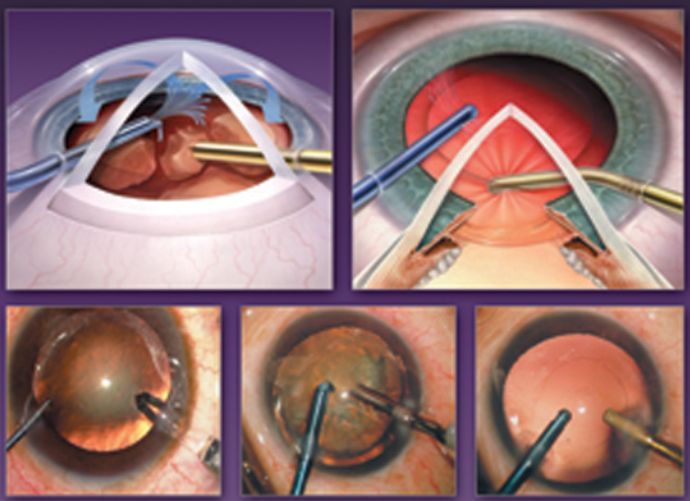
Bimanual Phaco

Mastering the Phakonit/MICS Technique



AMAR AGARWAL, MS, FRCS, FRCOphth

SLACK Incorporated

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Dedication

This book is dedicated to my parents, Dr. J Agarwal and Dr. T. Agarwal, who created Dr. Agarwal's Group of Eye Hospitals.

And to all the Indian ophthalmologists—Phakonit is India's gift to the world.

Contents

Acknowledgments

When Phakonit was started in 1998, I did not realize it would become so popular so fast. I wish I could say it was a brilliant invention of mine, but I cannot. The reason is that this invention (as do all inventions and discoveries) came as a message to me from the Almighty, and so the invention is HIS and only HIS.

About the Editor

Amar Agarwal, MS, FRCS, FRCOphth is the pioneer of Phakonit—Phako with Needle Incision Technology. This technique became popularized as bimanual phaco, microincision cataract surgery (MICS), or microphaco. He also discovered no anesthesia cataract surgery and FAVIT, a new technique to remove dropped nuclei. The use of an air pump to increase the fluid into the eye in bimanual phaco and co-axial phaco has helped prevent surge and built the basis of various techniques of forced infusion for small incision cataract surgery. He was also the first to use trypan blue for staining epiretinal membranes and published the details in his four volume textbook of ophthalmology. His latest discovery is a new refractive error called Aberropia.

Dr. Agarwal has received many awards for his work done on bimanual phaco, the most significant being the Barraquer Award. He has also written more than 20 books that have been published in various languages—English, Spanish, and Polish.

In his center, he also trains doctors from all over the world in phaco, bimanual phaco, LASIK, and retina surgery. Dr. Amar Agarwal is the director of Dr. Agarwal's Group of Eye Hospitals. He practices at Dr. Agarwal's Eye Hospital in Chennai, India.

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Preface

Since time immemorial, man has been trying to better his life. Time stands witness that, from the days of couching, we have indeed come a long way. Perhaps no other field of medicine has been so rapidly revolutionized as that of cataract surgery.

It took us many decades to understand that replacement of the lens is the best way to go about rehabilitating vision for the cataract patient. It took us years of experience to understand we need the help of high-energy sources to remove the clouding from the lens. And now we are on the brink of understanding that along with this, a highly efficient management of fluidics can do the job better, faster, and through a much smaller opening. Many thought that phacoemulsification would become obsolete. Though Charles Kelman was routinely doing phacoemulsification in the 1970s, it was only in the 1990s that phacoemulsification really caught on.

With standard phacoemulsification becoming the norm for cataract surgery, bimanual phaco was accepted much faster, as the prospect of breaking the 1.0-mm incision barrier was an exciting one and the potential benefits it held were tremendous.

"Necessity is the mother of invention." It was sheer luck that I chanced upon the idea of making a smaller incision by using a sleeveless phaco to compensate for not having a fragmatome for my vitrectomies. Only when I successfully completed cataract surgeries for vitrectomies in such a fashion did the full implication of the surgery hit me. With greater instrumentation and newer lenses, we have the opportunity to refine our technique further and further thus fully realizing the potential of a microincision surgery.

