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ARTICLE

Breast augmentation under local anesthesia with intercostal blocks and light sedation

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ABSTRACT

Introduction: This study of breast augmentations performed under local anesthesia with intercostal blocks and light sedation describes the outcomes and evaluates benefits and complications.

Method: From December 2005 until August 2019, 335 women consecutively underwent bilateral breast augmentation procedures. The anesthetic protocol consisted of an initial intravenous bolus of 1 mg midazolam and 0.25 mg alfentanil preoperatively. In 2017, this was changed to 2–4 mg midazolam intramuscularly, 1 mg midazolam intravenously, and 2.5 µg sufentanil intravenously. Intercostal blocks were injected at the midaxillary line into the intercostal spaces two to seven. The operating field was infiltrated with tumescent local anesthesia. Retrospective data extraction from patients' medical charts was done, registering demographics, dosage of anesthesia, surgical characteristics, complications, and reoperation rates.

Results: Two hundred and eighty-one women underwent primary augmentation and 54 had implant replacement. The most common complications included suboptimal cosmetic results, asymmetry, and healing-related problems. The overall rate of reoperation was 16.1% within an average follow-up period of 2 years, ranging from 0 to 12.5 years. The majority of the reoperations were due to cosmetic reasons. The change in anesthetic regime was associated with a significantly ($p < 0.0001$) decreased need for supplementary medication with no increased risk of complications.

Conclusion: Breast augmentations in local anesthesia with intercostal blocks and light sedation can be performed safely and can serve as an alternative to procedures in general anesthesia.

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Breast augmentation; local anesthesia; intercostal blocks; light sedation

Introduction

One of the most common cosmetic plastic surgery procedures is augmentation mammoplasty. It is usually performed under general anesthesia, though conscious sedation is a frequently used technique within other plastic surgical procedures [1].

One of the challenges in performing breast augmentation under conscious sedation is control of patient pain since the procedure requires a lot of undermining in a very sensitive body region to facilitate the development of the implant pocket. Reservations regarding effective pain control might be a reason for some surgeons to abstain from the procedure. We argue that it depends on the method of sedation and local anesthetics. We describe such an anesthetic technique and evaluate it as an alternative to operations performed in general anesthesia. Similar conscious sedation techniques have been described with the use of intravenous sedation combined with intercostal nerve blocks in breast augmentation to reduce post-operative nausea and speed up recovery compared to general anesthesia. The presented protocol differs from these previous studies by using lower doses of intravenous sedation as well as the combined administration of midazolam both intravenously and intramuscularly [2].

Studies of other types of surgeries performed in regional anesthesia have shown to offer several benefits for both patient and surgeon, such as lower levels of intraoperative complications and a simpler and less stressful post-operative recovery with a reduction of the post-operative side effects seen in relation to drugs used for general anesthesia [3].

Unconscious sedation using total intravenous anesthesia without paralysis is a common and intermediate alternative to breast augmentation in general anesthesia. This anesthetic technique makes use of a propofol infusion, local anesthesia, and a laryngeal mask airway and therefore does not involve a general endotracheal anesthetic. It does however require the presence of an anesthesiologist.

Since the anesthetic method described in this study corresponds to '*sedation level 2*' as defined by European guidelines [4] and does not include the use of propofol or similar medication, the surgeon or a circulating nurse can administer it if adequately trained also in resuscitation. Therefore, the procedure does not require an anesthesiologist or nurse anesthetist, which offers yet another benefit of lower costs for both surgeon and patient. The anesthetic method has also been approved by the National Danish Patient Safety Authority [5].

Another aspect worth considering is that many patients are apprehensive about general anesthesia whether it be due to bad experiences with adverse effects in the past, or the feeling of loss of control. Light conscious sedation and local anesthesia offer an attractive alternative for these patients.

The aim of the study was to retrospectively examine a consecutive series of breast augmentation procedures performed

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under light sedation with intercostal blocks and infiltration of local anesthesia and to evaluate complications and describe the outcome.

Material and methods

Patients and registered variables

The study population comprised 335 women who consecutively underwent bilateral implant-based breast augmentation at the Erik Loentoft Plastic Surgery Clinic, during a 14-year period from December 2005 to August 2019. The women were categorized into primary augmentations and implant replacements.

