SURGICAL OUTCOMES FOLLOWING THE USE OF CAVITRON ULTRASONIC SURGICAL ASPIRATOR (CUSA) VERSUS THE USE OF KERRISON'S BONE PUNCH IN PATIENTS WITH CHRONIC DACRYOCYSTITIS UNDERGOING ENDOSCOPIC ENDONASAL DACRYOCYSTORHINOSTOMY – A RANDOMISED CONTROLLED TRIAL

THESIS

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OTORHINOLARYNGOLOGY

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DECLARATION

I, hereby declare that the work reported in the thesis titled - "**Surgical outcomes following the use of cavitron ultrasonic surgical aspirator (CUSA) versus the use of kerrison's bone punch in patients with chronic dacryocystitis undergoing endoscopic endonasal dacryocystorhinostomy – A randomised controlled trial**" embodies the result of an original research work done by me in the Department of Otorhinolaryngology, All India Institute of Medical Sciences, Jodhpur. I further state that no part of the thesis has been submitted, in part or in full, to any other University or Institute for the award of any other degree.

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CERTIFICATE

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"A river cuts through a rock not because of its power but because of its persistence."

CONTENTS

LIST OF ABBREVIATIONS

NLDO	Nasolacrimal duct obstruction
NLD	Nasolacrimal duct
DCR	Dacryocystorhinostomy
CTRI	Clinical Trial Registry - India
CUSA	Cavitron Ultrasonic Surgical Aspirator
UA	Ultrasonic Aspirator
ROPLAS	Regurgitation on Pressure over the Lacrimal Sac
FDDT	Fluorescein dye disappearance test
LAC-Q	Lacrimal questionnaire
DNE	Diagnostic Nasal Endoscopy
CONSORT	Consolidated Standards of Reporting Trials

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INTRODUCTION

Nasolacrimal duct obstruction (NLDO), is a common disorder which presents clinically with epiphora and/or infection. Medical management with systemic antibiotics leads to resolution of the infection and addresses the symptoms. However, definitive management constitutes a surgical approach in which the patency of the nasolacrimal duct system is restored leading to improved lacrimal outflow. (1)

Dacryocystorhinostomy (DCR) is a surgical procedure to restore the drainage of tears into the nasal cavity from the lacrimal sac when the nasolacrimal duct does not function due to fibrosis following chronic infection. (2) The aim is to bypass any blockage in the nasolacrimal duct through creation of a bony ostium, allowing communication between the inferior meatus of the nose and the lacrimal sac. There are two ways of performing this - either by making a cut on the outside of the nose (external approach) or by operating from inside the nose under endoscopic guidance (endonasal endoscopic approach). (3)

Dacryocystorhinostomy has been done by an external approach since its first description in 1904 by Italian surgeon Addeo Toti. (4) In this an external vertical incision is made around 1 cm away from the medial canthus region protecting the angular vessels and reducing the risk of scars. The lacrimal sac is exposed by removal of the overlying bones of the lacrimal fossa, generally by a Kerrison bone punch. The lacrimal sac and nasal mucosa are then incised and opened longitudinally to establish patency of the lacrimal outflow passage. This approach has a high predictability and helps in direct visualization of the relevant anatomy. It also facilitates accurate anastomosis between the lacrimal sac mucosa and nasal mucosa. However, it carries some disadvantages also like facial scarring, lacrimal pump dysfunction due to disruption of the orbicularis oculi muscle fibres and medial canthal structures. (5)

The endonasal approach has gained popularity over the past two decades. Advantages include avoidance of an external incision, shorter operative duration, faster recovery periods, and avoiding disruption of the medial canthus or orbicularis oculi muscle thereby preserving the function of the lacrimal pump. (6) The endoscopic approach also helps in evaluating the intranasal anatomy, and thereby in diagnosing and managing the associated conditions, like a deviated septum causing blockage of the lacrimal outflow passage, disease in the paranasal sinuses and turbinate hypertrophy. (5)

The orbital walls are embryologically derived from the neural crest cells. Ossification of the orbital walls is complete by birth except at the orbital apex. The lesser wing of the sphenoid initially cartilaginous, develops via intramembranous ossification, unlike the greater wing of sphenoid and other orbital bones. The lacrimal excretory system is surrounded by membranous bones, which are well developed at 4 months of embryological age. They are seen to ossify by birth. The lacrimal gland begins development as a solid epithelial bud arising from the ectoderm of the superolateral conjunctival fornix (7). Mesenchymal condensation occurs around these buds, which forms the secretory lacrimal gland. Canalization of the epithelial buds forms the ducts.

The lacrimal gland, a bilobed gland, is located in the lacrimal fossa of the frontal bone in the supero-lateral quadrants of the orbits. The developing levator palpebrae superioris tendon, around the 10th week of development, bisects the lacrimal gland, into two lobes: a small palpebral part, continuous with the inner eyelid, and a larger orbital part. (8) The lacrimal gland continues to grow around 3 to 4 years after birth. (9), (10)

The excretory system starts development earlier, at the 7mm embryo stage. A depression called the naso-optic fissure develops, which is bordered by the lateral nasal process superiorly and by the maxillary process inferiorly. This fissure or groove gradually shallows, as the structure surrounding it gradually begins to grow and coalesce. Along the floor of this rudimentary fissure, there persists a thickened strand of surface epithelium, extending from the orbit to the nose. The thickened cord of epithelium becomes buried and forms a rod-like structure, connected to the surface epithelium at only two surfaces, the orbital and nasal ends. The superior part of this rod enlarges to form the lacrimal sac, which gives off two columns of cells, growing into the eyelid margins. This thereby forms the canaliculi. (11), (12), (13)

The lacrimal glands are responsible for emotional as well as reflexive tear secretion. The accessory lacrimal glands are located under the eyelids, which are responsible for secretion of the basal tears. These basal tears provide continuous nourishment and protection to the conjunctiva and cornea. (14)

The tear film is made of three layers: the inner mucin layer, the middle aqueous layer, and the outer lipid layer. The lacrimal glands secrete a large fraction of the aqueous

component of the tears. (15) The major component of the human tears consist of water, electrolytes (sodium, potassium, chloride, bicarbonates, and lower levels of magnesium and calcium), proteins (lysozyme, lactoferrin, lipocalin, secretory IgA) – albumin, IgG (leakage from conjunctiva), lipids (meibomian glands, lipocalin-associated), mucins (epithelial membrane-anchored type, soluble goblet-cell type) defensins, collectins, other small molecules. There may be certain additional components in various disease states like inflammatory mediators, cytokines, growth factors, white blood cells, antigens, signalling molecules, complement components and remodelling enzymes. (16)

The tear film is reflexively secreted by the "lacrimal functional unit" comprising of the ocular surface tissues (cornea and conjunctiva, goblet cells and meibomian glands), the lacrimal glands (main and accessory), and their interconnecting sensory (cranial nerve V) and autonomic (cranial nerve VII) innervation. This is initiated by subconscious stimulation of the highly innervated ocular surface epithelia. (17)

The part of the ocular globe exposed to the external environment is covered by the pre-ocular tear film. The maximum change in the refractive index of light occurs at this interface. Hence the cornea, which is the most powerful refractive medium in the eye (45 to 47 dioptres), derives the majority of its refractive power from the precorneal tear film. The tear film therefore provides an optically high-quality surface to the cornea and adequate lubrication to the eyelids during its blinking motion. (18)

Tears from the conjunctival sac pass through the upper and lower lacrimal puncta located in the upper and lower eyelids respectively to drain into the upper and lower lacrimal canaliculi, common canaliculi and then into the lacrimal sac, located in the lacrimal fossa. From the lacrimal sac, the tears empty into the nasolacrimal duct (NLD) along the lateral wall of the nose to open at the inferior meatus. Any obstruction occurring anywhere along this drainage pathway can result in excessive watering from the eyes (epiphora) as well as recurrent infections. (3)

The lacrimal passage consists of a bony passage and a membranous lacrimal passage. The bony lacrimal passage or the lacrimal fossa is formed by the thick frontal process of the maxillary bone anteriorly (anterior lacrimal crest) and the thin lacrimal bone posteriorly (posterior lacrimal crest). (19), (20)

The removal of the thick bone overlying the lacrimal sac, a critical step in the operation, may be accomplished by using a variety of instruments including powered (drills, microdebriders and lasers) or unpowered (curettes, rongeurs, hammer and chisel). (21) (22), (23) All of these conventional tools risk injury to adjacent mucosal surfaces and deeper elements of the lacrimal apparatus. Because bone removal occurs in the narrow confines of the axilla of the middle turbinate, even minor mucosal trauma can often lead to unwanted scarification and contribute to surgical failures. (24)