For hundreds of years, surgeons have used only one hand to do most of their work, needing mechanical pressure of sharp instruments to carry out their job. With time and evolution, we have understood that surgery carried out with both hands is far defter. Furthermore, surgery carried out with fluids discharged with high pressure can have a positive effect on tissues.

Thus came about the need and concept of bimanual phaco—or phakonit. Here the surgeon needs to be able to operate with both hands, while understanding the flow of fluids and the time and placement of the vibrating high energy of ultrasound. If the hands are inside the eye, the feet are on footswitches that control the whole works. Not just that, the surgeon needs to be operating with trained staff that work as a team inside the operating room, because many more hands have to be aiding his work that may take only 5 to 10 crucial minutes.

In this book, I have made an attempt to describe bimanual phaco in its entirety. Though one cannot master surgery by merely reading a book, this book offers to teach you what to do and how to go about it. In this effort, I have made an exhaustive description of the basis, various techniques employed, complications of bimanual phaco, and the practical ways of dealing with them.

Whether it is the air pump, special intraocular lenses, the irrigating chopper, or the sleeveless phaco probe, every piece of equipment necessary to make this surgery routine with your operating team is described by the experts in a manner that will make you want to perform the surgery once you have equipped your mind and body with the advent of newer technologies.

I have made an honest attempt at making this book useful for the surgeons who are newer entrants in the world of bimanual phaco. I am most appreciative of all those who stood by me through all the trying times.

I have also no words to thank John Bond, Amy McShane, Michelle Gatt, Robert Smentek, and the whole team at SLACK Incorporated who asked me to write this book and bore all my idiosyncrasies when I was writing it.

Most important of all, dear reader, this is just the beginning…

Amar Agarwal, MS, FRCS, FRCOphth
Chennai, India

Foreword

Charles Kelman's invention of ultrasonic phacoemulsification in 1967 began an inexorable march toward ever-smaller incisions for cataract surgery. In the 1970s, while phacoemulsification remained a specialized procedure, the concomitant development of irrigation/aspiration technology and techniques stimulated the movement from intracapsular cataract extraction to extracapsular cataract extraction, resulting in the first major reduction in incision size since the introduction of the Graefe knife. Refinement of ultrasonic disassembly of the nucleus led to the second transition from extracapsular cataract extraction (ECCE) to phacoemulsification, a transition that extended over two decades.

In addition to technology, a large part of the stimulus for this transition was a series of innovations in surgical techniques, all of which were designed to reduce the size of the principal incision and stabilize it mechanically. Large limbal scissors incisions closed with multiple interrupted sutures were replaced by shelved incisions and creative suture techniques that induced less astigmatism, which in turn gave way to sutureless clear corneal incisions. These innovations ran in parallel with the successive shift from large rigid PMMA lenses, to smaller profile rigid intraocular lenses (IOLs), to foldable silicone and acrylic IOLs.

Now, with the widespread use of injectors for both silicone and acrylic IOLs, permitting incisions slightly under 3.0 mm, some surgeons feel that the incision is now "small enough." But is it small enough? Even with an incision in the range of 2.5 to 3.0 mm, unpredictable shifts in astigmatism occur. With the increasing patient expectation for excellent uncorrected visual acuity, induction of unpredictable astigmatism of any level is undesirable. Furthermore, surgeons appear to be experiencing higher rates of postoperative endophthalmitis despite the use of the latest high penetration broad spectrum antibiotics. The structural integrity of a clear corneal incision is being questioned.

True microincision phacoemulsification, with incisions smaller than 1.5 mm, is, therefore, a logical goal.

Incisions of this size have been a mainstay of ophthalmic surgery for a century, in the form of a paracentesis. The techniques and technology for microincision cataract surgery are now a reality.

A surgeon might then ask whether there is any need to pursue surgical skills in microincision surgery until an intraocular lens is developed that can be inserted through an unenlarged microincision. I believe the answer is yes, for the following reasons. First, a separate larger keratome incision for the sole purpose of introducing the intraocular lens appears to seal more reliably than a keratome incision that is subject to the manipulations and trauma of the ultrasonic and irrigation/aspiration portions of the cataract surgery. Although not yet proven, one may suspect that the potential for postoperative wound leakage and endophthalmitis may be reduced utilizing microincisions for the cataract surgery and a larger incision only for the IOL insertion. Second, the development of microincision cataract surgery techniques serves as a stimulus for further development of small incision IOLs. Foldable and injectable IOLs would never have been developed in the absence of ultrasonic phacoemulsification. Many surgeons in the 1970s argued that Kelman's phacoemulsification was unnecessary because of the large incision needed for the insertion of a rigid intraocular lens. Third, surgeons

who pursue the development of microincision cataract surgery today have the luxury of learning at their own pace. Case selection can be optimized and judicious, with expansion as a surgeon becomes more comfortable with the new instrumentation. The surgeon's skills will then be refined and comfortable when smaller incision IOLs are available. Finally, surgeons who are experienced with microincision techniques already often state that it is an inherently safer and better operation, with a better control of the intraocular environment during the cataract surgery.

