

# Aesthetic Breast Surgery Under Cold Tumescence Anesthesia

## Feasibility and Safety in Outpatient Clinic

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**Abstract:** Throughout the last decade, aesthetic breast surgery has enormously spread in the outpatient clinic setting where plastic surgeons perform the vast majority of procedures under local anesthesia as day-case operations. The “tumescent anesthesia” is defined as the injection of a dilute solution of local anesthetic combined with epinephrine and sodium bicarbonate into subcutaneous tissue until it becomes firm and tense, which is “tumescent.” The “cold tumescence anesthesia” (CTA) derives from Klein’s solution with the introduction of a new concept, which is the low temperature (4°C) of the injected solution. This novelty adds further anesthetic and hemostatic power to the well-known benefits of tumescence anesthesia. The authors report their experience with CTA in the last 15 years in the setting of aesthetic breast surgery, describing in detail the anesthesia protocol, surgical outcomes, and patient satisfaction. A total of 1541 patients were operated on during the study period and were included in this retrospective analysis. The types of breast procedures were breast augmentation in 762 cases (49.4%), mastopexy with implants in 123 patients (8.0%), mastopexy without implants in 452 cases (29.3%), and breast reduction in 204 cases (13.3%). Patient mean age was 42.8 years (range, 18–67 years). The mean operating time was 37 ± 32 minutes for breast augmentation, 78 ± 24 minutes for mastopexy with implants, 58 ± 18 minutes for mastopexy without implants, and 95 ± 19 minutes for breast reduction. No major complications occurred, and no conversion to general anesthesia was required. The median recovery time was 150 minutes (range, 120–210 minutes), and all patients were discharged within 3 hours after surgery. Wound or implant infections occurred in 33 patients (2.1%), wound dehiscences in 21 (1.4%), and postoperative bleeding requiring return to theater in 2 cases (0.1%). Thirteen patients (0.8%) developed capsular contracture. Fifteen patients (1%) required reintervention due to implant rotation or rupture. The median visual analog scale score was 1.8 (interquartile range, 1–3) after discharge. Patient satisfaction was very high in 91.3% (n = 1407) of the cases. In experienced hands, CTA can shorten operating time with high patient satisfaction and a low complication rate. These preliminary data could be hypothesis generating for future multicenter prospective trials done to confirm the benefits of CTA in other surgical fields.

**Key Words:** aesthetic breast surgery, breast augmentation, breast reduction, cold tumescence anesthesia, mastopexy

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Throughout the last decade, aesthetic breast surgery has enormously spread in the outpatient clinic setting where plastic surgeons perform the vast majority of procedures under local anesthesia as day-case operations.<sup>1–3</sup> During the past 40 years, numerous studies have reported innovative techniques to make aesthetic breast surgery less invasive and less expensive, with surgeons proposing to operate under local anesthesia with intravenous sedation, intercostal or paravertebral blocks, epidural anesthesia, and, more recently, under local tumescence anesthesia with good results in terms of safety, patient satisfaction, and cost saving.<sup>4–11</sup>

Over the last 15 years of his experience, the first author of this article has applied a novel local anesthetic technique called “cold tumescence anesthesia” (CTA) in aesthetic breast surgery. “Tumescent anesthesia” is described as the injection of a dilute solution of local anesthetic combined with epinephrine and sodium bicarbonate into subcutaneous tissue until this becomes firm and tense, in other words “tumescent.”<sup>12</sup> Cold tumescence anesthesia derives from Klein’s<sup>13</sup> tumescence anesthesia, but the anesthetic formulation was refined by the last author of this article and published in 1995.<sup>14</sup> Original CTA was a solution of 0.1% to 0.2% lidocaine or mepivacaine and 1 to 2 µg/mL epinephrine in cold saline that was successfully used for superficial surgery (ie, hernia repair, breast augmentation, bursitis, hypospadias, bone biopsy, hemorrhoidectomy). Studies by Klein<sup>15</sup> reported that there is no standard or official recipe for the tumescence anesthetic solution, but the actual concentrations of lidocaine and epinephrine should depend on the areas to be treated and clinical situation. Current CTA is closely comparable to the standard tumescence solution in terms of lidocaine/epinephrine concentration; what is new is the low temperature (4°C) of the injected solution, which adds further anesthetic and hemostatic power to the well-known benefits of tumescence anesthesia as suggested by previous studies in other fields.<sup>16–18</sup>

In this report, the authors present their experience with CTA in the setting of aesthetic breast surgery, describing in detail the anesthesia protocol, surgical outcomes, and patient satisfaction.