The Kerrison Bone Punch (**Figure 1, 2)** has been conventionally used in various surgeries to safely and effectively remove bone. It has a shaft, a blade for holding and cutting the bony tissue and a guard, which protects the underlying vital structures. They are available in various sizes with varied additional features. The Kerrison bone punch has been used in removal of the thick bony lacrimal passage covering the lacrimal sac in dacryocystorhinostomy operations for years. The make of the instrument facilitates its use in the narrow confines of the intra-nasal anatomy. The handle can be held comfortably for delivery of a controlled force for osteotomy of the specified area. (25) The mechanism of removal of the bone from inside-out helps in preventing damage to the important structures beneath. (26)

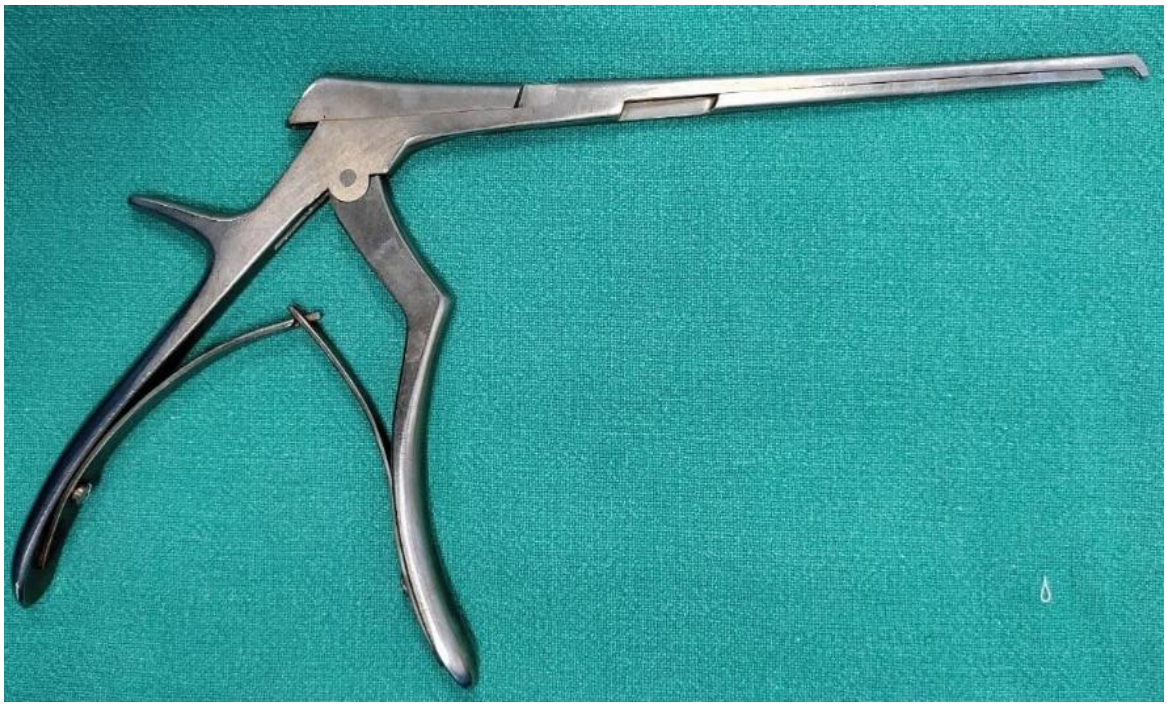


Figure 1: Kerrison's bone punch – Downturned

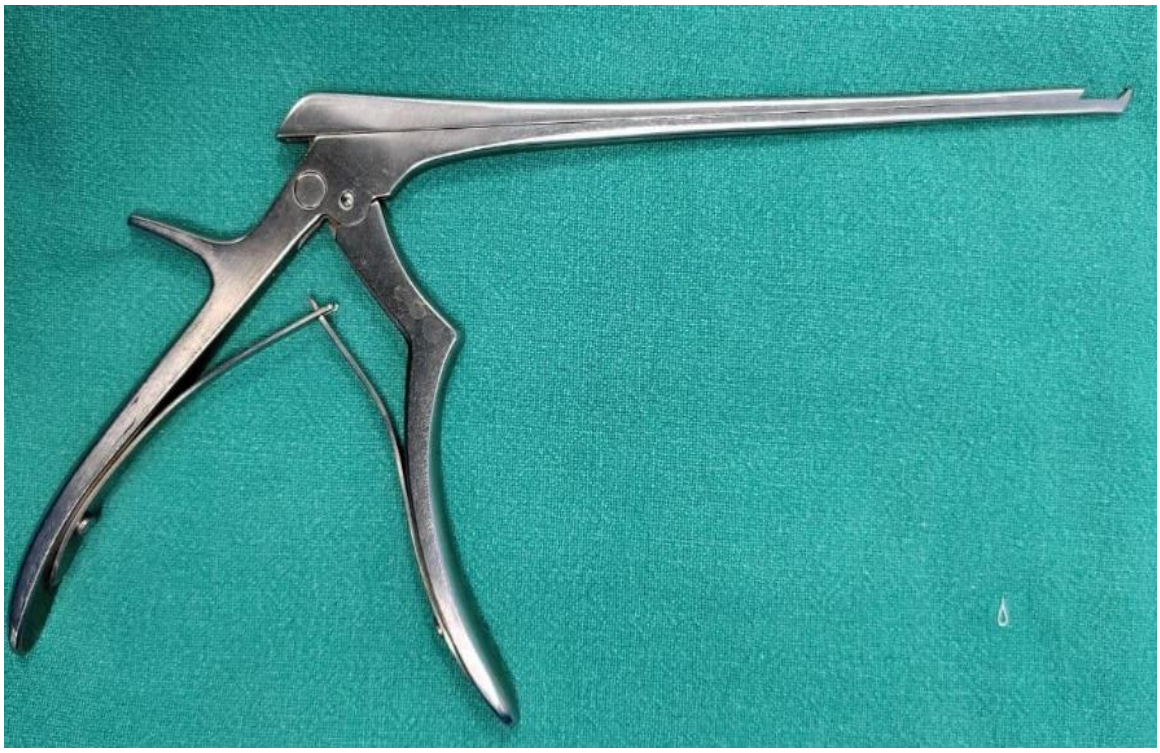


Figure 2: Kerrison's bone punch - Upturned

Ultrasonic Aspirators (UA) utilize ultrasonic frequency vibrations generated by a piezoelectric element in the handpiece to remove tissue. Continuous irrigation emulsifies dissected particles, and simultaneous aspiration removes fragments and liquid resulting in a comparatively clean surgical field. Minimal pressure is necessary, which makes tissue dissection better controllable and less traumatic compared to the use of standard drills. Advances in ultrasonic aspirator technology now permit in situ bone emulsification, which is respectful of nearby soft tissues. (24) There are several different tips available that allow selective dissection of soft or bone tissue and facilitate bone removal, smoothing and re-shaping.

The handpieces come in various configurations, allowing the surgeon to operate with confidence during procedures requiring the removal of a variety of tissue types. For soft tissue applications, the 35 kHz handpieces are used as the higher frequency produces lower power and allows for more controlled and precise dissection. This control is critical when removing tissue around or near critical structures. The 23 kHz handpieces are efficient in the removal of hard tissue (calcified or dense, for example – bone). The bone tips can be used to address targeted bone removal, requiring precise and selective control near important structures. They implement a longitudinal-torsional movement as opposed to the rotating motion of a drill preventing excess frictional heat. They fragment bone using localized ultrasound stress and cavitation instead of mechanical abrasion alone. This mechanism of action minimizes the heat generated at the surgical site and may help the surgeon avoid bone char and unintended damage to surrounding tissue. The tips feature a 90-degree cutting surface comprised of helically arranged pyramids. The relief angles of adjacent surfaces maximize the area exposed to ultrasonic energy and thus minimize resistance along the cutting path. This enhances bone fragmentation efficacy.