Microincision cataract surgery is the future, but it is also very much here in the present!

Roger F. Steinert, MD
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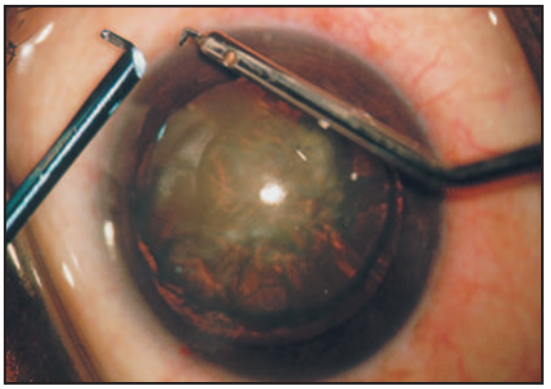
Section One



Introduction and Basics

Chapter

1

Evolution of Phakonit and Bimanual Phaco

Amar Agarwal, MS, FRCS, FRCOphth

How It All Started

I am basically a vitreoretinal surgeon and used to do all my lensectomies with the phaco handpiece. I did not have a fragmatome (an instrument to remove cataracts by vitreo-retinal surgeons), so I used to remove the infusion sleeve and pass the phaco needle into the lens through the pars plana. Infusion would be performed through the infusion cannula, which is connected in all vitrectomies. This way, I realized I could remove the cataracts in patients in whom I had to continue with vitrectomy for proliferative vitreo-retinopathy or any other posterior segment pathology.

I subsequently began to think about using this system for cataracts for the anterior segment surgeon. The problem was how to have an irrigation system present inside the eye. On August 15, 1998, India's Independence day, the thought of taking a needle, bending it like a chopper and using that for irrigation and chopping occurred to me (Figure 1-1). I also realized that there could be a corneal burn so I thought of irrigating the corneal wound from outside. With this idea in mind, I went to the operation theatre.

In our institute, we have doctors from all over the world training in phacoemulsification (phaco). When I reached the operating theatre, I knew that I could not operate on a patient with a decent soft cataract, since trainee doctors would have to operate on those patients, so I selected for myself a mature cataract. In hindsight, I realize it was a good thing this happened, as it made me understand that this technique could be done in any type of cataract.

When the procedure began, I took out the infusion sleeve from the phaco handpiece and took a 20-gauge needle and connected it to the irrigation bottle. Then I took a needle holder and bent the needle in such a way that it could also be used for chopping. It is easy to understand that a hand bent needle may not come out very well. Another problem with using a needle was that the needles have a bevel; if one pulls out the needle a little bit, the bevel comes out of the eye and the chamber collapses. For the incision, I used the microvitreoretinal blade (MVR blade) which vitreoretinal surgeons use for vitrectomies. While this does not create a perfect valve as the diamond and sapphire knives of today do, it was suitable at that time.

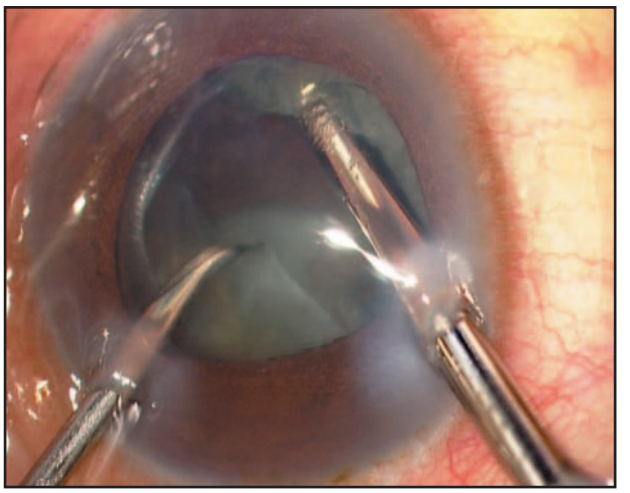


Figure 1-1. Bimanual phaco (Phakonit) done with a bent needle. The needle was bent like a chopper and the first case of Phakonit was done with this instrument. Later on instruments like the refined irrigating choppers were made.