## PATIENTS AND METHODS

A retrospective chart review was performed of 1541 patients who underwent aesthetic breast surgery from January 2002 to December 2017. All procedures were carried out by the first author under CTA in accredited facilities and following the standard protocol for ambulatory surgery. The team was composed of a plastic surgeon (the first author), an assisting surgeon, a scrub nurse, a circulating nurse, and an anesthesiologist (the last author). The patients were operated on after specific consent to the procedure under CTA and if they were classified as having an American Society of Anesthesiologists score I or II. Contraindications to CTA were standard contraindication to local anesthesia, cold agglutinin disease, coagulation defects, heart rhythm disorders, anxiety, breast cancer, or suspicious lump on preoperative testing.

Data on patients, surgery, complications, patient satisfaction, and pain control were collected from a prospectively maintained database. Patient satisfaction was graded using a 4-point Likert scale (unsatisfied,

neutral, satisfied, very satisfied). Pain was graded according to the visual analog scale (VAS) score (0–10).

### Preoperative Assessment

During preoperative consultation, the plastic surgeon evaluated each patient and consented to her suitability for the specific procedure and anesthetic technique. A blood check with a search for cold-reacting antibodies, cardiologic consultation, mammography (if >40 years old), and breast ultrasound were requested before surgery. All drugs impairing the coagulation system were suspended according to international guidelines.

### Sedation/Anesthetic Technique

The first dose of intravenous sedation was administered by the anesthesiologist through a 1-mg dose of intravenous midazolam, eventually followed by a second dose. During surgery, an additional dosage of 0.05 mg/kg of midazolam was administered, if needed. The patient remained conscious and collaborative during the whole procedure, and her comfort was repeatedly assessed. Heart rate, blood pressure, pulse oximetry, and electrocardiogram were monitored during surgery. The CTA protocol is reported in Table 1. All drugs were administered intravenously up until discharge, then oral therapy was prescribed.

The anesthesiologist prepared the cold tumescence solution just before surgery, by mixing a 1-mL ampoule of 1 mg/mL of epinephrine with a 50-mL vial of 2% lidocaine and then blended this combination with 1 L of saline at 4°C. The total injected volume and the points of infiltration varied according to each separate kind of breast procedure, breast volume, and operating time. The anesthetic infiltration was totally performed by the surgeon.

### Surgical Technique

Each surgical procedure was initiated with the infiltration of the cold anesthetic solution in specific landmarks. No waiting time was required before skin incision as the anesthetic effect was immediate after the injection (see Video, <http://links.lww.com/SAP/A335>). A 21-gauge needle was used for superficial infiltration into the subcutaneous tissue, while a blunt multiperforated 2-mm cannula was used to inject the cold solution into the gland or in deeper planes.

*-Breast Augmentation.* Cold anesthetic solution 200 to 300 mL was injected into each breast. First, the anesthetic was injected into the

subcutaneous tissue of the incision line, then along the inframammary fold and the periphery of the lower quadrants, hence along the parasternal line at the points of major pectoral insertion and at the lateral borders of the gland. After a 4-cm skin incision in the middle of the inframammary fold, further anesthetic solution was injected into the prepectoral or retropectoral plane according to the implant positioning.

*-Breast Reduction/Mastopexy.* Cold anesthetic solution 350 to 600 mL was injected into each breast. First, the surgeon infiltrated the solution along the incision line of the wise pattern and immediately under the skin to be de-epithelialized. Second, after the skin incision, the cannula was inserted perpendicularly through the aforementioned wise pattern in order to infiltrate the section planes; exception was made for the pedicle area. Further infiltrations into the retroglandular plane, and eventually retropectoral plane, were performed during dissection.