The straight or angled make of the tips, optimize tip visualization for the operating surgeon. Simultaneous cooling by the irrigation fluid emerging from the tip prevents heat injury of adjacent delicate structures. Use of the ultrasonic aspirator has been reported for various surgical procedures, including ear, nose, and throat, maxillofacial, orbital, oculoplastic, and open neurosurgical procedures. In rhinology, extra-long thin tips allow for trans nasal access through narrow surgical corridors. (27), (28) The temperature in the surrounding bone does not become high due to the

cool-controlled irrigation fluid used in the ultrasonic aspirators. Overall, the use of the ultrasonic aspirators is found to be safe, effective and simple. (29)

There are various models of ultrasonic aspirators which are currently being used in clinical practice widely, like the CUSA Excel/Clarity (Integra®, Plainsboro, New Jersey, USA), Sonopet (Stryker®, Kalamazoo, Michigan, USA), or Söring (Söring GmbH, Quickborn, Germany). (30)

In our institute, we have been using the SonaStar Ultrasonic Aspirator by Misonix (acquired by Bioventus® - October 29, 2021), which is comprised of a fully self-contained console with built-in irrigation, aspiration and vibration functions. (**Figure 3**) Two types of handpieces are available – a curved extended handpiece and a short straight handpiece. The handpiece can be connected to a microprocessor-based console, which works as a unit to provide precise surgical tissue ablation and removal. An infrared (IR), multi-pedal, wireless footswitch communicates, via infrared signals, with two integrated IR receivers mounted on the SonaStar console and an optional remote IR receiver. Together they facilitate wireless communications in the standard operating room environment. (**Figure 4**) There are two footswitch pedals for vibration and for flushing of irrigation fluid (saline). (31)

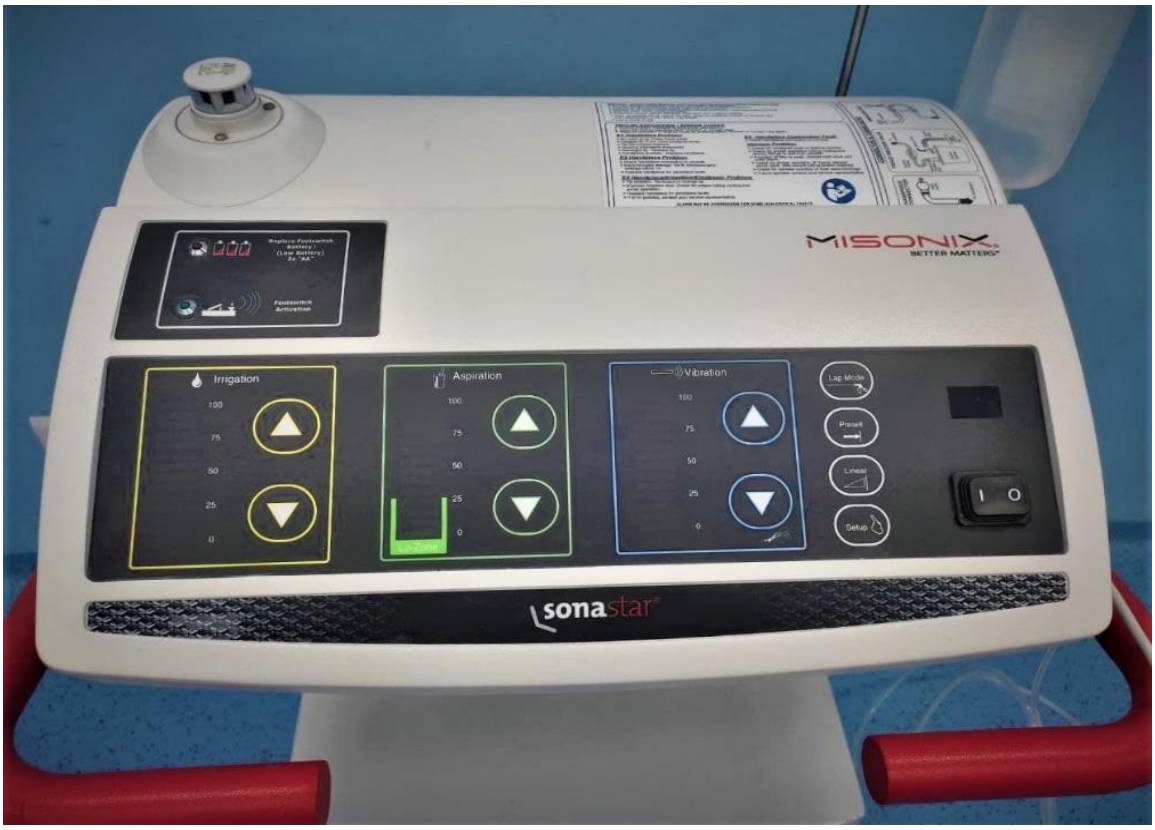


Figure 3: Cavitron Ultrasonic Surgical Aspirator (CUSA) machine used in our institute showing the three different modes – Irrigation/ Aspiration/ Vibration

Figure 4: Cavitron Ultrasonic Surgical Aspirator (CUSA) machine with wireless footswitch used in our institute

Surgical dissection can also be performed with lasers where it is used to ablate the nasal mucosa, bone of the lacrimal fossa and the lacrimal sac underneath. Argon, carbon-dioxide, potassium titanyl phosphate (KTP) as well as holmium-YAG lasers can all be used for DCR operation. They have the added advantages of better intraoperative haemostasis, reduced patient morbidity and early recovery.

The procedure is performed under endoscopic guidance and with a video camera. A 20-gauge fibreoptic light probe is passed through a canaliculus into the lacrimal sac. The light probe, then trans illuminates the lateral nasal wall, marking the area of the lacrimal sac. The area of maximal brightness corresponds with the posterior end of the lacrimal sac where the overlying bone is the thinnest. The area of the nasal mucosa is then ablated followed by vaporising the underlying bone (5-7mm in diameter) with laser, creating a rhinostomy of nearly 5mm diameter. The medial wall of sac which is then exposed, can be removed with laser. This procedure is known as endoscopic laser dacryocystorhinostomy (32), (33). The rhinostomy site is more inferior and posterior than those performed in conventional external approaches. (34) However, the cost effectiveness with lasers can be a drawback in some cases.

Multidiode lasers have also been used in trans canalicular, laser assisted dacryocystorhinostomy. In this a diode laser fibre optic probe is used. The probe is introduced into the lacrimal sac through both the upper and lower canaliculi. The transillumination from the beam, occurring lateral and superior to the middle turbinate was observed via the nasal endoscope. The diode laser is applied to make an osteotomy, approximately 8-10 mm in diameter under endoscopic guidance.(35)

Endocanalicular, high pressure, 5mm balloon catheter endoscopic dacryocystorhinostomy has also been used in some cases to treat acquired nasolacrimal duct obstruction. In this a 3-4 Bowman probe is passed through the superior canaliculus to enter the lacrimal sac. Under nasal endoscopic guidance, the probe is pushed posteroinferiorly to puncture the medial sac wall, adjacent fossa and reach into the nose. A few additional entrances (three or four) are fashioned in a similar manner. A 5-mm balloon catheter is then introduced through the superior canaliculus upto the opening in the nose. The balloon is then inflated via a saline-filled inflation device to 8 atm for 90 seconds and repeated until the size of the ostium becomes satisfactory. It has shown to be effective and simple with shorter operative

durations and lesser adverse events like bleeding and synechiae formation. (36) Studies have also been performed with 8mm or 9mm balloon catheters. (37)**,** (38)

Hence, the DCR surgery has undergone a massive evolution over the years, in terms of the wide variety of equipments used to re-create the nasolacrimal drainage pathway. Many studies have been done over the world, comparing these instruments to one another, in terms of their surgical outcomes and efficacy in DCR. However, there has been no study done so far, specifically comparing the kerrison bone punch with the cavitron ultrasonic surgical aspirator (CUSA) in endonasal dacryocystorhinostomy. With this idea in mind this study was selected in order to compare the two modalities and understand the superiority of one over the other, if present.

The wide variety of tools used in endoscopic dacryocystorhinostomy surgery, make it difficult to determine the best approach. Hence comparison of the available techniques seemed to be an important area of research to gain insight into the advantages and disadvantages of using each equipment. (22)

With the advent of each new modality of performing the surgery, it is important to take into consideration the learning curve involved and the challenges faced by the operating surgeon. It is possible to assess and quantify the surgical learning curve for a single surgeon, operating in a consistent environment over a period of time. However, the difficulty arises when comparison is to be done between different surgeons working in different institutions. This is due to variability of the surgical techniques among each surgeon with varied setups of instruments, nursing staff and operating room conditions. In the event of multiple cases being performed sequentially in a hospital per day, there may be bias in the results due to familiarity of the surgeons or the staff with the instruments and technical details. (39), (40).

However, no research has yet been conducted about the surgeon’s experience in using the Kerrison’s bone punch versus CUSA. The current study was devised with this goal in mind as well.