The study retrospectively collected patient chart information. Data extraction was performed in a standardized manner by using a computerized SPSS (IBM SPSS® Statistics) data registry to record data points from each patient chart. Registered data included the following variables: demographic, date of surgery, anesthesia doses, surgical characteristics, implant characteristics, post-operative course including complications, reoperations, and length of follow-up, which was defined as the period from the date of surgery until the last date of the patient visit. No information about the time used for anesthesia or surgery for the individual patients was available.

Complications included both the surgery requiring and/or potentially life-threatening complications seen within 30 days post-operatively and the non-surgery requiring complications. The minor hematoma was defined as not requiring reoperation. Minor infection was defined as requiring a prescription of antibiotics but not requiring reoperation.

Surgical procedure

The team in the operating room consisted of one plastic surgeon and one circulating nurse, who only scrubbed in during the time the implants were placed, assisting with a retractor. The same surgeon (EL) performed all these procedures.

Before surgery, all patients attended a preoperative examination by the surgeon, going over the possibility of breast augmentation, implant types, surgery procedure, complication risks including (but not restricted to) infection, bleeding, rejection, bad wound healing, capsule contracture, and sensory disturbances. Based on a dialog between patient and surgeon the specific procedure was decided upon, taking patient preference into consideration. This included decisions about implant type (round *vs.* anatomic), implant size, incision site, and pocket placement. Furthermore, the fasting procedures were reviewed, and the patient received written information on the procedure and gave informed consent.

Anesthetic technique

The patient arrived fasting on the day of surgery and was given paracetamol 2 g orally upon arrival. With the patient in an upright position, preoperative photos were taken, and preoperative markings were done to define pocket dimensions and skin incision. The anesthesia was then initiated, a procedure that has undergone a change during the study period. In the period 2005–2016, the patients received 1 mg midazolam (hypnoticum) and 0.25 mg alfentanil (opioid) intravenously (i.v.) From 2017 onwards, this was changed into 2–4 mg midazolam intramuscularly (i.m.), depending on patient weight, followed by 1 mg midazolam i.v. and 2.5 μg sufentanil (opioid) i.v. Further supplementary doses were given intravenously depending on the patient's weight and pain during the procedure. The change from alfentanil to sufentanil was made when the commercial brand of alfentanil (Rapifen®) went out of stock.

When the maximum effect of the intravenously administered medicine was achieved within a few minutes, bupivacaine (0.25%)-epinephrine (5 μg/mL) intercostal blocks 2×20 cc were introduced using a 20 cc syringe with a 21 gauge needle with the patient in the supine position and the arms at a 90-degree angle (Supplementary Video 1). The injections were made at the midaxillary line before the takeoff of the anterior and lateral cutaneous branches of the intercostal nerve, ensuring both branches were anesthetized. Beginning at the uppermost palpable costae (costa three), the injections were done by palpating the costae with the non-dominant hand and using the same hand to retract the skin overlying the costae cephalad. With the dominant hand, the needle was placed and advanced through the skin just above the upper margin of the rib using the non-dominant hand still in contact with the patient for needle support. 1.5–2 cc of the anesthetic solution was slowly injected into the intercostal space, targeting the neurovascular bundle of the rib above. The needle was then walked caudad off the inferior margin of the rib, further injecting 1.5–2 cc into the neurovascular bundle of the next intercostal space. This process was then repeated for the next lower rib continuing down to the intercostal space just inferior to the inframammary fold [6], corresponding to the intercostal spaces from above costa three to below costa seven. This technique ensures injection into two intercostal spaces by only one puncture of the skin, reducing the overall number of injections. A maximum of 20 cc was used on each side of the thorax.

The intercostal blocks were immediately followed by submuscular infiltration of a modified Klein fluid [7] consisting of 500 cc of 0.9% saline to which 20 cc of 2% lidocaine, 0.5 cc epinephrine (1 mg/mL), and 10 cc of 8.4% sodium bicarbonate were added. An overall of 250–450 cc Klein fluid was injected into each breast in the space between the pectoralis major muscle and costae, again using a 20 cc syringe and a 21 gauge needle (Supplementary Video 2). This space was easily defined by lifting the pectoralis major muscle at the lateral border and introducing ~5–8 injections into this interspace. Medially, the submuscular space was reached with another five to eight injections with punctures close to the midline. The precaution was taken to sufficiently infiltrate the site of the cutaneous incision, being primarily inframammary. The surgical procedure was initiated 15 min later, and the patient was monitored with a pulse oximeter besides oral communication during the procedure. Conversion to general anesthesia was not an option.