Considering that all the infiltrations followed the surgical planes, the surgical maneuvers were optimized by hydrodissection and mostly completed through scalpel. Tissues were impregnated with the cold tumescent solution, which was partially absorbed by gauges, thus reducing the total amount of anesthetic and impairing the use of cautery. Hemostasis was always excellent before the end of surgery, and the need for unipolar forceps was minimal. Implant positioning followed standard hygienic guidelines: new gloves, change of drapes, and pocket irrigation, and in addition an antibiotic (a vial of 80 mg gentamicin) was injected into the implant package before opening. Surgical drains were always placed into the implant pocket or into the retroglandular plane and then removed in 24 hours if empty. Wound closure was always performed in layers with reabsorbable sutures. Once the scars were covered by sterile dressings, a compressive brassiere was realized with elastic tape and removed 1 week later.

### Postoperative Management

Once the surgery ended, the patient was asked about her general conditions. If vital parameters and pain control were regular, she left the theater walking on her own 2 feet with the nurse. Immediate postoperative monitoring continued in a relaxing “ad hoc” room where a nurse was available if needed. Ten minutes after surgery, the patient was allowed to drink, and unless nausea occurred, 30 minutes later she could eat. All patients were discharged starting from 2 hours after surgery once they were in good local and general condition and a caregiver was present.

**TABLE 1.** Cold Tumescence Protocol for Aesthetic Breast Surgery

Purpose	Drug Administration
Sedation	Preoperatively <ul style="list-style-type: none"> <li>• 1 mg midazolam (to be repeated once, if needed)</li> </ul> Intraoperatively <ul style="list-style-type: none"> <li>• 0.05 mg/kg midazolam, if needed</li> </ul>
Antibiotic prophylaxis	Preoperatively (within 60 min before skin incision) <ul style="list-style-type: none"> <li>• 2 g cefazoline</li> <li>• 80 mg gentamicin (if implant surgery)</li> </ul> Postoperatively <ul style="list-style-type: none"> <li>• 400 mg cefixime tablet, once a day for 5 d</li> </ul>
Pain control	Intraoperatively <ul style="list-style-type: none"> <li>• 1 g paracetamol (15 min before the end)</li> </ul> Postoperatively <ul style="list-style-type: none"> <li>• 30 mg ketorolac +1 g paracetamol (before discharge)</li> <li>• 10 mg oxycodone+325 mg paracetamol capsule, twice a day for 3 d</li> </ul> From the 8th postoperative day on <ul style="list-style-type: none"> <li>• 10 mg montelukast tablet, once a day for 90 d</li> </ul>
Capsular contracture prophylaxis	

Postoperative checkup visits were scheduled at days 1, 7, 14, 30, 60, 180, and 365 after surgery. Major (deep venous thrombosis, pulmonary emboli, pneumothorax, deaths) and minor complications (postoperative bleeding, wound/implant infections, wound dehiscence, capsular contracture, implant rotation/rupture) were prospectively noted up to 1 year after surgery. Patient satisfaction with CTA and postoperative pain were assessed on discharge and 1 week later.

**Statistical Analysis**

Mean and SD were calculated for all normally distributed variables, whereas median and interquartile range were calculated for others.

**RESULTS**

A total of 1541 patients were operated on during the study period and were included in this retrospective analysis. The types of breast procedures were breast augmentation in 762 cases (49.4%), 51.7% (n = 394) of these being subglandular and 48.3% (n = 368) submuscular (type II dual plane positioning); mastopexy with implants in 123 patients (8.0%); mastopexy without implants in 452 cases (29.3%), and breast reduction in 204 cases (13.3%). Patient mean age was 42.8 years (range, 18–67 years). The mean operating time was 37 ± 32 minutes for breast augmentation, 78 ± 24 minutes for mastopexy with implants, 58 ± 18 minutes for mastopexy without implants, and 95 ± 19 minutes for breast reduction.

No major complications occurred, and no conversion to general anesthesia was required. There were no signs of epinephrine or lidocaine toxicity reported or electrocardiographic alteration, respiratory depression, and acute hypotension or hypertension. In cases in which the patient felt pain during surgery, a further localized 10 mL injection of cold solution was administered by the surgeon within the same volume reported before. No patient experienced hypothermia symptoms (slurred speech or mumbling, slow shallow breathing, weak pulse, clumsiness or lack of coordination, drowsiness or very low energy, confusion or memory loss, loss of consciousness or bright red, permanently cold skin) apart from 15 minutes, on average, of mild shivering immediately after surgery. The median recovery time was 150 minutes (range, 120–210 minutes), and all patients were discharged within 3 hours after surgery.

