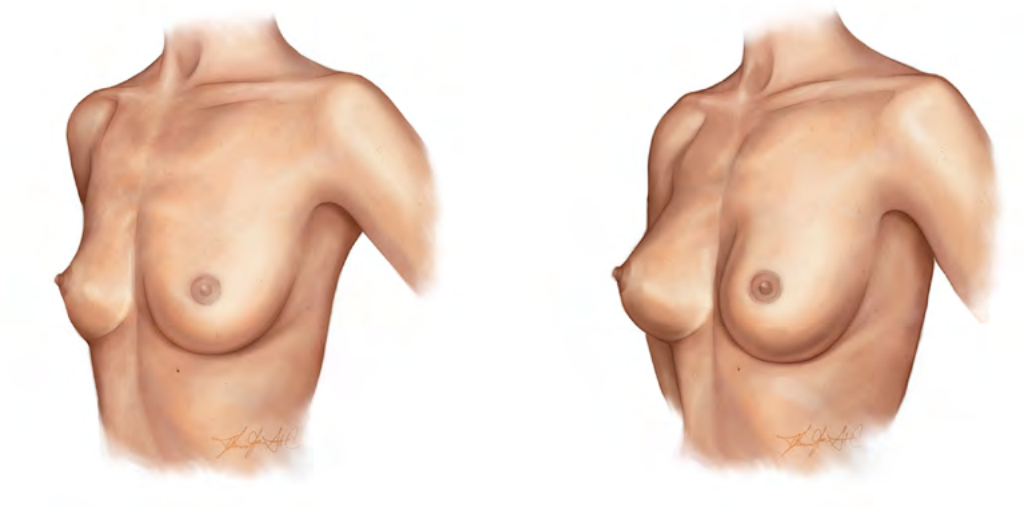
# *Breast Augmentation*

*Every day I meet women who desire more attractive breasts. I have operated on thousands of women over the years. When I first started in practice there were many patients with truly unsatisfactory outcomes from surgery in the 1970s and 1980s. The results of this operation have improved dramatically in the time since.*



*Plastic surgery can play a role in enhancing your body image.*

There is little doubt that breast size and shape is an important part of attractiveness. Human behavior and the subconscious motivations behind our sense of well-being and attractiveness are studied extensively by psychologists, anthropologists, and others. Though we may wish to transcend the idea of our physical appearance playing a role in our happiness and how we appear to others, biology is difficult to overcome.

Please review this related article posted on the *US National Library of Medicine National Institutes of Health* www.ncbi.nlm.nih.gov/pmc/articles/PMC3210352

# INTRODUCTION

*Breast augmentation with implants has been done since the 1960s by plastic surgeons. The operation is far more sophisticated and successful today than it was a generation ago, and continues to evolve and improve.*

In the 1950's some women, usually involved in burlesque shows or in the US entertainment industry, wanting to increase in the size of their breasts, were treated outside North America, by the injection of materials such as liquid silicone or paraffin, directly into the breast, often with rather disastrous results. They experienced painful cyst formation, drainage of infected material, and distortion of the breast shape, so surgeons in North America began searching for reliable and reasonably safe ways of increasing the breast size. This resulted in the development of an implant with a silicone rubber shell, or balloon, which could be filled with either silicone gel material made to have approximately the same feel as normal breast tissue, or filled at the time of surgery with sterile salt water (saline). Instead of in the breast gland itself, the implant was placed under the breast, leaving the breast, nipple, and areola, pretty much intact.

The operation was gradually refined and some modifications were introduced, but in principle it is much the same today. To understand how the dimensions of the breasts change, we can think of the breast as roughly a cone-shaped part of the body which is increased by both its base width and its forward projection by adding a round disc (the implant) to the base of the cone.

The first augmentation with silicone filled implants was done in 1962. Saline, or salt water filled implants were developed a few years later. Periodically there has been controversy about the operation, the patients, and the plastic surgeons ever since. Sometimes there have been good reasons for this but usually not.