REVIEW OF LITERATURE

The ancient Egyptians documented the lacrimal sac infections in the Ebers Papyrus (1500 BC). They recommended a mixture of antimony, wood powder, myrrh, and dried honey which they rubbed into the eyes for four days for treatment of the condition. Hippocrates (460 BC–377 BC) thought that old age was the cause for watery eyes. In case the discharge turned thicker, he recommended a mixture of dried juice of the white grapes with copper sulfate. (41) Another old evidence of lacrimal surgery dates back to 1706 BC in the Codex of Hammurabi, which contained a reference to surgical treatment of a lacrimal sac abscess and lacrimal fistula. (42)

The Greeks also documented significant contributions to lacrimal surgery. Celcus (25 BC–50 AD) advocated red-hot cautery to cure 'fistules', i.e. the diseases of the lacrimal system. (43) Claude Galen (129–200 AD), after one century, also advocated using hot iron to achieve charring of the 'fistules', thereby finding a cure. (44)

Galen's description of the causes of epiphora was remarkable*:*

''A canal goes from the eyes to the palate and empties there the secretion formed in the eye. Watering may have three causes; either this canal is blocked, or the secretion is excessive, or a scar at the nasal canthus. The latter most is incurable''. (43), (45)

Later descriptions started coming from other Greek and Roman texts. (46) Pauli Eginetoein (47) in his Chirurgie in the seventh century also wrote about performing plunging of cautery into the nose through the lacrimal bone.

The lacrimal bone was previously thought to be the seat of the disease process. Probably the first observations on the physiology of the lacrimal drainage apparatus were made by Fallopius (48) in 1584. He noted that tears and pus could be made to flow from the puncta by making pressure over the dilated sac, and concluded that at least a part of the lacrimal fluid came from the sac.

A true understanding of the lacrimal passages awaited the work of Antoine Maitre Jan. In 1701 this observer wrote that lacrimal tumors were caused by a coagulation of tears resulting from obstruction of the nasal duct. (49)

In 1713 Dominique Anel recommended probing and irrigation of the duct. (50)

In the 18th century, the technique of Woolhouse began to be followed. In this the lacrimal sac was lifted from its bed, extirpated and the lacrimal bone was perforated.

A drain was then inserted and was later replaced by a gold, silver, or lead cannula. Frequent irrigation was performed through the cannula. (50)

In 1836, Montaigne described a new technique. In this the lacrimal sac was opened through a skin incision and a hole punched into the nose through the sac. Through this a gut drain was put in which was changed daily and the sac irrigated. After around ten to twenty days, the external wound was left to heal. (51)

Bowman introduced his probes in 1851, paving the way for dilatation of the duct. Thus, operations for forming an artificial passageway into the nose were temporarily abandoned. (52)

Andrew in 1883, suggested slitting the canaliculus after punching through the lacrimal bone with insertion of a lead stylet through the pathway. (53)

Killian in 1899, performed an intranasal procedure by resecting the anterior portion of the inferior turbinate, opening the nasal duct from the nose. (54)

In 1904, Addeo Toti, the famous Italian rhinologist of Florence, laid the foundation of dacryocystorhinostomy. He exposed the area overlying the lacrimal sac with an external incision of 35mm and opened the lacrimal sac on the medial side. After punching out a piece of bone in the lacrimal fossa, he resected the corresponding area of nasal mucosa. The success rate was only 10-15 per cent. (55) West in 1910 and Polyak in 1911 also described intranasal methods but with unsatisfactory results. (56), (57)

A French surgeon, Dupuy-Dutemps, in 1920, was working as the Chief Ophthalmic surgeon at the Saint Louis Hospital and at the Rothschild Foundation in Paris where he worked in a modern environment with up-to-date equipment. He along with colleague Bourguet adopted an approach which was entirely from the outside, which they termed as "*Plastic dacryocystorhinostomy*". They advocated preservation of the intact lacrimal sac; maintenance of the patency of the newly-made drainage pathway and preventing the formation of granulations, which would defeat an otherwise successful surgery. The suturing of the nasal mucosa to the lacrimal sac with 000 catgut sutures, helped in formation of a new lacrimal drainage canal. (58) This brought about great improvement in the results. In 1925, with over 500 operations,

they reported relief in over 97% cases, which was an unusually high percentage of cure rate. (59), (60)

Mosher in 1923, advocated an external operation following unfavourable experiences with intra-nasal operation. It was done with a straight skin incision (nearly 10 mm from the inner canthus) followed by removal of the anterior tip of middle turbinate and anterior ethmoid cells. High deviated nasal septum, if present, was corrected. The bony and membranous inner wall of the nasolacrimal duct were removed, up to the upper border of the inferior turbinate. Nasal mucous membrane was flushed with the edges of the opening in the bone. (61)

In 1936, Chandler performed hundred dacryocystorhinostomy operations in three series: 53 operations by Mosher's technique, with 70 percent success; 25 operations as per Ohm-Depuy-Dutemps-Bourguet technique, with 80 percent success; and lastly 22 operations by the new technique of anastomosing lacrimal sac with nasal mucous membrane, all of which were successful. (50)

In 1938, H. Arruga, an ophthalmologist in Barcelona, Spain, improved the technique further to ensure proper anastomosis. He exposed the lacrimal sac by cutting the medial palpebral ligament and removing the lacrimal fossa bone by cylindrical trephines operated by a dental motor. The medial wall of the sac was incised vertically and its edges sutured with the nasal mucosa. He used Silk (no. 0 or no. 00 silk) preferably to catgut for the suturing. With this technique there was 80-96 percent success. However, in 1961, another ophthalmologist, Foster reported only 55 percent success. The cause of failure was attributed to the high tendency of the sac to undergo cicatrisation and the canaliculi being clogged by the cicatrix due to cutting of the medial palpebral ligament. There were also reports of stenosis and closure of the bony opening due to granulations and osteoblastic reaction. (62)

Iskander H. Girgis, Lecturer of Otolaryngology, at Kasr El-Eini Hospital, Cairo University, modified this technique by avoiding the two points causing failure. The medial palpebral ligament was not cut and the periosteum was incised just medial to the attachment of the ligament. The lacrimal sac with the periosteal covering was retracted to give wide exposure of the lacrimal fossa. Using dental drill, a 1.6 x 2cm wide bony opening was made. The sac was transected at its lower end and the nasal mucoperiosteum was incised with an ‘H’ incision to make tough flaps. The flaps were

sutured together using silk 4-0 sutures and fine needles, making all the knots remain inside the lumen. (63)

External DCR was largely considered as the gold standard in the treatment of acquired nasolacrimal duct obstruction with success rates of more than 90% till the early 20^{th} century. (19), (64), (65) It was generally performed by the ophthalmologists.

The DCR surgery was grossly divided into two types, endoscopic endonasal and external. In 1893 Caldwell first introduced endonasal DCR but it had a poor success rate due to low visibility. (66) However, with the advent of nasal endoscopes (67), and evolution of functional endoscopic sinus surgery in the early 1990s (68), a renewed interest was observed in endoscopic endonasal DCR. (69) A thorough understanding of the endoscopic and surgical anatomy of the nose became crucial in order to gain skilled usage of these surgical devices. However, Ophthalmologists lacked familiarity with the use of such devices. Nasal endoscopy was popularised in India around that time itself in various conferences being held on rhinology. In 1989 endonasal DCR in its present form was introduced by McDonogh (70) . The reported success rate for endonasal DCR ranges from 63% to 96%. (1), (71), (72)

In 1990, Massaro et al, introduced endonasal laser-assisted DCR in a cadaveric study. In this, the intranasal dacryocystorhinostomy fistulas were created using a high-powered blue-green argon laser, coupled to a 300-microns quartz fiberoptic catheter, in fresh-frozen cadaver heads. (33)

Levin and Stormogipson (73), brought about endocanalicular laser-assisted DCR in cadavers followed by Silkiss et al (74) and Michalos and Pearlman (75). They used the Nd:YAG laser or a "thulium-doped or holmium-doped" laser. Endocanalicular laser DCR had many advantages like laser energy being directed away from the globe, familiarity of instruments with the ophthalmologist, short duration of procedure, use of local anesthetic, and rapid healing. (76)

The first clinical trial of endonasal laser-assisted DCR was introduced by Gonnering et al. (34) They used carbon dioxide (CO2) and potassium titanyl phosphate (KTP)/ neodynium-yttrium-garnet (YAG) laser for the bone removal. These reported a success rate of 100 percent initially. However, CO2 laser had poor coagulation properties and its delivery process was seen to be cumbersome. (77)

Woog et al discussed the use of holmium:YAG laser in the bone ablation part of DCR. (1), (32) This laser caused efficient bone ablation, good hemostasis, and minimal collateral damage. Flexible fiberoptic delivery system was also applicable here. (76) Success rate was about 82%. (19)

Javate et al (78) introduced a radiofrequency unit for incision of the nasal mucosa and bone in endonasal DCR. This utilised cutting and coagulation simultaneously with minimal surrounding thermal damage. They also used the Kerrison rongeur to enlarge the bony osteotomy. Mitomycin-C and silicone stents were also used to prevent closure of the ostium.