Table 2 shows the minor complication rate at the 1-year follow-up. Wound or implant infections occurred in 33 patients (2.1%), wound dehiscences in 21 (1.4%), and postoperative bleeding requiring return to theater in 2 cases (0.1%). Thirteen patients (0.8%) developed capsular contracture, 6 having a subglandular pocket, 5 having a dual-plane pocket, and 2 having had mastopexy with implants. Fifteen patients (1%) required reintervention due to implant rotation (8 patients having a shaped implant) or rupture (7 patients) within the follow-up time (1 year). The median VAS score was 1.8 (interquartile range, 1–3) after discharge. Patient satisfaction for the anesthetic technique was very high; in 91.3% (n = 1407) of the cases, 8.5% (n = 131) of the patients

were satisfied, and 0.2% (n = 3) of the patients gave a neutral answer. No patient regretted the choice of having chosen CTA.

**DISCUSSION**

The history of “tumescent anesthesia” started more than 100 years ago when “massive or hard infiltration” analgesia with weak analgesic solutions was proposed. The benefits of a tumescent infiltration were already clear: both the epinephrine and the mechanical effect of massive infiltration caused vasoconstriction, which checked the rapid removal of anesthetic by the bloodstream, prolonging its effect and preventing local hemorrhage.<sup>19,20</sup> The current technique of “tumescent anesthesia” was rendered popular by Klein<sup>13,21</sup> for liposuction with no need for supplemental anesthesia, and its formulation has evolved in time. Previous studies on tumescent anesthesia reported the advantages in terms of less narcotic use, less bleeding and pain, faster recovery, and minor risks for the patient if compared with general anesthesia.<sup>22,23</sup>

Focusing on aesthetic breast surgery under tumescent local anesthesia, recent literature has already shown the feasibility of breast augmentation under tumescent anesthesia and accurately reviewed literature on this topic.<sup>10,11</sup> We share with Rusciani et al<sup>10</sup> the use of a tumescent anesthetic solution alone with no need for intravenous anesthesia or nerve block. Our data confirm that it is possible to avoid the use of propofol, ketamine, or Fentanyl, thus reducing the risk of drug-related complications (respiratory depression, hypotension or hypertension, bradycardia, nausea, or emesis). Similarly, we chose American Society of Anesthesiologists I or II patients and administered only midazolam with its excellent anxiolytic and amnesic effect. However, the greatest difference in CTA when compared with the protocol of Rusciani et al<sup>10</sup> and all previous formulations of tumescent anesthesia is the temperature and all its related effects. The relevance of the temperature of an anesthetic solution has been proved to be an added value to the standard tumescent anesthetic solution.<sup>14,17</sup> Dumantepe and Uyar<sup>17</sup> demonstrated that cold tumescence fluid infiltration was equally effective as, but safer than, room temperature tumescence fluid infiltration and gave better VAS scores. Cold tumescent anesthesia is obtained using a dilute solution of 0.1% lidocaine and 0.01% epinephrine in 4°C saline. This anesthetic solution has a very rapid onset because of the coldness, and no waiting time is needed in comparison to standard tumescent formulation.<sup>10,11</sup> Consequently, the patient is not infiltrated outside the theater, and operating time is reduced. In addition, low temperature also increases the effect of the tumescent solution on vasoconstriction, thus strengthening the ordinary benefits of tumescent anesthesia. Despite the similar or higher concentration in lidocaine (0.1% vs 0.03%–0.05% for standard tumescence<sup>24</sup>), the total quantity of lidocaine is greatly lower than the safety limits (55 mg/kg in adults) and lower than recommended concentrations for effective tumescent anesthesia by Klein.<sup>15</sup> In fact, he suggested a dosage of 1500 mg/L of lidocaine and 1.5 mg/L of epinephrine for breast surgery, whereas we used 1000 mg of lidocaine (a 50-mL vial of 2% lidocaine) and 1 mg of epinephrine (1-mL ampoule of 1 mg/mL epinephrine) in 1 L of saline.<sup>15</sup> Additionally, the mean volumes injected per (in each) breast are lower than those reported previously (ie, 200–300 vs 400–700 mL in breast augmentation), thus decreasing the total amount of lidocaine and epinephrine per patient.<sup>10,11</sup> Furthermore, this is the first study to report on the whole range of breast aesthetic surgery under local tumescent anesthesia; thus, no proper comparison is available for breast reduction and mastopexy. However, the low complication rate, no intraoperative complication, and no conversion to general anesthesia in our large series provide good data on the feasibility and safety of the CTA protocol. Our data confirm previous evidence on high patient satisfaction, low postoperative pain, faster recovery, and no regret for the choice of similar local anesthesia after breast augmentation and also after other procedures, which are usually performed under general anesthesia.<sup>2,3</sup>

