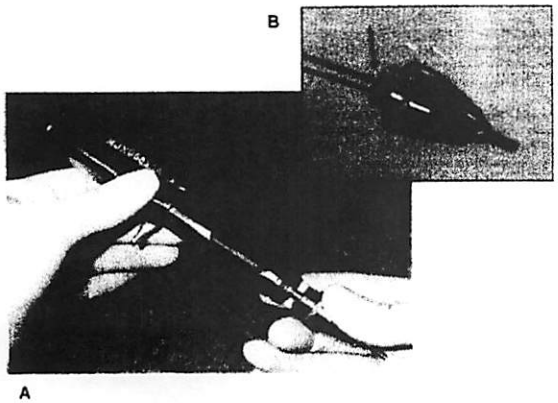

FIG. 2. Injector is primed by moving main assembly back and forth within headpiece several times prior to tightening (*A*). Few drops of lidocaine solution are placed on injector head to ensure good seal (*B*).

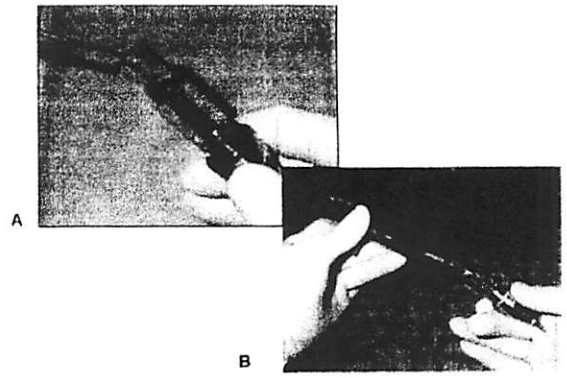

FIG. 3. About 4.5 to 5 ml lidocaine solution without epinephrine is loaded into fill chamber for injection (*A*). Main injector assembly is attached to filling chamber/headpiece (*B*).

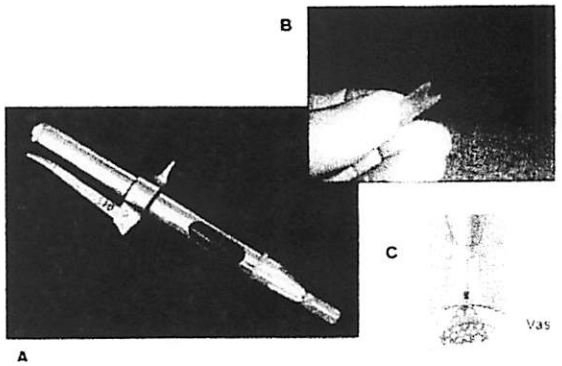

FIG. 4. Assembled injector is loaded with lidocaine solution (*A*) and special spacer (arrow) is placed on tip (*B*). Spacer can be modified by carving out 4 mm diameter notch to fit snugly over vas while administering anesthesia (*C*).

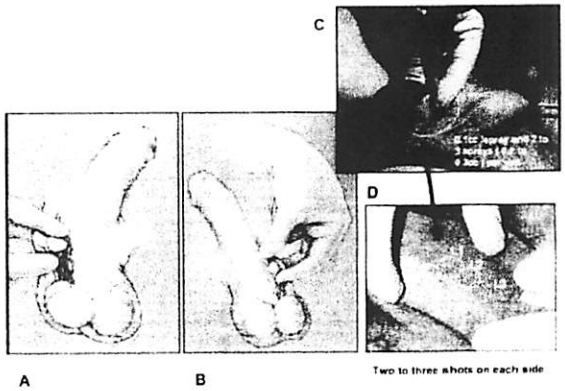

FIG. 5. Three finger technique is used to fix and isolate right (*A*) and left (*B*) sides of vas from spermatic cord. Injector is placed over vas and fired (*C*). Two or 3 injections are placed over each vas on right (*R1*, *R2* and *R3*) and left (*L1*, *L2* and *L3*) sides 4 mm apart and just lateral to median raphe at junction of upper third and lower two-thirds of scrotum (*D*).

the right lateral aspect of the median raphe. This achieves 2 results. 1) Surface anesthesia may be described as a series of intersecting circles at each injection point. The 4 to 6 intersecting circles provide sufficient surface anesthesia for performing the initial skin puncture and spreading in the no-scalpel vasectomy technique. 2) There will be sufficient anesthesia of the scrotal septum by this cross anesthesia, further decreasing the risk of intraoperative discomfort.