Conventionally endonasal DCR was based on the principle of creating a fistula between the lacrimal sac and the nasal cavity without the preservation of the nasal mucosa. (79) However, failure was commonly seen due to varied reasons like re-closure of the stoma created by granulation tissue, fibrosis or synechiae. (80)

Another school of thought is that the preservation of nasal mucosal flaps can help reduce failure rates by reducing incidence of post-operative re-stenosis. (81) Several authors have described different techniques of nasal mucosal flap creation and preservation like U-shaped (82), L-shaped mucosal flap (83) , free nasal mucosal flap (84) or preservation of the whole nasal mucosal flap (85).

The reported incidence of congenital NLDO is 5-20%. (86) It is higher in children with craniofacial anomalies and Down syndrome. (51) Persistent epiphora, matting and crusting of eyelashes, persistent infection with presence of excoriated skin along eyelid margins most commonly lead to a diagnosis of NLDO in the pediatric age group. (87) In almost 20% of infants, failure of canalization of the nasolacrimal duct, predominantly at the valve of Hasner, leads to a persistent membrane at the distal end of the nasolacrimal duct. Any bony obstruction, or mucosal hypertrophy of the neighbouring nasal mucosa can also cause narrowing of the duct's opening in the inferior meatus.Approximately 90% of the cases resolve spontaneously or with minimal treatment. (88)

It is generally managed conservatively at first, followed by syringing, probing, using balloon dacryoplasty, and applying topical antibiotics. Only on failure of these conservative modalities, DCR is considered.

Congenital dacryocystocele, a variant of congenital NLDO, involves sterile cystic dilatation of the lacrimal sac with expansion of this cyst intranasally. So, in cases of bilateral NLDO, it may lead to an emergency condition where the neonate has respiratory distress due to nasal obstruction because neonates are obligate nasal breathers. Such a situation, thus warrants early surgical intervention in these neonates. (87)

The Kerrison's bone punch is an instrument which holds and cuts bone. It has a blade, a guard for saving the underlying structures, a shaft and a handle facilitating its use in smaller areas by application of a controlled force. This is used commonly in pediatric surgeries, neurosurgeries and cardiac surgeries. It was Dr. Robert Masters Kerrison, an English physiologist and physician who first designed this instrument, and it took more than 100 years to modify the original design of the instrument to bring it to its current form with a purpose to make it more effective and operator friendly. (25)

Philip D. Kerrison, born in Charleston, South Carolina, in 1872, was practising as an assistant surgeon and professor of aural diseases at NYU around 1908. During this period, Kerrison presented the rongeur in The Laryngoscope and described its usefulness in chronic suppurative otitis media treatment, which required bone removal from the area overlying the descending portion of the facial nerve. The Kerrison bone punch has the advantage of allowing bone removal from inside-out, rather than outside-in, so that deeper structures like the facial nerve could be protected with its blunt distal end plate. Previously, these procedures were being performed with a hammer and chisel. (26)

In 1880, the piezoelectric effect was first discovered by French physicists Jacques and Pierre Curie. They observed that applying mechanical stress or pressure to certain materials resulted in a shift of positive and negative charges, and generation of an external electric field.

Thus, mechanical energy gets converted to electrical energy. The reverse also holds true where applying an external electric field to a piezoelectric material causes its rapid compression and expansion and thereby creates ultrasonic vibrations. Ultrasonic aspirators are based on the principle of harnessing this inverse piezoelectric effect. (89), (90)

The Cavitron Ultrasonic Surgical Aspirator (CUSA) is a device that generates ultrasonic waves in the frequency of 23 kHz and with an adjustable stroke of 0-300 microns for the removal of dense calcified tissues like bone. It has a handpiece, with a hollow titanium tip driven by a magnetostrictive transducer. The tip vibrates along its axis longitudinally with the frequency of 23 kHz. Another handpiece is available in some models which vibrates at a frequency of 35 kHz for soft tissue emulsification.

The hand-piece contains a stack of tubular piezoelectric crystals or discs which when exposed to an external electric field causes the attached bit to vibrate against the target tissue. These high frequency ultrasonic waves induce formation of cavitations, that is formation, expansion and subsequent implosion of small vapor bubbles within the tissue. It is a process of boiling in a liquid as a result of pressure reduction rather than heat addition. This leads to tissue denaturation by breakdown of the hydrogen bonds and the emulsified tissue is subsequently removed by continuous suction and irrigation.

Soft tissue ultrasonic aspirators have a longitudinal motion, cutting tissue on the downstroke and emulsifying it through cavitation in the upstroke. Bone-cutting aspirators emulsify with a grinding mechanism by longitudinal or torsional movement, or a combination of both. (91), (92)

When placed in contact with the target tissues, this tip emulsifies the tissue depending on its collagen and water content, which are irrigated and removed through an in-built suction system. Vessels with diameters more than 0.5mm, nerves and fibrous tissue capsules have higher collagen content. Thus they rebound with ultrasonic waves generated by the CUSA, and are thereby left unaffected by CUSA. (93)

The removal of the thick bone overlying the lacrimal sac is a critical step in DCR operation which can be accomplished by powered (drills, microdebriders and lasers) or non-powered (curettes, rongeurs, hammer and chisel) instruments. All these conventional instruments risk injury to the underlying mucosa and lacrimal apparatus which can further lead to surgical failure. The advent of the ultrasonic aspirators help in in-situ bone emulsification thereby respecting the surrounding soft tissue structures. (24)

The bone-cutting capability of the ultrasonic aspirators has been used in various other specialties. (28), (92) Piezosurgery has been reported to be used in various otologic

surgeries like stapedotomy, atticoantrostomy, classical intact canal wall mastoidectomy, posterior tympanotomy, facial nerve decompression and excision of middle ear tumors like glomus tympanicum tumors and primary B-cell lymphomas of the middle ear. (94), (95)

Ultrasonic aspirators were first used in endoscopic DCR by Anitsdel and colleagues. They performed 16 procedures and reported about 12 subjects with respect to the ease of using the device in creating the bony rhinostomy. Even on inadvertent contact with nearby mucosal surfaces, no instances of damage or unexpected penetration into the lacrimal sac were seen. With a mean follow-up of 20 months, postoperative endoscopic assessment showed wide open rhinostomy sites without any synechiae formation. (24)

Salami and colleagues performed a similar study with 20 subjects with a follow-up at 12 months post-operatively. The aspirator was used to completely remove all the overlying maxillary bone and widely expose the lacrimal sac. Postoperatively, all patients had complete recovery from epiphora, with no evidence of dacryocystitis or granulation or synechia formation at the neo-ostium. Histologic studies showed improved bone healing in terms of better and more rapid bone formation as compared to the use of drills for osteotomies. (2)

In a retrospective review, Steele and colleagues compared endoscopic DCR by ultrasonic aspirators and microdrill. Out of the 63 study subjects, 29 underwent DCR by microdrill and 34 by ultrasonic bone aspirator. No statistical significance was noted in the success rates of the two, although ultrasonic procedures reported a slightly higher success rate of 94.1% as compared to 86.2% by micro drills. (6)

Another retrospective study by Murchison et al, involving 123 subjects, showed 79.7% success rate in those undergoing ultrasonic endoscopic DCR against 81.3% in subjects not undergoing ultrasonic endoscopic DCR. However, this was also not statistically significant. (96)

A prospective trial was performed in 2014 comparing the surgical time of endoscopic DCR with a mechanical drill to that by using an ultrasonic aspirator. It included 29 subjects in the drill group and 26 in the piezosurgery group. No significant operative time difference was noted (3.71 min vs 4.12 min, P 5 .17). (97)

The use of anti-proliferation agent, mitomycin C (MMC), topically to the osteotomy site during dacryocystorhinostomy surgery has been shown to increase the surgical success rates in multiple studies. (98), (99), (100), (101), (102), (103), (104) MMC is a cytotoxic agent which acts by inducing DNA strand cross-links. This leads to arrest of DNA replication and triggers apoptosis which further suppresses granulation reactions during wound healing. This reduces closure rates of the osteotomy. It was applied with a mean concentration of 0.02–1.0 mg/ml for a duration of around 2–30 minutes.

Multiple studies have been done on endonasal DCR with or without the use of silicone stenting which have collectively implicated that there is no statistically significant difference in outcomes of endonasal DCR with or without using stents. (105), (106), (107), (108).