**TABLE 2.** Minor Complication Rates at 1-Year Follow-up

Complications	n (%)
Wound/implant infection	33 (2.1)
Wound dehiscence	21 (1.4)
Postoperative bleeding	2 (0.1)
Capsular contracture	13 (0.8)
Implant rotation/rupture	15 (1.0)
Overall complication rate	84 (5.5)

One of the strengths of this work is the innovative use of a “cold” solution for tumescent anesthesia, which adds anesthetic, hemostatic, and analgesic power to the standard formulation. This allows an immediate starting of the procedure, and the way of infiltration is completely different from that of previous reports. Cold tumescent anesthesia should be considered as both an anesthetic and a surgical technique as infiltration does not end before the beginning of surgery; as a matter of fact, the surgeon continues infiltration during the same surgical procedure in parallel with surgical dissection. The same anesthetic infiltration in specific landmarks helps the surgeon's work with hydrodissection, resulting in reduced bleeding and so better visualization of anatomical planes and easier harvesting of the implant pocket and de-epithelialization when needed. Additionally, this is the first study to report on patients undergoing breast augmentation, breast reduction, and mastopexy with or without implant under local tumescent anesthesia with data on satisfaction and postoperative pain. The application of CTA in surgical procedures, which are longer and more complex than breast augmentation, requires a full knowledge of the technique with its advantages and disadvantages. When operating on larger volumes (ie, macromastia), a longer operating time and larger infiltration volumes are required, and larger resections are needed, and more anesthetic fluids are partially lost. Most longer procedures in this series were performed in the second half of the study period when the learning curve was complete, and the surgeon's confidence with CTA allowed an operating time shorter than 3 hours. Cold tumescent anesthesia should not be recommended for longer procedures as data are still not available.

The limitations of this study are its retrospective nature, its single-surgeon experience, and the lack of data on patient body temperature. Nevertheless, the eventual role of hypothermia was considered from the beginning. The authors first assessed that CTA only caused minor temperature changes (0.5°C–0.7°C) in body temperature during surgery, and then they started to apply this technique routinely. Despite large amounts of data in the literature on the risks of hypothermia and the increase in infection rate, we had a low infection rate (2.1%), and no signs of hypothermia were reported, which may be due to the fact that the small volumes injected do not affect thermoregulation and local anesthesia does not impair the immune system.<sup>25,26</sup> The advantages of the CTA technique are limited by the steep learning curve, as the surgeon has to fully understand how the action of the anesthetic solution strongly affects the surgery. The local cooling effect allows immediate skin incision; anesthetic infiltration in specific landmarks makes small quantities sufficient. Furthermore, the infiltration and the surgical dissection should be combined in the same planes. Cautery in impregnated tissues does not work properly, and the scalpel should be preferred. Surgical timing is closely linked to a precise technique of infiltration. Injecting volumes that are too large into the wrong planes can alter anatomy and hamper the surgeon's work, prolonging the procedure and increasing the anesthetic quantity. The surgeon needs to adapt his/her surgical maneuver to CTA. Only precise infiltration in the areas to be dissected makes the surgery easier and faster with no pain for the patient.

## CONCLUSIONS

Cold tumescent anesthesia is a new technique that involves both the anesthesiologist's and the surgeon's work. It differs from the previous tumescent solution by temperature, infiltration technique, injected volume, and onset time. Additionally, the total amount of anesthetic and epinephrine is lower if the total volume injected rather than the absolute concentration is considered. Furthermore, CTA does not need continuous infiltration and suction of the surgical site or the addition

of potent analgesic drugs.<sup>10,11</sup> In experienced hands, CTA can shorten operating time with high patient satisfaction and a low complication rate. This preliminary data could be hypothesis generating for future multicenter prospective trials done to confirm the benefits of CTA in other surgical fields.

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