After the completion of jet injection and scrubbing with povidone-iodine solution the scrotal skin is washed with clear water based antiseptic solution prior to vasectomy. Patients were asked to complete a visual analog scale (VAS) questionnaire immediately following the completion of surgery. Information regarding preoperative anesthetic pain with no-needle injection and the subsequent pain of vasectomy on 2, 10 cm lines (0—no pain to 10—worst pain ever) were documented. A ruler was then used to measure the response in mm. When the response was between 2 values, the larger of the 2 values was recorded. The anesthetic and surgical records were kept in the physician's office.

RESULTS

In this study of 465 patients between March 2004 and June 2004 none required any additional anesthesia after the no-needle jet injection anesthetic technique. Three of the 465 cases were disqualified as a result of previous vasectomy with or without vasovasostomy. The average VAS pain score for jet injection itself was 1.71 of 10 (range 0 to 7.40, median 1.3). The average VAS pain score for vasectomy following jet injection was 0.66 of 10 (range 0 to 6.60, median 0.2). No hematomas were noted.

The average volume of anesthetic solution per injection was 0.1 cc. Therefore, the total volume used in an entire vasectomy procedure was about 0.6 cc, a fraction of that required using conventional needle delivery of up to 3 cc per vas and about 6 cc per vasectomy. The onset of anesthesia is almost immediate (average time between 10 and 20 seconds). The jet injection technique significantly decreased the volume of anesthetic solution. It cost approximately US$0.07 dollar for the anesthesia. Therefore, it could lead to a significant cost savings in high volume vasectomy practices (see table). The cost of the MadaJet Medical Injector is US$562, which must be factored into costs per injection (see table).

DISCUSSION

The major advantages of this jet injection technique are elimination of the needle for vasectomy and a decrease in the fear of vasectomy in men. No-needle jet injector anesthetic application is a safe, virtually painless and effective technique for vasectomy as well as for almost all primary care office small procedures. The anesthetic effect is almost immediate and it is more profound than that achieved by the needle. A small amount of anesthetic solution is forced through a tiny opening under high pressure, creating a fine mist stream that acts as a virtual needle, easily passing through the scrotal skin without requiring a needle. However, unlike a needle technique this fine stream spreads beneath the skin in a cone-shaped distribution, perfusing all tissue in its path (fig. 1). Normally the mist stream penetrates about 4 to 4.5 mm into tissue, which disperses to approximately 5 to 6 mm in diameter. Injection leaves a pinpoint mark at the entry site that is easily recognizable in most men. This is less clear in nonwhite men and the surgeon may choose to mark the scrotum with a marking pen in these patients, so as not to lose the area of anesthetic application. It is not necessary to wait following injection and the surgeon may proceed immediately. However, one may choose to administer local anesthesia first and then prepare the sterile field. This has the advantage of affording the surgeon more time to set up prior to preparation of the sterile surgical field. In our experience there are rare cases in which jet injection anesthesia is less effective than the use of a needle. In particular, when the scrotal skin is thickened and ruddy, and when there has been previous scrotal surgery with adhesion, the surgeon would do better to perform a conventional vasal block by needle. Use of the jet injector also decreases the possibility of needle injury to the vas artery, which may lead to hematoma formation, one of the commonest post-vasectomy complications.[14]

Unlike conventional vasal block anesthesia as performed in no-scalpel vasectomy, which is administered after the sterile preparation, jet injectors may be used in many patients sequentially as long as the devices are partially immersed in an appropriate disinfectant. Previous experience with jet injectors for mass immunization programs led to contamination with blood-borne contaminants. Earlier designs of these injectors and insufficient attention to disinfection regimens between applications may have made it more likely for such contamination to occur. However, to our knowledge there have been no reports of the transmission of blood-borne contaminants among patients when this new type of injector is used in this manner.