Surgical technique

The breast augmentation was then performed with an operating procedure similar to breast augmentation in general anesthesia. With inframammary access as the favored choice, the pocket, primarily placed in a submuscular plane with the inferolateral part subglandularily, was dissected as dual plane if necessary, using monopolar electrocautery, hereby also securing hemostasis and no surgical drains were required.

Implants were placed, and closing was done with Vicryl® 4-0 in the subcutaneous tissue and fascia without fixation to the underlying tissue and with Monocryl® 4-0 intracutaneously in the skin. Micropore tape was applied to the suture lines.

Preoperatively, an injection of cefuroxim 1.5 g i.v. was given as a single dose. At the end of the procedure, an injection of ondansetron 8 mg i.v. was given as a single dose to prevent nausea. Isotonic NaCl 1000 ml i.v. was given continuously during the procedure. Vital parameters (including oxygen saturation, pulse, and

blood pressure) were monitored during surgery as well as post-operatively.

Post-operative course

After the procedure, a nurse helped the patient to put on an adherent sports brassiere and the patient left the theatre walking to the recovery room next door with the support of the nurse.

If patients were stable post-operatively, they were discharged after about 1–2 h of observation once they had been drinking or eating, had a check of vitals, were warm and dry, and had free urination. All patients were seen by the surgeon right before discharge checking for any signs of complications. Before discharge, the patients received information about the post-operative regime, the expected course, signs of deviating course, and the use of analgesics, which were handed out. The post-operative regimen included the use of adherent sports brassiere 24 h a day for the first 2 weeks, followed by additional 2 weeks of only daytime use. Showering was allowed from day three. Patients removed the dressing typically during the first shower and were recommended to use micropore tape on the suture lines for 3 months. Training activities were allowed after a month. Post-operative follow-up consisted of a telephone call the day after surgery including standardized questions to discover any deviations from the normal post-operative course, a post-operative visit at the clinic after 2 weeks, and again after 3 months including post-operative clinical photos. Any additional follow-up was added if required, and patients were advised to contact the clinic in case any further questions or complications occurred.

Statistical analysis

The data was analyzed and produced using IBM SPSS® Statistics. Descriptive statistics were generated. These included frequency and crosstab analyses of demographic and surgical characteristics, medication doses, complication and reoperation rates, and reasons for reoperation. Fisher's exact test was used for testing differences among groups, and 0.05 was chosen as the level of significance.

Ethical approval was granted by the regional committee (case no. S-20192000). Approval of data protection responsibility was obtained through the regional organization of information security.

Results

Demographic and surgical characteristics

A total of 335 female patients underwent bilateral augmentation mammoplasty using the presented anesthetic technique; there were no cases of unilateral augmentation. The median patient age was 35 years with a wide range of 17–78 years. As might have been expected, the youngest patient belonged to the primary augmentation cohort whereas the oldest was found in the implant replacement cohort. Nineteen women had primary augmentation combined with a lift of the breast and thirteen women had additional procedures, such as liposuction, scar revision, and blepharoplasty performed during the same surgery. Within the implant replacement cohort, two women combined surgery with a breast lift and seven women with additional procedures (data not shown). The implants were all textured and during the first 5 years Mentor implants were used, hereafter Eurosilicone. Time used for the anesthesia and the surgical procedure was generally about 2 h in total, and time in the recovery room was generally 1–2 h, however, this was not registered on an individual basis.

Table 1. Demographics.

	Primary augmentation $N = 281$	Implant replacement $N = 54$
Median age (years), range	33 (17–58)	46 (23–78)
Median BMI (kg/m^2), range	20.9 (15.6–30.4)	20.8 (17.3–26.6)
Births (%)		
No children	24.2	18.8
1 child	15.2	28.1
2 children or above	60.2	53.1
Current smoking (%)	25.7	18.0

Table 2. Surgical characteristics.