*From April 1992 until October 2006, silicone implants were effectively off the market and only available for research purposes. The only implants available for general use were filled with sterile salt water (saline).*

The reasons the Food and Drug Administration (FDA) in the United States and the Canadian Health Protection Branch (HPB) had, had more to do with "bad optics" and "politics" than actual dangers. The controversy over whether implants were "safe" or "unsafe" erupted rather suddenly, and both plastic surgeons and the manufacturers were taken by surprise by the suddenness and extent of public concern. Not enough research had been done to satisfy the government agencies responsible for approving the implants, and a decision had to be made that would satisfy the public. On top of this, late in 1991, it suddenly became clear that leakage of the silicone filled implants occurred earlier and more often than was suspected by anyone. In the confusion surrounding the issues of safety, the regulators stepped in with a "moratorium" on the use of silicone implants;

*Many years of careful research were needed, and many, many cases documented, to demonstrate to the FDA and HPB Canada that the implants could be used and recommended safely.*

In the meantime, extensive experience with similar implants accumulated around the world, with good research in Australia, Sweden, Great Britain, and other modern medical communities.

In 2006 the FDA and HPB Canada finally ended the moratorium and approved the implants for general use *(www.canada.ca/en/health-canada/services/healthy-living/your-health/medical-information/breast-implants.html)*. This required extensive documentation by the two remaining implant companies with a commitment by them and by plastic surgery organizations to continue studying implants and their safety.

There are still people who believe breast augmentation should not be done and that it is "mutilating surgery" that puts women at "unreasonable risk", but studies have now clearly shown the implants do not cause or contribute to any of the illnesses they were accused of in the late 1980's and early 1990s. Like any operation, however, this is surgery, and therefore not "risk free".

*The typical woman having breast augmentation is either in her early twenties and has very little breast development or is in her thirties and has lost breast volume after pregnancies and breast-feeding periods. We have seen women for augmentations well into their sixties, however.*

## So what is it about this operation that makes it so controversial?

Firstly, there is great emotional and sexual importance to breasts in our culture and in most cultures. They are part of what are referred to as secondary sexual characteristics, and a major part of how women define themselves as *women*. In its early days the operation had a very high rate of re-operation for often less than satisfactory results. Also, there was the tendency of some women *and their surgeons* to over-do the degree of augmentation. This resulted in some patients with excessively large and unnaturally hard breasts, and the operation became the subject of scorn, ridicule and negative moral judgement.

This doesn't need to be so.

*When carefully considered and for the right patient, breast augmentation is a wonderful way to make a woman feel feminine and whole.*

- Many patients prior to surgery have little or no breast volume and are embarrassed by their chest anatomy.
- Some have never developed and feel like they have the chest "of a boy".
- Others who may have had moderate breasts in their teens and twenties have lost nearly everything after pregnancy and breast feeding.

*Why would we, as a society, not doubt the motives of the woman who wants a breast reconstruction after cancer surgery but look down upon the woman who has lost all her sense of femininity after she has born children or who never had any?*

# RISKS & POSSIBLE COMPLICATIONS

*Complications are fortunately few, and most are treatable to a satisfactory conclusion. As with any procedure being done very often (and there are likely at least ten million women who have breast implants) cases of major problems can and do periodically occur.*

Despite controversy which has hovered around the operation since its beginnings, the vast majority of patients continue to be satisfied by the surgery. Although the procedure does not always result in excellent results, only a very small proportion of those having the surgery would even consider having the implants removed, and satisfaction rates with both surgeon and patients are high. Despite this, controversy about the operation forced a re-evaluation and careful assessment of the success of surgery.

*The long-term results of the surgery are under more careful study than they were previously.*

Fortunately, the general impression we have always had which is that it is a rewarding procedure, has largely been reinforced by the current studies.

## Hematoma

As with any surgery, breast augmentation can occasionally result in **bleeding**. Because a rather large space is created under the breast to allow placement of the implant, if post-operative bleeding occurs under the surface, it can fill this space, cause painful swelling, and require urgent treatment. This usually requires a return to the operating room and this may require admission to hospital. A Hematoma is quite rare, in our practice occurring about once in every 400 or so patients.