The jet injectors require regular maintenance and inspection. The MadaJet System should be disinfected between patients in a glutaraldehyde solution or another appropriate disinfectant solution (cold sterilization times vary by solution). In addition, the spacer tips can be changed between uses and the units may be autoclaved in their entirety on a regular basis. Finally, firing the injectors before and after use helps clear any possible debris, further decreasing the risk of transmission of blood-borne contaminants. With continued use wear and tear causes deterioration of the numerous rubber O rings that maintain seals within the unit. As a result, the unit will not function properly and the anesthetic effect may be compromised. With some guidance provided by the manufacturer the operator may replace these O rings and other seals or simply let the manufacturer do it.

While the jet injector eliminates needle stick injury and syringe waste management, it introduces the possibility of self-injection of the operator's third digit through an exit wound when using the 3 finger no-scalpel vasectomy technique. We have experienced this on a few occasions only when the injector was empty of anesthetic solution. However, the theoretical possibility of an exit wound exists and the surgeon is advised to use protection. A protective finger thimble may provide some protection. Custom molded thimbles are available for this purpose. Unfortunately the use of a thimble creates an insensate barrier to the third digit when palpating the vas deferens. The surgeon may find that it takes some accommodation to maintain the 3 finger technique when only the thumb and index fingers maintain sensation. It is essential to use this technique in our view to ensure that the jet injection stream passes through the vas and not other scrotal vessels with the attendant risk of hematoma. It is not unusual with a practiced technique to witness subfascial congestion due to the disruption of smaller vessels by the jet stream.

When perfected, this anesthetic technique allows virtually pain-free vasectomy to be performed with a minimal risk of hematoma. Jet injection eliminates local edema and the onset of anesthesia is more rapid than with the needle technique. The

Jet injection for local anesthesia in no-scalpel vasectomy

Per Vasectomy	Conventionnl Needle Anesthesia	No-Needle Jet Injection
Av lidocaine vol (cc)	6	0.6
Av time to anesthesia onset	2–3 Mins	10–20 Secs
Injection cost (US$)	0.79	0.07*

* Not including capital outlay for injector.

avoidance of multiple punctures and excess needle injection may also minimize the risk of hematoma. More importantly, it also decreases the cost of medical waste. Little research currently exists comparing conventional local anesthesia by needle delivery vs by the jet injection technique. A study that compared the subcutaneous administration of midazolam demonstrated less discomfort with jet injection.[10] While these results were not statistically significant, reports of persistent discomfort at the injection site were greater in the needle group. A number of studies have shown the superiority of jet injection for the delivery of anesthesia prior to dental surgery and for intravenous catheterization.[11–13] A multicenter study comparing jet injection anesthesia with needle delivery for no-scalpel vasectomy has been proposed. Like any new surgical technique, it requires a short learning curve to master at the beginning and 5 to 10 cases to achieve proficiency. It requires the performance of a series of precise maneuvers executed in a specific order with accuracy.

CONCLUSIONS

Our patients respond overwhelmingly favorably to the no-needle jet anesthetic method for vasectomy. Men have feared vasectomy for various reasons, among them needle phobia. It decreases the risk of needle stick injury and limits syringe waste management. It is a safe, economical and virtually painless anesthetic application. Since eliminating the scalpel for vasectomy has enhanced the acceptance of vasectomy in many countries, the no-needle jet injection technique may decrease the fear of this procedure in patients and encourage more men to undergo surgical sterilization. No hematomas were noted in this study group.

Dr. Marc Goldstein and Dr. Barry Rich provided assistance and advice. Custom molded thimbles are available from David Batten, Ottawa, Ontario, Canada.