Surgical characteristics	No. patients	%
Incision		
Inframammary	310	94
Wise incision	18	5
Other	3	1
Pocket placement		
Submuscular	287	92
Subglandular	26	8
Implant style		
Round	155	46
Anatomical	179	54
Implant brand		
Eurosilicone	226	67
Mentor	109	33
Implant size (ml)	No. implants	%
≤200	15	2
200–400	546	81
401–600	99	15
≥600	10	1
Median implant size	ml	Range
	345	140–750

Patient follow-up ranged from 0 to 12.5 years with an average of 2 years. Table 1 summarizes the patient demographics, and the surgical characteristics are listed in Table 2.

Anesthetic dosage

All patients across the two cohorts received the same initial dose of conscious sedation medication described in the anesthetic technique paragraph, whereas Table 3 lists the difference in supplementary doses administered. A statistically significant decrease ($p < 0.0001$) was observed in the requirement for supplementary doses of any of the administered sedation medications (Figure 1) after the change of midazolam administration into a combination of both intravenous and intramuscular administration in 2017.

Complications and reoperations

The complications recorded during the study period are listed in Table 4, where one patient may contribute with more than one complication. In none of the 335 cases was conversion to general anesthesia required. Only one procedure had to be aborted because the patient went into anaphylactic shock when the pre-operative intravenous prophylactic antibiotic was administered. The patient was taken to the hospital immediately and returned to the clinic a few months later to have an uneventful procedure, with the use of a different antibiotic. One year post-operatively, the same patient underwent reoperation because of implant rotation and had no further complications. Two patients (0.6%) developed pneumothorax. Both were identified during telephone calls, one of the 5 h post-operatively, since per- and post-operative clinical signs, saturation and other vital parameters had shown no indication of abnormalities. The other was diagnosed three days

Table 3. Supplementary intravenous medication during surgery.

Patients who received supplementary medication	2005–2016	2017–2019
Midazolam		
No. patients with available data	288	47
No patients who had supplementary doses	133 (46%)	4 (8.5%)
Dose, mg		
Median	0.50	1.50
Range	0.25–7.0	0.5–2.0
Alfentanil		
No. patients with available data	287	13
No patients who had supplementary doses	88 (30.7%)	2 (15.4%)
Dose, mg		
Median	0.50	0.25
Range	0.125–1.75	0.25–0.25
Sufentanil		
No. patients with available data	0	32
No patients who had supplementary doses	–	3 (9.4%)
Dose, µg		
Median	–	2.5
Range	–	2.50–7.5

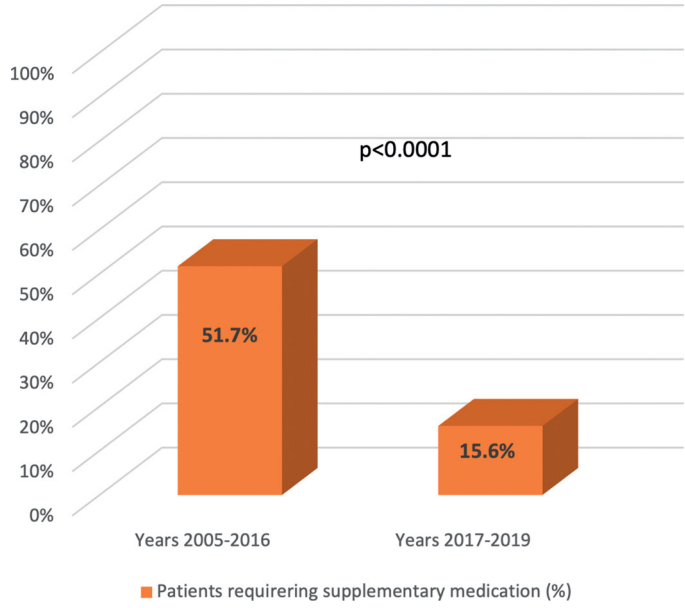

Figure 1. Requirement of supplementary medication before and after intramuscular administration of midazolam.

post-operatively. The second patient required a chest tube during hospital admission whereas the first patient was admitted for observation with no interventions due to a small marginal pneumothorax. Both patients were followed, but no changes were required regarding the implants, and both patients were satisfied at the end of the follow-up. Four patients (1.2%) had an infection requiring an operation, one progressed into sepsis 2 weeks post-operatively. All four patients had to have one implant temporarily removed, and they all had a reimplantation procedure performed 3–4 months post-operatively (using the same type of anesthesia).