*Although **infection** is highly unusual, it can occur, and if it does, may require removal of the implant for a period of several months until everything is completely settled, followed by re-augmentation.*

**Loss of feeling** or reduced feeling of the breast and nipple occurs more frequently, probably in 15% or more of patients. This is usually temporary. Although feeling usually gradually returns, it may not, or it may result in increased sensitivity for several months.

**Breast Pain** occasionally occurs even years after surgery. This is usually short periods of pain radiating through the breast and into the nipple often over over a period of a few weeks, and often ends as mysteriously as it begins. Sometimes it may be related to a tight fitting bra putting pressure on the nerves running into the breast; at other times it seems there may be pressure on the nerves from the implant when a patient is sleeping in a position causing this pressure. Most times there just doesn't seem to be a good explanation. It is highly unusual for this to be persistent.

## Capsular Contracture

When a foreign object, whether it is a sliver, a piece of glass, shrapnel, or a breast implant is placed under the surface of the body, the body recognizes it as "foreign", and if it cannot digest it, reacts by forming a wall around it. This wall, which we call a capsule, is very much like scar, and may be thin and soft, or tough and thick.

If the capsule contracts around the implant and the space for the implant becomes tight, the implant comes under pressure, is forced into a more rounded shape, and becomes firm or even hard—*this is called capsular contracture.* It is by far the most common problem for both plastic surgeons doing breast augmentation and for our patients.

We cannot explain why one patient will get contractures and another will not, nor why in some patients one side will develop a contracture and the other will not. Nor can we predict who will get it. It is not a major health risk but may cause enough firmness on occasion to be uncomfortable or even painful and certainly, the more severe, the less natural they appear and feel.

Years ago, we generally found that 75–80% of patients had a very good to excellent result, and of the other 20–25%, many accepted a reasonably soft result. But longer term, many patients ended up with hard, unnatural looking and feeling breasts. Re-operation long term was very very common. Surprisingly few patients were troubled enough to want to have their implants removed for treatment of contracture.

*Things are better today.*

Many solutions were tried with few successes. In earlier days of breast augmentation, surgeons used cortisone and other medications in and around the implant to reduce scar formation, but this resulted in unreasonable numbers of patients having implants break through the skin or the surgical incision site, requiring removal. Antibiotics were placed in and around the implant on the theory that unrecognized low grade infection, or at least contamination with normal skin bacteria, caused the contractures. However, this brought little or no success. Many surgeons, and their patients believed that contracture could be warded off by daily massage like exercises to keep the implant moving within a space larger than the implant, to maintain a large, relaxed space.

*Recent studies have shown massage is ineffective.*

In the early 1980's, some surgeons began to believe strongly that placing the implant beneath both the breast and the underlying pectoralis major muscle resulted in a reliably smaller chance of contracture. Because the muscles are being used constantly, as the theory goes, the implant is constantly being moved about within the space, and therefore even without having to think about the exercises, the patient is doing them in her daily life. There is also the feeling that muscle has so much nutrition and defense against infection that placing the implant in this location has a better chance if infection is felt to be a cause.

*The risk of capsular contracture may be as low as 1 –2% or even less, over many years, when implants are routinely placed "under the muscle".*

Some surgeons dispute the value of under the muscle placement of the implants, but many now believe this to be the single best way to reduce the chances of developing symptomatic capsular contracture to as little as 1% of all augmentation patients.

However, even placement under the muscle results in occasional contractures, so the search for a reliable solution continues. An implant with the same silicone rubber shell and silicone gel content , but with a foam (polyurethane) covering was developed, and this seemed reliably to reduce the contracture rate to 1% or less for the first five to seven years after surgery, but concerns were raised about the long term health risks of the foam as the body digested it, and the product (Meme, or Replicon) was withdrawn from the market in 1991.

Following the theory that it was the rough surface of the foam-covered implant that reduced the contracture rate, a textured surface silicone rubber shell implant was developed. Combined with a firmer silicone ("cohesive" or "memory" gel), these implants could be made in a traditional round shape, or a shape meant to mimic a typical mature breast with greater fullness at the bottom and a profile tapering towards the top (giving a so-called *anatomical*, *teardrop*, or *natural shape*). The lay public has referred to them as "gummy bear" implants

because of their resemblance to the candy with the same name. This implant has met with some success although opinions vary as to how reliably it results in soft breasts, and there are other problems with their use.