When I had finished the rhexis, I knew hydrodissection was important and tricky. The reason was that the incision size was very small, and therefore, the amount of fluid escaping from the eye would be minimal. So, I was careful to not hydrodissect with a lot of fluid, in order to avoid getting a dropped nucleus during hydrodissection.

When the surgery started, I realized I was having a lot of anterior chamber shallowing. Whenever I would start to remove the nucleus, the chamber would partially collapse. It was obvious that the amount of fluid entering the eye was not enough compared to the amount exiting the eye, so I stopped the surgery and shifted to an 18-gauge needle. To my surprise, everything went well after that. I knew then that the amount of fluid now was balanced with an 18-gauge needle. I could chop the hard cataract (though not as well compared to a chopper), but I knew with more refined instruments this surgical technique would work. Once the surgery was complete, I realized that this could be the next frontier in cataract surgery as the incision was reduced drastically.

Terminology of Phakonit

I wanted to give a name to this surgical technique and started thinking of various names. Some names which came to me at that time were microphaco, miniphaco etc. Then I thought of *Phakonit*—phaco with needle incision technology. The reason I thought of this was because we did phaco using a needle (N) through an incision (I) and with the tip (T) of the phaco needle for the surgery. I used a K (and not a C) in its spelling, as I felt it looked better as PHAKONIT.

Bimanual Phaco

Internationally, the name for Phakonit is *bimanual phaco*. The idea was to separate it from coaxial phaco in which the irrigation is with the phaco handpiece.

In this book we have tried to standardize the terminology and use, by and large, bimanual phaco. It is also known as Phakonit, microphaco, or microincision cataract surgery (MICS). These names are all synonyms of bimanual phaco.

No Anesthesia Cataract Surgery

At this stage I would like to digress a bit, and mention another discovery of mine. I was operating on a patient with a posterior polar cataract. Normally in such cases, I used to prefer to do an extracapsular cataract extraction (ECCE). When my fellow rang me up and informed me that the case was a posterior polar cataract, I told her not to block the patient, as I would do ECCE. In those days, I used to do the ECCE under pinpoint anesthesia or subtenons anesthesia, in which I would make a small nick in the conjunctiva and pass a cannula with xylocaine under the conjunctiva and give anesthesia to the patient. This way, the patient does not have an injection and is quite comfortable. When I reached the theatre, I saw the patient and decided to do phaco. When I was in the middle of the case, my fellow came running into the theatre and was very anxious, as she had left before I had started the case. She informed me that she had not put any topical anesthetic drops in the eye as I was going to do subtenons anesthesia for ECCE. She was worried that I would be angry with her. However, I was actually shocked that I was in the middle of the surgery and the patient was not expressing discomfort at all. I told her let us see what happens as this patient obviously did not mind the cataract surgery without anesthesia. When I finished the case, the patient got up shook my hand and thanked me and left the theatre. This set my mind working as I knew this was abnormal.

On June 13, 1998, I was in Ahmedabad, India for a live surgery for a workshop organized by the Indian Intraocular Implant and Refractive society. Although I had discovered that cataract surgery can easily be done without any anesthesia and termed that as *no anesthesia* cataract surgery, I was apprehensive to do it as I felt it was really absurd. In this surgery, no topical anesthetic drops or intracameral anesthesia is used. However, absurd as it may sound, it was true. On June 13, 1998, I decided to do the live surgery without any anesthetic drops. The surgery went very well and there were about 250 eye doctors from all over India watching the surgery. In hindsight, I do not know what made me do the live surgery without anesthesia since I had no way of knowing how successful it would be. When I came back to Chennai (Madras) where I work, I started thinking about it more. At that time, I had a eye doctor from the United States named Dr. Vipul Lakhani training with me. He told me to look at it scientifically and said he would do a double-blind study with me. We took 30 patients that were operated on by my wife (Dr. Athiya Agarwal) and me: 10 were with no anesthesia, 10 with topical, and 10 with topical plus intracameral anesthesia. We did not know which patient we were operating upon. Following the surgery, Dr. Lakhani asked each patient his or her pain factor. At the end, he informed me that his p values showed there was no difference between the three groups. Then I knew no anesthesia surgery was a reality, and since then, have never used topical or intracameral anesthetics. If there is a tough case or an uncooperative patient, I would operate with a peribulbar block. Later, a similar study was done by us with David Apple and Suresh Pandey which was subsequently published in the *Journal of Cataract and Refractive Surgery*.[1,2]