The minor infections (0.6%) were treated with peroral antibiotics. Three percent developed healing problems, which included minor closure defects and problems with suture resorption. Four seromas (1.2%) were seen, only one required reoperation whereas the three others were minor and treated with ibuprofen and had no further complications.

We evaluated if complications were associated with the regime for administration of anesthesia but found no such association ($p = 0.159$) (Figure 2). In the period before the modification of midazolam administration, 57 out of 288 had complications, whereas in the period after the change five out of 47 had complications.

A total of 54 patients (16.1%) had at least one reoperation performed within the follow-up period on an average of 2 years. Among these women, 57.4% had only one reoperation, 26.0% had two reoperations, and 16.7% had three or more reoperations. Most of these reoperations were due to cosmetic reasons, which included asymmetry, capsular contracture, ptosis, excessive skin, wrinkling/double breast contour, areola correction, unsightly scarring, implant size/style change, and patients unable to reconcile to the idea of having implants, and who had them removed ($n = 3$). The non-cosmetic reasons for reoperation included healing-related problems, infections, hematoma, seroma, rupture, implant rotation, prolonged breast pain, and others. Reoperation frequencies are shown in Table 5. No statistics were calculated since numbers within subgroups were too small for this to be clinically meaningful.

The clinical result of augmentation with anatomical textured implants of 345 cc is shown in Figure 3.

Table 4. Complications within an average follow-up period of 2 years (range 0–12.5 years).

	Primary augmentation $N = 281$		Implant replacement $N = 54$		Total study population $N = 335$	
Complication data	*N*	%	*N*	%	*N*	%
Hematoma	1	0.4	0	–	1	0.3
Pneumothorax	2	0.7	0	–	2	0.6
Infection*	2	0.7	2	3.7	4	1.2
Anaphylaxis	1	0.4	0	–	1	0.3
Healing related problem	10	3.6	0	–	10	3.0
Unsightly scar	7	2.5	0	–	7	2.1
Minor infection**	1	0.4	1	1.9	2	0.6
Minor hematoma***	1	0.4	1	1.9	2	0.6
Seroma	4	1.4	0	–	4	1.2
Asymmetry	9	3.2	4	7.4	13	3.9
Capsular contracture	4	1.4	3	5.6	7	2.1
Rupture	1	0.4	0	–	1	0.3
Suboptimal cosmetic result	18	6.4	1	1.9	19	5.7
Persistent pain	2	0.7	0	–	2	0.6
Foreign body reaction****	1	0.4	0	–	1	0.3
Implant rotation	2	0.7	1	1.9	3	0.9

*One of these infections progressed to sepsis.
**Minor infection was defined as requiring prescription of antibiotics but not requiring reoperation.
***Minor hematoma was defined as not requiring reoperation.
****This included a foreign body reaction to cotton residue.

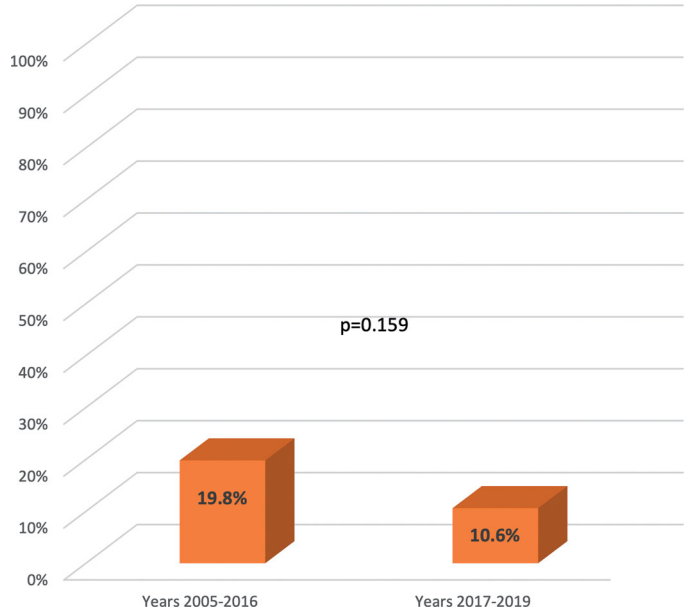

Figure 2. Complication rates before and after intramuscular administration of midazolam.