*The most recent studies show little difference between contracture rates between smooth and textured implants when both are placed in the sub-muscular position.*

### ALCL

There are reports now that women who receive breast implants may be at a higher risk of developing a very rare form of lymphoma. There are only about 200 individual cases of this among all the millions of women who have had implants over the years. ALCL seems to be linked only to the use of textured implants, and one manufacturer's implants in particular, although research is ongoing. *Please read related article by The American Society for Aesthetic Plastic Surgery www.smartbeautyguide.com/procedures/breast/breast-augmentation/*

Both plastic surgery professional organizations and federal regulatory agencies—the FDA in the US and HPB Canada—are working together to develop a clearer understanding of this illness and how it may be affected in women with implants. We have, in the meanwhile, been told the operation is safe for us to continue to offer to our patients.
*Please read related article by Health Canada www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/65224a-eng.php*

---

## THE SILICONE SCARE (1992)

*This is a difficult topic to discuss in a non-technical fashion, while dealing effectively with the facts as we know them.*

Silicone gel filled implants were taken off the market except for investigational purposes in 1992 by the US Food and Drug Administration and Canada's parallel body, the Health Protection Branch, soon followed with a similar ruling.

There were several concerns which prompted these rulings: possible risk of cancer, a possible link to immune related diseases, and leakage of the implants.

### Breast Cancer

We know that breast cancer occurs in about one out of every nine women in North America today. Some women with breast implants, therefore, are bound to develop breast cancer. However, large numbers (many thousands) of patients have been followed for long periods, especially in studies done at the University of Calgary, and it seems quite clear that implants do not increase the risk of a woman developing breast cancer, nor do they result in significant compromises in its treatment, when it is found. Implants do make mammograms somewhat less accurate, although saline-filled implants are better than the gel filled implants.

### Immune Disease

Connective tissue diseases are illnesses, the most common of which is *Rheumatoid Arthritis*, in which the body's immune system reacts to parts of the body, causing symptoms. In arthritis, these symptoms are mainly in the joints, but may also involve other body systems. In a small number of patients with breast implants, symptoms of allergic or immune illness have been seen, such as scleroderma or other diseases.

*Scleroderma* is a disease which causes hardening and thickening of the skin and other organs, caused by fibrous tissue ingrowth. We expect to see approximately 2% of all women developing these symptoms, so it is not surprising that some patients with implants will develop similar symptoms, but not caused by the implants. Since the ban on gel-filled implants, research has continued to show the unlikelihood of a link between the implants and these types of illnesses. However, these conclusions are based on statistics, and it remains possible, although unlikely, that a very small number of patients develop immune related illness from implants. Scleroderma seems to be most common in Japan, where liquid silicone for injection is still used for procedures such as breast augmentation. Liquid silicone is chemically different from silicone gel. Furthermore, since it is not bound by a capsule, there is more risk that it will migrate into undesirable locations.

### Leaking implants

The third concern relates to leakage of the implants. Careful study, especially from the University of Toronto has shown that gel filled implants used between approximately 1972 and 1987, leaked much earlier and at a much higher rate than was previously thought. The main reason the implants were taken off the market by the FDA was that Dow Corning knew there was a higher risk of leakage than they told plastic surgeons.

*Implants now in use have silicone which is "cohesive" (Allergan's term) or "Memory gel" (Johnson and Johnson's Mentor corp term), meaning that it tends to remain in place even with a break in the outer covering, so there is less concern for the consequences of a leak.*

*Most of the time leaks and rupture of implants is "silent", meaning there are no symptoms or signs.*

The FDA in the USA suggests MRI testing three years after surgery and intermittently thereafter, to check for leaks. Canadian authorities suggest no special tests unless the patient is experiencing symptoms or signs of concern. If a doctor's examination suggests suspicion of leakage may be a concern, an ultrasound or mammogram should be the first step, only moving on to an MRI if the ultrasound is inconclusive.