First Live Phakonit Surgery

On August 22, 1998, I had to do a live surgery in Pune, India for the Indian Intraocular Implant and Refractive society conference. The organizers asked me what live surgery was I going to perform. I informed them that I was going to perform a new

surgical technique which I had called Phakonit, and would remove cataracts through a 1.0-mm incision. They were very happy and trusted me enough to give me the confidence to proceed.The night before the live surgery, I could not sleep at all. I knew I had to do this new surgery and I had done only five cases at that time. I also knew I had to operate with just a needle, with no refined instruments, and without any anesthesia; this put me under lot of tension. However, the surgery went off very well, and there were about 350 ophthalmologists who watched the live surgery.

Previous Work Done

In 1985, Steve Shearing[14] published a paper on separating the infusion from the phaco handpiece. In 1987, T. Hara from Japan[15] also did the same. I had not heard of any of this work when the concept of Phakonit was started by me. As Phakonit became gradually more popular, work done by these early pioneers was appreciated more and more.

Phaco Book

At the time I was writing my first book, *Phacoemulsification, Laser Cataract Surgery, and Foldable IOLs*, which was to be released in September 1998, I immediately contacted the publishers and informed them that I was sending a chapter titled "Phakonit." Although the chapter was quite late and the book was already in press, they agreed and that is how the "Phakonit" chapter came into publication in 1998 itself.[3-13]

Irrigating Choppers

I subsequently worked with many companies to make the irrigating chopper and other instruments for Phakonit like the phakonit knife, etc. Various companies now have bimanual phaco instruments designed by various surgeons of the world.

Air Pump

One of the main problems in bimanual phaco/Phakonit was the fluidics. As explained earlier, the amount of fluid entering the eye was less than the amount of fluid exiting the eye. My sister, Dr. Sunita Agarwal, understood this problem and started pushing air into the infusion bottle to get more pressurized fluid out of the bottle.[9] When it worked, she then took an aquarium air pump and connected it to the infusion bottle via an IV set. This gave a constant supply of air into the infusion bottle and the amount of fluid coming out of the irrigating chopper was quite enough for us to move from an 18-gauge irrigating chopper to a 20- or 21-gauge irrigating chopper. This was the first time pressurized fluid was used in anterior segment surgeries. The invention of the air pump was made in 1999, and since then we have never looked back. We use the air pump not only in bimanual phaco, but in all our phaco cases.

Three-Port Bimanual Phaco

Before the air pump I tried to solve the surge problem by fixing an anterior chamber maintainer. This was a three-port bimanual phaco.[2] Once the air pump invention was made by my sister Sunita Agarwal, we realized we did not need the anterior chamber maintainer. The usage of the anterior chamber maintainer made bimanual phaco more cumbersome as three ports were made rather than two.

Live Surgery From India: Telecast to ASCRS 99

We applied for an instruction course in the ASCRS 99 conference in Seattle; this surgery was to be telecast live via satellite from India to the United States in order to demonstrate Phakonit and no anesthesia cataract surgery. To date, we are very grateful to Dr. Manus Kraff, David Karcher, and the whole ASCRS team for giving us this course. The live surgery went very well, and we took the next flight out to give lectures at the ASCRS meeting, taking advantage of the time difference between the two countries. Many courses were subsequently conducted by us on Phakonit and no anesthesia cataract surgery at the ASCRS, AAO, and ESCRS conferences.

Work Done in 1999

In 1999, P. Crozafon reported the successful use of a sleeveless 21-gauge Teflon-coated tip for minimally invasive bimanual phaco. Crozafon felt that thermal burn could be prevented by coating the phaco tip with Teflon, which has low thermal conductivity.

In 1999, Hiroshi Tseunoka from Japan[16,17] studied the use of ultrasonic phacoemulsification and aspiration for lens extraction through a microincision. Tseunoka used a larger incision as he felt that when the incision size is larger than the phaco tip, the tip gets cooled by the leakage of infusion solution through the incision. The extra space according to him also prevents deformation at the incision site due to tip movement.