Table 5. Reoperations categorized by indication within an average follow-up period of 2 years (range 0–12.5 years).

Reoperation $n = 94$	Primary augmentation $N = 281$		Implant replacement $N = 54$	
	N	%	*N*	%
No. of reoperations*	78 (45 patients)	16.0	16 (9 patients)	16.7
Reoperations due to				
Asymmetry	13	16.7	5	31.3
Capsular contracture	4	5.1	3	18.8
Ptosis	13	16.7	0	–
Excessive skin	6	7.7	2	12.5
Wrinkling/double contour	4	5.1	0	–
Areola correction	2	2.6	0	–
Unsightly scar	10	12.8	0	–
Implant style/size change	2	2.6	1	6.3
Unable to reconcile with implants	9	11.5	0	–
Healing related	1	1.3	0	–
Seroma	2	2.6	0	–
Prolonged breast pain	1	1.3	0	–
Rupture	1	1.3	0	–
Hematoma	2	2.6	0	–
Serious infection	4	5.1	4	25.0
Foreign body reaction	2	2.6	0	–
Implant rotation	2	2.6	1	6.3

*One patient can contribute to the table with more than one reoperation.

Discussion

Though breast augmentation is commonly performed under general anesthesia, different studies have demonstrated the safety and advantages of performing breast augmentation under conscious sedation and local anesthesia [2,8–10]. The time spent for application of the local anesthesia procedure is probably associated with prolonged overall operating time compared to general anesthesia procedures, due to the longer anesthesia introduction time. However regional anesthesia offer advantages, such as shorter recovery time, reduced side effects associated with general anesthesia, such as post-operative nausea and emesis [11], decreased post-operative pain, higher patient satisfaction, and cost containment have been reported [12]. These advantages contribute to a less stressful post-operative course where patients also get to rest and recover at home from an earlier time.

Aside from the above mentioned, local anesthesia procedures can also serve as an attractive alternative for patients that are apprehensive about general anesthesia due to e.g. concerns about safety and outcome and fear of loss of control [13,14].

Results from this study support the use of local anesthesia, intercostal nerve blocks, and light sedation as a suitable anesthetic protocol for breast augmentation that can be used as an alternative to general anesthesia.

Anesthetic protocol

The presented anesthetic protocol is characterized by relatively low doses of sedatives, analgesics, and Klein fluid compared to other local anesthesia studies [2,8,9]. Use of lower doses of both local anesthesia, hypnotica, and opioids secure a low risk of drug-related complications, such as cardiopulmonary effects, respiratory depression, nausea, and emesis [15,16]. The change of administrating midazolam both intravenously and intramuscularly was done due to the assumption that an additional initial intramuscular midazolam dosage would improve patient relaxation throughout the whole procedure. The intravenous administration ensured rapid high plasma concentrations with a following rapid effect that allowed the introduction of intercostal nerve blocks; a procedure which would otherwise be rather painful and uncomfortable. Intramuscular administration has a slower absorption rate and therefore a later onset of action. It offered steady plasma concentrations and a longer duration of sedation thereby reducing the requirement for supplementary peak doses of midazolam intravenously during the procedure. The results of the study confirmed that administration of preoperative midazolam both intravenously and intramuscularly was associated with a significantly decreased need for supplementary medication. We did not observe a higher risk of complications associated with this change in method.

The use of tumescent local anesthesia with dilute epinephrine causes vasoconstriction and therefore aids in reducing bleeding during the procedure [7]. This could be one explanation for the observed hematoma rates in this study as it was only reported in three cases (0.9%), of which only two required intervention, as well as seroma formation, which only occurred in four cases (1.2%). Other studies of primary breast augmentation and revisions-augmentation performed in general anesthesia, without the use of tumescent local anesthesia, report hematoma rates ranging from 1.5 to 2% [17–19], as well as seroma occurring in 1.2 to 6.0% cases [20,21]. A Danish prospective study based on a nationwide cohort of primary breast augmentation of more than 5000 women, primarily operated in general anesthesia (97%), reported hematoma in 1.2% of cases, whereas seroma was found in 0.6% within 30 days of follow-up and to 0.2% within 5 years post-operatively [22]. These figures compare nicely with the current study.