However, the presence of a leak does not seem to cause illness, nor does it seem to cause very significant silicone amounts to circulate elsewhere in the body.

If a leak is detected, most surgeons and most patients feel it is best the implants be removed and replaced. Manufacturers guarantee against this and will cover the cost of new implants (for life) as well as the operating room costs for a limited time.

### Mammograms

Routine pre-operative mammograms are recommended for patients who are thirty-five or older. After surgery, the usual recommendation is for a mammogram every year after forty years of age.

Saline implants placed under the muscle give a better mammogram picture than what was possible with above the muscle implants, but an extra view done by the mammographer is often advised to get the best possible assessment. Silicone implants under the muscle also allow effective examination on mammograms.

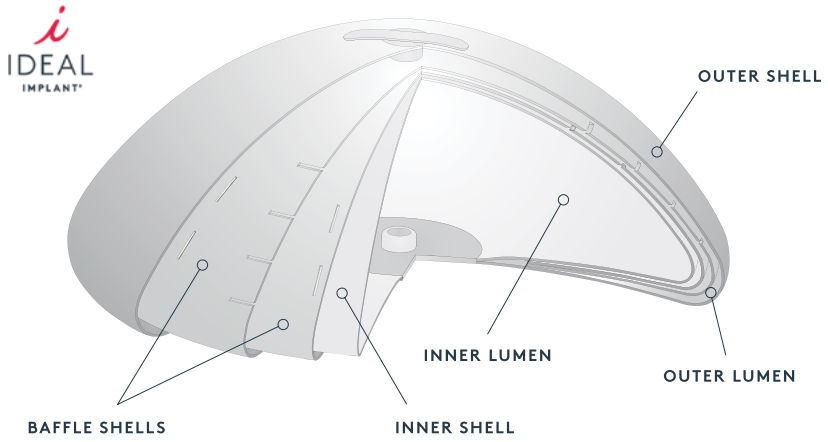
# ALTERNATIVE FILL SUBSTANCES AND OTHER FORMS OF AUGMENTATION

*Research continues in the attempt to find a more ideal implant. To try to make rippling less of a problem, and to make mammograms more accurate, soy oil filled implants were tried. This was a short-lived idea … within a few years the "tri-lucent" implant was withdrawn and women with the implant were urged to have them removed.*

## Ideal Implant®

The Ideal Implant®, is filled only with salt water (saline). It may cause less rippling and have a better feel than traditional saline filled implants because its internal structure may prevent excessive fluid movement and "sloshing". It was approved in November 2014 and reached the market in a limited release in September, 2015. How successful it is at achieving its aims remains to be seen.*

**Disclosure: Dr. Gelfant is an investor in the Ideal® Implant corporation.*




*The new, internally structured, saline-filled Ideal® implant was released in 2015*

Dr. Gelfant has, as of late 2017, an experience with the implant totaling over 70 cases of all types (breast augmentation, breast augmentation and lift, and revision surgery).

*Patient satisfaction so far, has been very high.*

## Fat Grafting

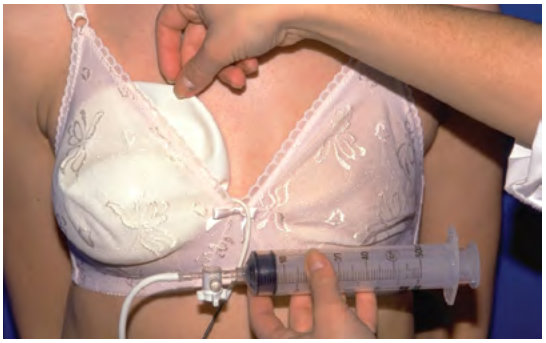
The use of fat taken first by liposuction and then injected in multiple tiny amounts through the breast *(Autogenous Fat Grafting)* has becoming a mainstream procedure. Sometimes this is done with preparation by use of a vacuum bra (the Brava® bra) for six weeks before, and sometimes it may be done along with the use of an implant (composite augmentation). We have done several dozen cases of grafting along with breast lift to achieve upper pole fullness without the use of an implant, and with apparent lasting success. At this time, our experience with fat augmenting the breast without other simultaneous procedures is limited.