Microincision Cataract Surgery

Dr. Jorge Alió from Spain[18] coined the term *MICS* or microincision cataract surgery. This meant cataract surgery being done through a 1.5 mm incision or less. This included laser cataract surgery (pioneering work done by Jack Dodick from the United States) and ultrasound.

Microphaco

In the fall of 1999, Dr. Randall Olson was the first to create interest in the United States starting by doings studies published in peer review journals to answer the concerns of early critics.[19-22] He helped in developing new equipment that did not restrict inflow. In 2001, Olson reported the feasibility of sleeveless phaco through a 1.0-mm incision using the Sovereign (Advanced Medical Optics [AMO], Santa Ana, Calif) with WhiteStar technology. Olson found that tip heating could be minimized by setting the machine for pulse mode so that ultrasound was generated for extremely short intervals. He coined the term *microphaco*.

Hub of Infusion Sleeve

One problem in bimanual phaco was that there would be a spray of fluid over the cornea whenever it was performed. To solve this problem, one can use the hub of the infusion sleeve. There is no infusion sleeve over the rest of the phaco needle but only over the base of the needle.[3]

Sub-1.0 mm Bimanual Phaco Surgery

Using videos and a special vernier caliper, sub-1.0 mm bimanual phaco surgery was documented and demonstrated. In this case, a 21-gauge irrigating chopper and an 0.8-mm phaco needle were used.[3]

Ultrasmall Incision IOLs

Acri.Tec GmbH IOL

Christine Kreiner from Germany made an ultrasmall incision IOL[12] using a special copolymer as the lens material. She founded Acri.Tec GmbH (Berlin, Germany) to manufacture these lenses. Their first lens, the Acri.Smart IOL, was implanted by Kanellopoulos from Greece in 2000.[2] The Acri.Smart was a single piece acrylic IOL which was dehydrated and prerolled.

ThinOptX Rollable IOL

The ThinOptX company (Abingdon, Va), headed by Wayne Callahan, made an ultrathin lens using the Fresnel principles.[8,10] Wayne and Scott Callahan begin developing such a product using an inexpensive lathe, milling machine, and blocking fixture. They then developed a manufacturing process for an extremely thin lens. Most of the work took place in a garage. The first such lens was implanted by Jairo Hoyos from Spain. The second was implanted by Jorge Alió from Spain. They had heard of my work through Kenneth Hoffer (the first President of the ASCRS) and sent me some lenses. I then implanted the lens after bimanual phaco. I realized also that it would be better to have a smaller optic lens, and as a result, designed a special 5.0-mm optic rollable IOL for ThinOptX. They then made this special lens for me and we implanted five such lenses. This was the first 5.0-mm optic ThinOptX rollable IOL implanted. The first smaller sized rollable IOL was implanted on October 2, 2001. These lenses could be rolled, and, hence, the name Rollable IOL—rather than Foldable IOL. The company received a CE Mark in September of 2002, and received approval in the spring of 2004 to start a clinical study in the United States.

Summary

Today, bimanual phaco or Phakonit has taken the ophthalmologic world by storm. This procedure is also known by other names such as MICS or microphaco. The only problem right now is to get more lenses into the market that will pass through sub-1.0 mm incisions, and at the same time not reduce the quality of vision for the patients. These should also have an excellent injector system and should be user friendly. As one will notice many surgeons and pioneers from different parts of the world have made bimanual phaco reach its present status. We have come a long way in cataract surgery but still have a long way to go.

Key Points

- ✔ Phakonit was started in 1998 using a needle bent like an irrigating chopper and a sleeveless phaco handpiece. Fluid was injected over the clear corneal wound to prevent any corneal burn.
- ✔ Phakonit is Phaco with Needle Incision Technology.
- ✔ Other names for Phakonit are bimanual phaco, MICS (Microincision cataract surgery), or microphaco.
- ✔ No anesthesia cataract surgery was discovered in 1998. This procedure is done without any topical or intracameral anesthetics.
- ✔ The air pump (first used in 1999) revolutionized bimanual phaco as it pumped air into the infusion bottle, thus allowing more fluid to come out of the irrigating choppers. This was the first time pressurized fluid was used in anterior segment surgeries.
- ✔ Ultrasmall incision IOLs changed the way the world looked at bimanual phaco. With Acri.Tec GmbH and ThinOptX IOLs in the market, the advantage of the bimanual phaco incision could be utilized.

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