A study done by Mohamad *et al.* on 89 patients showed success rate at six months follow-up to be 70% in the stent group and 97% in the non-stent group. (109) Stent placement can be associated with a number of complications like prolapse of the stent, damage to the puncta, granuloma formation, damage to the canalicular system with false passage formation or infection. (110) Another study stated that stenting was beneficial for cases with a tight common canaliculus as observed intra-operatively. (111)

A study conducted by Lee et al, advocates that a novice surgeon when beginning to learn endoscopic endonasal DCR should perform the surgery on at least 30 eyes until he or she becomes adept with the necessary surgical skills, including using the endoscope and allied instruments for obtaining a broader visualization of the operative site. This is the single most important learning step which can ensure a higher surgical success rate. (40) It was a retrospective review of the records of 386 eyes of 337 patients operated for DCR by three surgeons at three tertiary hospitals to ascertain the learning curve for DCR. All three surgeons showed a significant increase in their surgical success rates after operating the first 30 eyes ($p < 0.05$).

In 2014, Chappell reported that the use of the ultrasonic aspirator (Sonopet) for endoscopic DCR surgery involves a significant learning curve and high cost efficacy. Appropriate selection of the handpiece tip and getting acquainted with the machine’s

adjustment settings are extremely crucial for successful adoption of this technology and avoidance of complications. (39)

In 2003, Peter John Wormald and Angelo Tsirbas opined that excellent collaboration between the ear, nose, and throat surgeon and the ophthalmologist, where both were present in all surgeries, allowed the learning curve effect that may have been present, to be significantly ameliorated. (112)

AIM AND OBJECTIVES

AIM:

To compare the outcomes in Endoscopic Endonasal DCR performed by using CUSA and with Kerrison's bone punch in adult patients.

OBJECTIVES:

1. To assess the outcomes of using CUSA with those of using Kerrison's bone punch.
2. To assess surgeon's perspective about using the two instruments.

RESEARCH QUESTION:

Does the use of Cavitron Ultrasonic Surgical Aspirator (CUSA) provide a better outcome in patients with chronic dacryocystitis undergoing Endonasal Endoscopic Dacryocystorhinostomy than with the use of the Bone punch?

Null Hypothesis:

The use of Cavitron Ultrasonic Surgical Aspirator (CUSA) does not provide a better outcome in patients with chronic dacryocystitis undergoing Endonasal Endoscopic Dacryocystorhinostomy than with the use of the Bone punch.

Alternate hypothesis:

The use of Cavitron Ultrasonic Surgical Aspirator (CUSA) provides a better outcome in patients with chronic dacryocystitis undergoing Endonasal Endoscopic Dacryocystorhinostomy than with the use of the Bone punch.

MATERIALS AND METHODS

The study was carried out in the Department Otorhinolaryngology at All India Institute of Medical Sciences, Jodhpur, after approval from the Institutional Ethics Committee (**IEC Reg. No. AIIMS/IEC/2019-20/982**) and registration with Clinical Trail Registry - India (**CTRI Registration No. CTRI/2020/03/024297**).

STUDY DESIGN: Randomized Controlled Trial.

STUDY SETTING:

The study was conducted in the Department of Otorhinolaryngology in conjunction with the Department of Ophthalmology, at a tertiary care institute i.e. All India Institute of Medical Sciences, Jodhpur (Rajasthan).

DURATION OF STUDY:

The study was done over a period of 20 months, following the procurement of the CTRI Registration number in March 2020.

SAMPLE SIZE:

- As there was a lack of studies comparing the outcomes between CUSA and Kerrison's bone punch, this pilot study was devised.
- Sample size was taken as time bound, based on the previous hospital records of approximately 30 cases of endoscopic endonasal dacryocystorhinostomy being done in a duration of 2 years in the Department of Otorhinolaryngology, AIIMS Jodhpur. Hence, sample size was initially kept as a total of 34 cases (including 10% attrition rate). However, with the advent of the crisis situation of COVID-19 pandemic, all elective surgical procedures were kept at a halt for more than a year. Thus, a sample size of only 20 subjects was feasible

INCLUSION CRITERIA:

All patients more than 18 years of age diagnosed with Naso-Lacrimal Duct Obstruction (NLDO), undergoing Endoscopic Endonasal Dacryocystorhinostomy in the Department of Otorhinolaryngology at AIIMS Jodhpur.

EXCLUSION CRITERIA:

1. Patients with age less than 18 years
2. Patients with congenital dacryocystitis
3. Patients with common canalicular block
4. Patients with multiple co-morbidities like tuberculosis or malignancy
5. Revision cases
6. Presence of nasal pathologies like atrophic rhinitis or nasal polyps

BLINDING:

- Double blinded study.
- The observer as well as the patient was blinded to the instrument used (CUSA or Kerrison's bone punch) in the procedure (Endoscopic endonasal dacryocystorhinostomy).
- Observer evaluated the patient pre-operatively as well as post-operatively for all the outcome variables.
- The patients gave subjective responses to the outcome variables and were therefore blinded to the procedure that was undertaken.

RANDOMIZATION:

- Thirty-four (34) randomised numbers were generated by a computerised random number generator system.
- All odd numbered patients underwent the procedure with CUSA and were placed in Group A.
- All even numbered patients underwent the procedure with the Kerrison's bone punch and were placed in Group B.

ALLOCATION CONCEALMENT:

- Allocation concealment was done by opaque sealed envelopes, which contained the information of the random number generated with the name of the instrument (CUSA OR Kerrison's bon punch) to be used in the procedure.
- One envelope was randomly selected and opened by the operating surgeon, just before starting the procedure, after shifting of the patient to the operation theatre.
- Surgeon then used the instrument (CUSA OR Kerrison's bon punch) as per the information in the envelope, for the procedure.
- Surgeon then filled his 'Per-operative surgeon's perspective' questionnaire which was kept separately in a file inaccessible to both the observer and the patient.

FUNDING:

No fund was received from any source for the completion of this study.

PRE-OPERATIVE WORKUP

Patients were subjected to a detailed clinical assessment, general physical examination and routine workup. A detailed history was taken and a complete physical examination was performed for all patients included in the study.

Objective evaluation done by the Blinded observer, who was not a part of the study, based on the following parameters:

1. **Syringing** – To confirm diagnosis and rule out common canalicular block

Method: The patient was placed in a supine position and a topical anaesthetic (4% lignocaine) instilled in the eye. The lower punctum was dilated (if required) with a punctum dilator; a blunt lacrimal cannula (**Figure 5**) connected to a 5cc syringe (containing normal saline) was inserted into the inferior canaliculus and irrigation done to look for any reflux of fluid or discharge from the upper or the lower canaliculus (**Figure 6**). The patient was then asked whether the fluid had reached the pharynx.

If syringing could not be performed through the inferior canaliculus, the superior canaliculus was utilized.