**Age Restriction:** Health Canada and the FDA in the USA state "breast augmentation with silicone implants is appropriate for women age 22 and older …" and it had long been my practice and that of most plastic surgeons to not offer silicone filled implants to women 21 and under. However it is acceptable to use silicone gel filled implants for these women if they will provide a superior result and when the patient is capable of understanding the pros and cons of their use. The surgeon can use the devices "off label". Discuss this if you are under 22 with your surgeon.

**Size:** Historically there were many methods used to determine breast implant size, but these were, surprisingly, usually dependent on the surgeon's sense of balance and esthetics. We have modified a method first described in the early 1980's by a Canadian surgeon practicing in the Los Angeles area, along with information learned

from surgeons in Texas and the eastern USA. We ask the patient to put on a standard bra on and trial a series of sizing devices in the bra. The patient's chest dimensions are used to determine whether her desires are possible, and the volume (cc's) and dimensions are used to decide which line of implants (standard – mod profile; narrower – mod plus; or very narrow – high profile) to use. We find the terms *High Profile* and *Moderate Profile* to be very confusing, and it frequently requires explanation. *Read more on this topic at our website: www.drgelfant.com/sizing-for-breast-ugmentation.*

*Most important: The patient determines the size, with our help.*



Here are links to the implant size catalogues of two manufacturers:

- **Mentor Medical**

*Please note, we use only smooth round implants of either moderate, moderate plus, or high "profile"*
www.mentorwwllc.eu/products/Breast/4/82

- **Ideal Implant®**

www.idealimplant.com/wp-content/uploads/6-10-17-Size-Chart.pdf

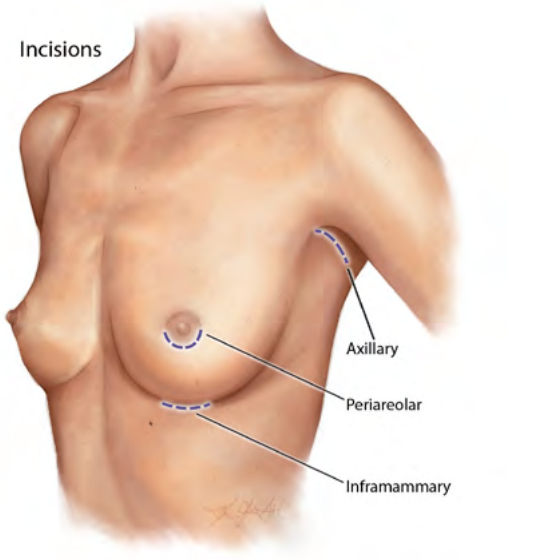
We used computer imaging many years ago but no longer do so. If you are interested in a visual predictor of sizing, you may want to upload a photo and use this facility from Mentor Medical Corporation. We do not endorse this process nor use it in determining size.

*More on this at www.breastimplantsbymentor.com/breast-augmentation/visualizer.*

## TECHNICAL DETAILS

### Incisions and Placement Location

Three incision locations are possible, and our main aim is to keep the scar as inconspicuous as possible, while maintaining patient safety and excellent results.




*Three possible incision areas*

**Inframammary**

Most plastic surgeons use the incision under the breast.

**Periareolar**

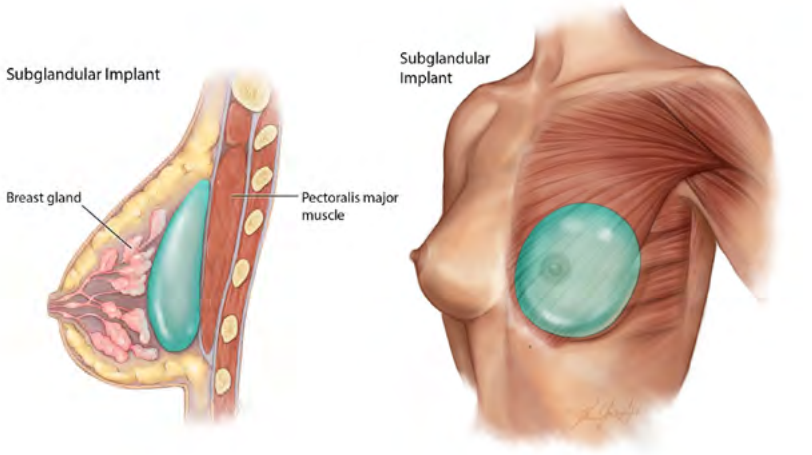
The incisions along the edge of the areolae have fallen out of favour in recent years because of more sensation loss and a possible risk associating possible low level infection leading to capsular contracture.