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No-Scalpel Vasectomy:

Standard no-scalpel vasectomy 3- finger technique is used to elevate the vas away from other scrotal structures. A grooved spacer designed for vasectomy is placed over the end of the MadaJet. The injector is placed gently, but firmly, over the vas (at the median raphe at the junction of the upper third and lower two thirds of the scrotum) anchored within the grooved spacer and fired. 2 more shots are administered 4-5 mm apart along the median raphe. The operator's third digit should be protected from accidental self-injection with a finger protective device.

There are several important facts concerning the **operation** and **care** of the MadaJet XL which should be known in order to provide maximum benefits and minimize problems for the physician.

Physical Aspects: *(See Product Manual)*

Please note the diagram of the major parts of the MadaJet XL.

The major parts are:

a. Release Button
b. Cocking Lever
c. Shaft
d. Finger Rest
e. Body of MadaJet XL
f. Head Assembly
g. Pyrex Fill Chambers
h. Sheath
i. Extenda Tip
j. Orifice

Function: *(See Product Manual)*

a. Filling the Fill Chamber
b. Priming Action
c. Cocking & Firing
d. Holding the MadaJet XL

To familiarize yourself with the MadaJet XL, all of the functions should be practiced before using.

NOTE: Each MadaJet XL is enclosed with the following information:

a. Warranty
b. Medical Applications
c. Product Manual
d. Order Form

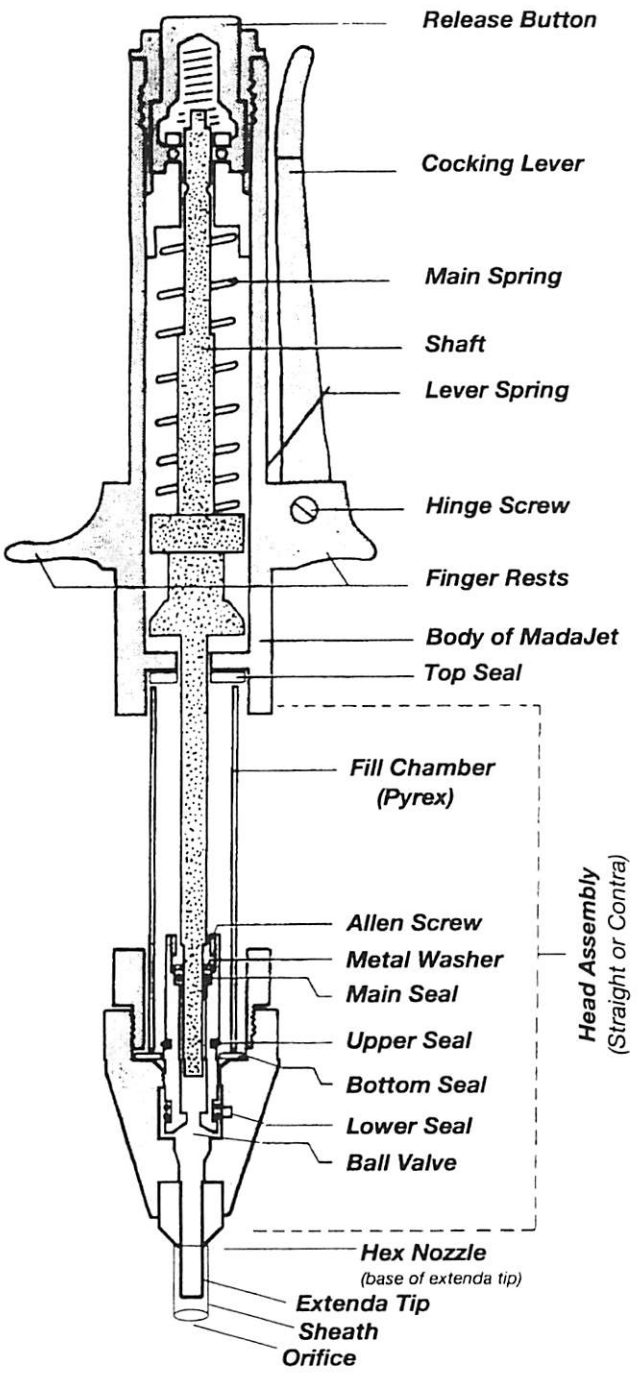
The MadaJet XL Product Manual combines step by step procedures on the use and care of the MadaJet XL.