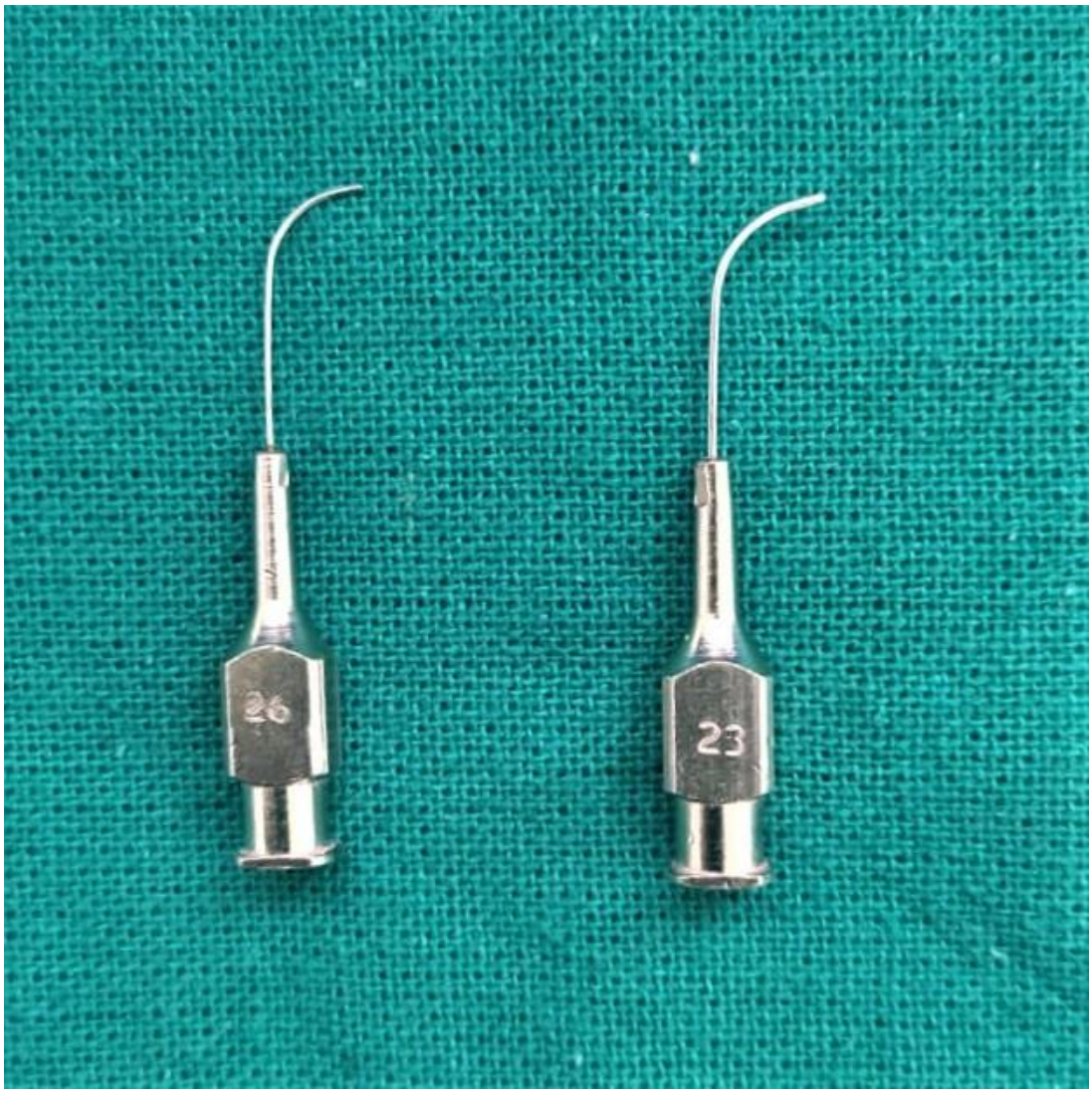


Figure 5: Lacrimal cannula used for syringing

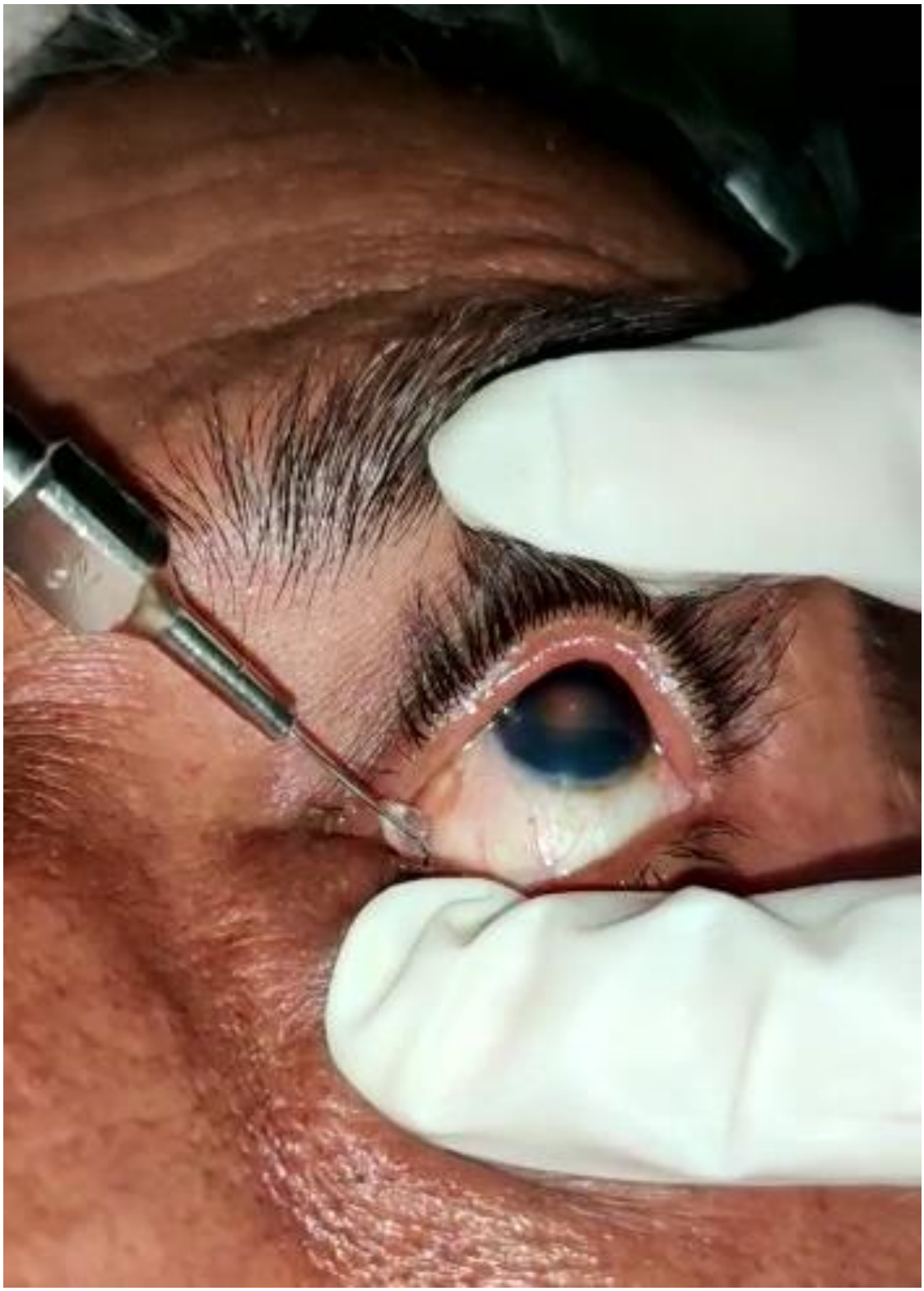


Figure 6: Syringing being performed on a patient through the lower canaliculus. Reflux through the upper punctum suggests obstruction at the common canaliculus or more distal structures

2. **Probing** – To rule out common canalicular block

Method - After topical anaesthetic was instilled, the punctum was dilated. An appropriately sized lacrimal probe (**Figure 7**) was advanced into the canaliculus. First the probe was passed vertically through the punctum and then horizontally with the eyelid on a stretch until it encountered the lacrimal bone or met the canalicular obstruction. (**Figure 8**)

If the probe encountered the lacrimal bone, when advanced into the canaliculus, the feeling was called "hard stop", i.e., the probe passed into the lacrimal sac following which it touched its medial wall, and the common canaliculus was thus patent. If there was a reflux through the opposite punctum in syringing, a "hard stop" suggested an obstruction of the sac or duct. If there was a canalicular block, then the length of the advanced probe was measured. This length was suggestive of the patent proximal part of canaliculi, i.e. the distance between the punctum and obstruction was measured.

If there was an obstruction close to the lacrimal sac and the probe was not negotiable into the lacrimal sac to feel the lacrimal bone, a "soft stop" was experienced. This spongy feeling suggested that the obstruction was probably within the common canaliculus and the lacrimal probe was pressing the common canaliculus and the lateral wall against the medial wall of the sac. The probing was done very gently.

It was important to notice the inner canthus while one was advancing the probe towards the hard stop. If there was a medial shift of the inner canthus on advancing the probe towards the lacrimal bone, it indicated that the probe was dragging the common canaliculus medially towards the bone and the lacrimal bone was not yet reached. Hence it was seen in "soft stop".