**Axillary**

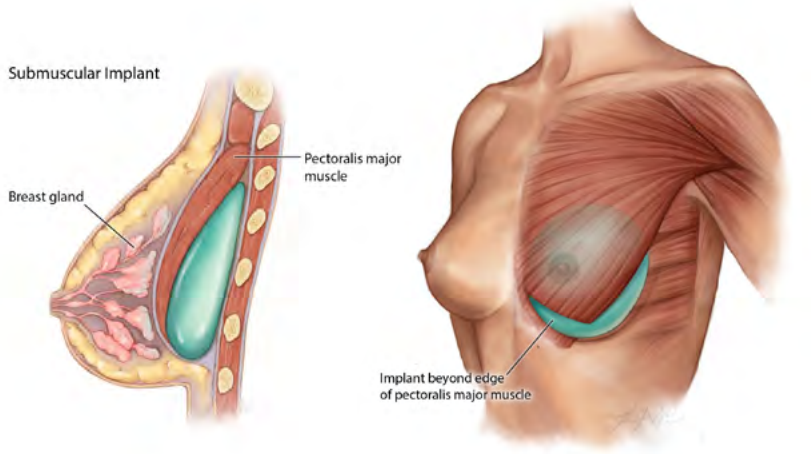
*When endoscopic surgery made the armpit approach more accurate in the 1990s, we embraced the technique and subsequently have used this approach on well over 2000 patients,* first with saline and more recently with silicone gel implants. It is our preferred approach, but certain conditions relating to pre-surgery breast shape make us opt for a traditional under the breast approach.

## Above or "below" the muscle

The implant can be located either above or what is known as "under the muscle" which usually means the implant is partially covered by the pec major muscle as shown below.




*Subglandular, or "above the muscle"*




*Partial Sub-muscular Placement*

Division of the lower pec major fibres, to a greater or lesser extent, is nearly always done in sub-muscular implant (dual plane approach). There are variants of this technique which your consultation may discuss.

Sub-muscular augmentation is the single most significant way to reduce the risk of contracture or hardness occurring. Because of the clearly reduced risk of contracture, implants in our practice are *always* in the *sub-pectoral location*. ***Always.*** And there is reduction of visibility and rippling as well as a more natural shape. Although augmentation can be done under local anaesthetic with sedation (twilight anaesthesia), we no longer feel this provides the kind of comfort and atmosphere today's patient desires and deserves.

*With early post op range of motion exercises (beginning on the day of surgery) most patients experience minimal pain and rapid return to normal activities, even with routine placement of implants under the muscle.*

*For more on this topic, please watch our video https://youtu.be/kG6EAUMO_hQ*

## Post-op

We usually see patients the first working day after surgery and check carefully for any problems, discuss how they are feeling, and review any concerns they may have. There are usually no sutures (stitches) to be removed but we have a second visit at about one week for a checkup. Barring any problems or concerns, we usually have another visit six weeks later and at six months.

## Breast Feeding

There is usually no interference with the function of the breast gland, and as long as there is some sensation to the nipple (it is rare for complete loss of sensation to occur) nursing is possible. However, not all new mothers are successful at nursing even without implants, so no guarantees can be made.

## SUMMARY

*Breast augmentation with implants has been done for over fifty years. The last two decades have brought improvements in safety, reliability, and the aesthetic outcome of surgery. Recovery time has become shorter, pain dramatically lessened, and return to an active life much quicker.*

*The addition of fat grafting as a possible option and the development of new implant choices for the future mean an already very good operation will become even better.*

*The Ideal® implant provides an option for patients who want the assurance of safety of saline with a better feel than traditional saline filled devices.*