Important: Although proper care of the MadaJet is easy and takes only seconds to perform, most of the problems that physicians encounter are mainly due to not following directions.

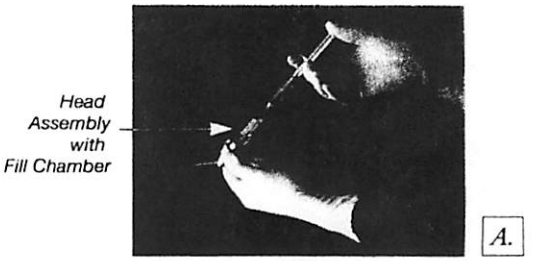
MEDICAL

MadaJet XL

with Extenda Tip

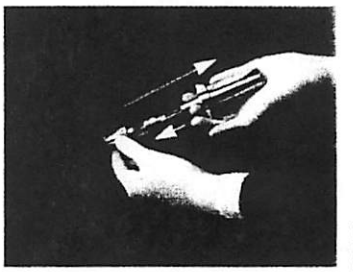


FILLING THE MADAJET XL



A.

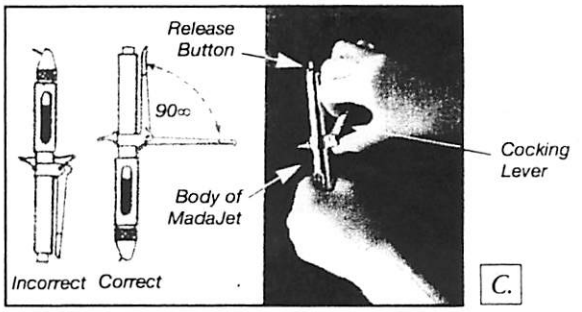
PRIMING ACTION



B.

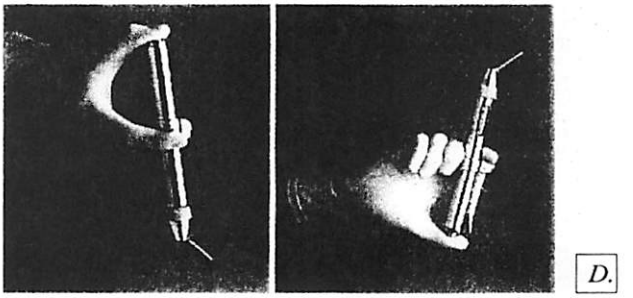
COCKING AND FIRING:

Hold the MadaJet nose down in the vertical position. Grasp the body of the instrument with one hand and with the other hand, pull the cocking lever down until it clicks into the firing position (90°). Repeat for each firing.



C.

After cocking the instrument, the MadaJet can be fired by depressing the **RELEASE BUTTON** *(see picture below)* in any position.



D.

Care of the *MadaJet XL* with MADACIDE-FD Disinfectant/Cleaner

Your MadaJet XL requires very little maintenance; however, similar to any other precision instrument, some cleaning and care should be observed.

When instrument arrives: Your MadaJet XL is in a non-sterile sealed plastic bag. Although it has been thoroughly disinfected with a surface disinfectant, we recommend you autoclave it prior to its first use. Please follow directions:

1. Open plastic bag and unscrew head assembly and Pyrex fill chamber from the body.
2. Wrap body, head and fill chamber separately and place in the autoclave.
3. Autoclave at 273 degree F for 7 minutes at 30 psi (time begins when temperature of 273 degree F has been reached). Also check directions by manufacturer.
4. After autoclaving, remove all parts and allow to cool to room temperature before assembling and use.