As previously mentioned this specific anesthetic protocol corresponds to sedation level 2, where the patient is cooperative, oriented, and tranquil, as defined in the European guidelines [4]. It eliminates the need for an anesthesiologist or nurse anesthetist since the sedative and analgesic drugs can be administrated by the surgeon or even the circulating nurse after appropriate training. This way of administrating sedatives and analgesics has also been demonstrated as a safe procedure in a similar, but smaller US study [2]. Such reduction in personnel requirements compared with general anesthesia or deeper sedation procedures is associated with reduced costs. The specific costs were not analyzed in

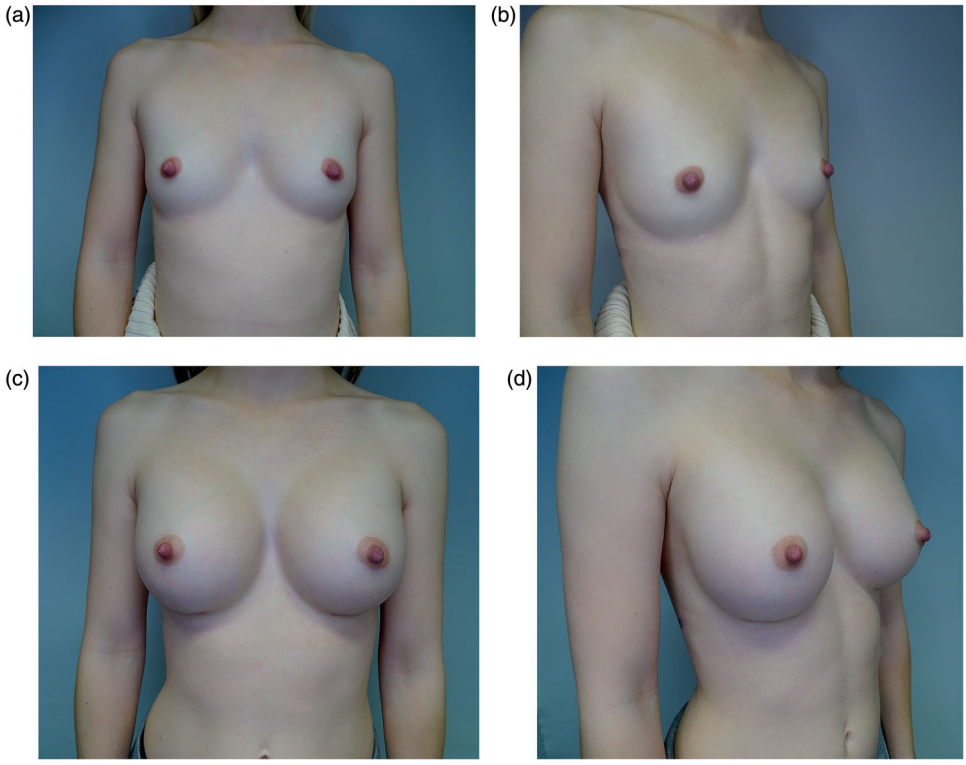

Figure 3. (a–d) Patient photos pre- and 3 months post-operatively. A 26-year-old woman augmented with Eurosilicone textured anatomical implants, style TMF3, 345 cc. (a) Before augmentation, frontal view. (b) Before augmentation oblique view (right). (c) After augmentation frontal view. (d) After augmentation oblique view (right).

this study, but the cost containment associated with local anesthesia procedures has been demonstrated by other studies. The major concern about performing breast augmentation in local anesthesia is if pain control can be obtained. This study is of retrospective nature, and the medical charts contained no structured or formal information regarding patient pain(scores) neither intra- nor post-operatively. We can therefore not demonstrate, by data concerning the patients' pain experience, that pain control can be obtained, however, the high completion percentage, the fact that patients accepted re-operations with the same kind of anesthesia, the low medication doses, and the surgeon's experience substantiates that the procedure is indeed feasible.

Complications and safety

This study demonstrates rates of complications that are comparable to standards of other published studies of augmentation mammoplasty performed in either local [8,9] or general anesthesia [17,18,20,21].

One of the very serious potential complications to be considered when performing this anesthetic protocol is pneumothorax. Any use of a needle in the thoracic region, e.g. local infiltration, acupuncture, or intercostal nerve blocks has a known risk of causing pneumothorax, which in this study occurred in 2 (0.6%) patients. If the surgeon is familiar with the use of ultrasound-guided injections, this can be combined with the intercostal blocks for further precaution [23,24]. Of note is that administration of intercostal blocks has been associated with lower surgical stress response and post-operative pain [25].

The overall reoperation rate (16.1%) was in line with or even better than observed rates in other studies [17,20] and cosmetic reasons accounted for most of the reoperations. In a prospective study of women augmented with Sientra breast implants, reoperation rates of 24 and 38.8% within 10 years in primary augmentation and revision augmentation, respectively, were reported, and overall 50.6% of reoperations were due to cosmetic reasons [21]. Reoperation rates will always differ, depending on for instance setting, follow-up time, if unsatisfied patients are reoperated without additional costs, etc. Patient satisfaction can be affected by subtle differences or irregularities in cosmetic appearance. In this study, the surgeon widely attempted to meet the patient's individual preferences and offered reoperation as far as this was professionally justifiable. The same considerations can be applied to inconsistent definitions of complications, leading to differences in prevalence values, and impairing comparison between studies.

Another factor that may influence and cause differences in the prevalence of complications between studies is the length of patient follow-up. In their 10-year core study, Sientra [21] investigated the timing of capsular contracture events and reported that over 50% of events within the primary and revision-augmentation cohorts did not occur until after 3–4 years. They also reported that no ruptures were suspected/confirmed until after 3 years post-implantation and the risk of reoperation increased from 10% 1-year post-implantation to 31.5% 10 years post-implantation. In accordance, this study also found that most (75%) of the seromas, capsular contractures, and ruptures were reported 3–6 years post-operatively (data not shown).

Limitations

As already mentioned above, the retrospective nature of this study has left it susceptible to incomplete medical chart data and among these is a lack of information on pain, operating time, recovery time, and patient satisfaction. These parameters would have been relevant to investigate in the current study. It could

have been interesting to explore if the long time used in the operating room for administration of anesthesia was compensated for in reduced recovery time.

Another limitation worth discussing is the length of this study's follow-up time. Some of the included patients had <1 year follow up which could be considered a rather short follow-up time. This was mainly due to the fact that the clinic stopped booking fixed annual post-operative appointments as it was realized that a lot of patients did not appear for these appointments if there were no complications. Instead, patients were told to actively book an appointment if any complications or questions occurred, and this offer was without a time limit. Though we cannot be sure that all patients came back in case of complications, this is the general experience, since reoperations generally were done free of cost, and we thus assume that the overall majority would.

In this study, the post-operative follow-up consisted of a telephone call the day after surgery, and a post-operative visit at the clinic after 2 weeks and after 3 months. In the revision of this manuscript, as a quality improvement initiative, an earlier follow-up visit with the clinic is being planned for the future. This is done to ensure patients' well-being and the absence of any complications shortly after surgery.

Further research is needed to determine differences in the outcome of breast augmentation under general *vs.* local anesthesia, including the peri- and post-operative pain management effect of the intercostal blocks.

Conclusion

Based on our retrospective analysis of outcome in 335 consecutive breast augmentations, we conclude that the presented anesthetic protocol is safe and feasible to use for this procedure.

The preoperative administration of hypnotica and opioid allows the introduction of intercostal blocks for better intra- and post-operative pain control. The infiltrations of modified Klein fluid contribute to vasoconstriction and possibly reduced bleeding. Administering preoperative midazolam both intravenously and intramuscularly, rather than only intravenously, is associated with a significantly decreased need for supplementary medication, suggesting improved patient relaxation throughout the surgical procedure.

With complication and reoperation rates comparable to other studies of breast augmentations, this anesthetic protocol can be considered a reasonable alternative to general anesthesia procedures. It may serve as an alternative for patients with concerns regarding adverse effects and complications related to general anesthesia.

Disclosure statement

EL does perform the described procedure in his clinic, otherwise, the authors have no financial interest to declare in relation to the content of this article.

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