For Daily Use:

1. Unwrap parts using sterile gloves.
2. Insert chamber onto head assembly and transfer 3 cc of anesthetic with your syringe from a carpule or multi-dose vial into the chamber (see illustration A).
   (***Hint:*** *For a better seal between the fill chamber and head assembly, "wet" the base of the chamber with sterile water or anesthetic prior to insertion into the head).*
3. *Priming Action:*
   Insert head assembly gently back into the body keeping the instrument in a vertical position with the head pointing DOWN.
4. PRIME the instrument by gently pushing the body into the head assembly up and down on the shaft until the solution comes out of the Extenda Tip. Screw the head assembly back on the body, cock and fire 1-2 times.
5. Place MadaJet XL into the stand provided with each instrument after you have put approximately 30cc of MADACIDE-FD disinfectant into the stand. You are now ready to use your MadaJet XL. After use on each patient, place it back into the stand with the head immersed in the MadaCide-FD solution. DO NOT LAY UNIT FLAT.
6. The MadaJet XL should be sterilized between uses on patients.

After Daily Use:

1. Unwrap head assembly and pour out any unused anesthetic solution.
2. Pour 3cc of MadaCide-FD disinfectant solution into the head assembly and prime 2-3 times to clear out any anesthetic or medication solution.
3. With the remaining MadaCide-FD solution left in the head assembly, place unit into the MadaJet XL stand and leave overnight or until next use.

Next Use:

Simply follow points from **#2** through **#6 For Daily Use.**

Caution: Most anesthetic solutions will cause a discoloration of metal parts if allowed to remain in the instrument for more than 1-2 days. Always pour out any remaining anesthetic solutions each evening. See **After Daily Use.**

Cleaning and Sterilization Techniques:

There are several methods for disinfecting and sterilizing the MadaJet XL.

a. The sheath which covers the Extenda Tip should be removed after each patient use. These sheaths may be autoclaved or cold sterilized. A sterile sheath should be used on each patient to eliminate cross contamination.

b. The metal Extenda Tip, although it does not touch the patient, may also be removed with the enclosed wrench, and sterilized as above.

c. Additional sheaths and Extenda Tips may be ordered as accessory components.

d. Your MadaJet XL was supplied with Ready To Use MadCide-FD solution, which is licensed by E.P.A. as a Hospital Level Disinfectant/Cleaner. A 10-15 minute soak of the sheath and Extenda Tips will provide bacteriocidal action for most pathogens observed in a dental practice. Technical information on MadaCide-FD is available upon request.

e. We suggest that enough MadaCide-FD solution be placed in the holder of the Stand to cover the MadaJet head assembly. This will provide disinfection between patients.

f. The entire MadaJet XL may be autoclaved in a steam sterilizer. Do not use dry sterilization or chem-clave. When autoclaving, flush out medication by priming and firing with MadaCide-FD solution several times. Remove head assembly and wrap components, including pyrex glass fill chamber and autoclave. Allow to cool before reassembling.

g. If you desire to clean the MadaJet XL by ultrasonic, the Mada Ultrasonic (#6008) is specially designed for the MadaJet XL and is recommended.

h. Note: After continued use, if patients begin to complain of pain, our experience suggests that this is most likely due to improper cleaning or a partially blocked Extenda Tip. This will inhibit the fine jet stream for easy tissue penetration.

The Extenda Tip should be removed using the enclosed wrench. Gently probe and twist the enclosed stylet into the small aperture of the Extenda Tip. The Extenda Tip should also be soaked in MadCide-FD solution to remove any anesthetic salts which tend to clog the orifice. Reassemble Tip and sheath.

Helpful Suggestions When Using The MadaJet XL:

a. Do not push the MadaJet XL forcibly against any tissue.
b. Place the teflon sheath gently but firmly at the site to be injected.
c. Position the sheath and Extenda Tip perpendicular to the site of injection.
d. Never use less than 2% Lidocaine.
e. See extra fill chambers and extra Extenda Tips in the MadaJet XL case plus wrench, etc.
f. We are only a telephone call away if you have any problems.
g. Extra heads and Extenda Tips are readily available.
h. **It's recommended that once a year you send in your MadaJet XL for a complete overhaul at a reasonable charge.**