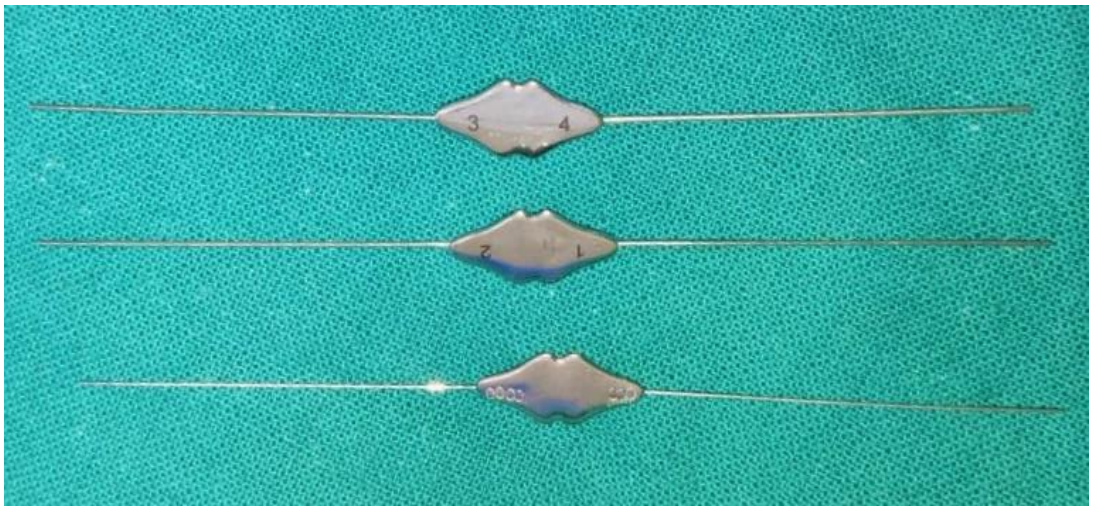


Figure 7: Bowman Probes used for probing

Figure 8: Diagnostic probing being done in a patient

3. **ROPLAS (Regurgitation on pressure over the Lacrimal Sac)** –

A positive ROPLAS test required neither irrigation nor probing as it has a very high specificity (99.3%) with a negative predictive value of 99.2%. (113), (20)

Method – The inferior orbital margin was traced medially and superiorly till the anterior lacrimal crest was identified. The index finger was then directed behind the crest and pressure was applied on the sac area in an upward and medial direction so as to express the contents of the lacrimal sac onto the conjunctiva. Any reflux of fluid or mucopurulent material from the puncta was noted and the ROPLAS test was said to be positive in such a case.

4. **Diagnostic Nasal Endoscopy** –

Method - The nasal mucosa was topically decongested and anaesthetized with a spray or pledges soaked with anaesthetics. Diagnostic nasal endoscopy was performed with a rigid endoscope of 4-mm diameter, 0 or 30° viewing angle. The endoscope was directed above the inferior turbinate to examine the lacrimal ridge and view the area of the axilla of the middle turbinate. Endoscopy of the inferior meatus was also done to visualize the ostium of the nasolacrimal duct.

Assessment was done for any anatomical abnormalities which could potentially affect the proposed lacrimal surgery (nasal cavity extent, septal deviation, hypertrophic turbinate, previous nasal surgery).

Assessment for any co-existing nasal pathologies causing lacrimal symptoms (tumor, Wegener's granulomatosis, etc.) was also done.

5. **Schirmer's test** – Schirmer's test was done for assessing and ruling out dry eye.

Method – White Whatman filter paper No. 41 in 35x5-mm strips was folded 5 mm from one end and placed into the inferior fornix at the junction of the medial two-thirds and lateral one-third of the lower eyelid. (**Figure 9**)

In semi-darkened room, the patient, without any eye drops, and without any verbal stimulation, was asked to blink normally for 5 minutes. The amount of wetting to the paper was measured from the fold along its length after the paper was removed.

Interpretation -

1. Normal being ≥15 mm wetting of the paper after 5 minutes
2. Mild: 14-9 mm wetting of the paper after 5 minutes
3. Moderate: 8-4 mm wetting of the paper after 5 minutes
4. Severe: <4 mm wetting of the paper after 5 minutes

Figure 9: Schirmer's test being performed in a patient

6. Fluorescein-dye disappearance test (FDDT) –

This is a physiological test based on the evaluation of residual fluorescein in the eye following instillation of one drop of fluorescein into the unanaesthetised conjunctival sac to check for normal lacrimal flow.

Method **–** One drop of 0.125–2% fluorescein was instilled into the unanaesthetised lower fornix of each conjunctival sac. After 5 minutes, the thickness of the fluorescence of the tear meniscus was measured under slit lamp with the help of cobalt blue filter. (**Figure 10, 11**). The tears normally drain down the lacrimal system in 5 minutes. However, in case there was a residual fluorescein stained tear film present in the lower conjunctiva, after 5 minutes, the test was considered as positive. (**Figure 12**)

Interpretation - The fluorescein dye test grading scale is as follows:

0 = no fluorescence in the conjunctival sac
1 = thin fluorescing marginal tear strip persists
2 = more fluorescein persists, between l and 3
3 = wide, brightly fluorescing tear strip

Grades 0 and 1 are considered to be normal, i.e., the drainage function is good. Grades 2 and 3 are considered to be abnormal i.e., the lacrimal drainage system is not functional.

Figure 10: Fluorescein dye instilled into the eye

Figure 11: Fluorescein-dye disappearance test being performed in a patient

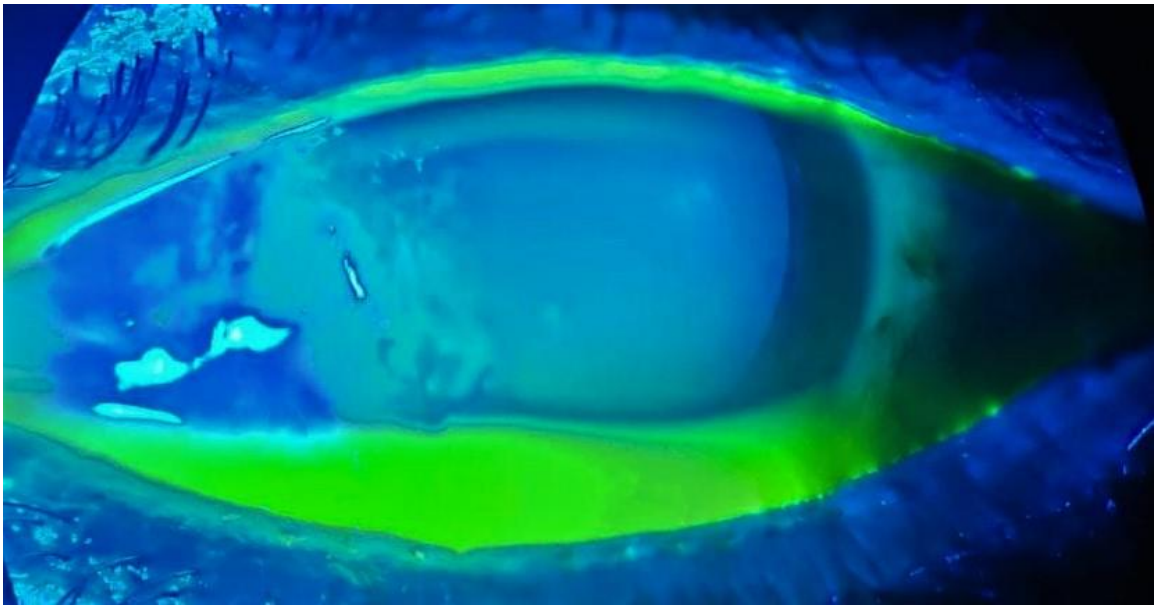


Figure 12: Fluorescence of the tear meniscus is measured under slit lamp with cobalt blue filter

Subjective evaluation from the Blinded patient based on the following parameter:

7. **Lacrimal Symptom Questionnaire (LAC-Q)**- It takes into account the following problems faced by the patient in the last eight weeks:

- **Social and lifestyle impact of tear duct problem – One point for each problem faced (Maximum score - 5)**
    - Friends and family commenting about the watery eye problem
    - Causing embarrassment in company
    - Interference with everyday activity (Reading, Driving, Wearing make-up, Wearing glasses, Hobbies, other activity)
    - Blurring of vision
    - Taken medical attendance (visiting family doctor hospital eye clinic)

- **Problems with each eye separately – First 3 problems graded from 0 to 4, swelling graded from 0 to 2, as described by the patient about the problem in the last 8 weeks – (Maximum score – 14 for each eye)**
    - Watery eye – No watery eye problem, occasional watering, especially outdoors, Troublesome watering some days or most days or every day.
    - Pain in or around the eye; soreness of eyelids – No pain, some pain but not sought treatment, used prescription eyedrops, painful or swollen (lacrimal abscess) requiring antibiotics or surgical drainage
    - Sticky eye – No sticky eye problem, sometimes sticky, everyday sticky, sticky throughout the day, fistula formation
    - Swelling or lump at medial canthus (mucocoele) – No swelling/ lump, intermittent swelling, swelling present at all times.

POST-OPERATIVE WORKUP

Objective evaluation done by the Blinded observer based on following parameters:

1. Schirmer test

2. Fluorescein Dye Disappearance test (FDDT)

Subjective evaluation obtained from the Blinded patient based on the following parameters:

3. Pain assessment using:

a. Visual Analogue Scale

b. Faces pain rating scale

4. Lacrimal Symptom Questionnaire (LAC-Q)

5. Epiphora (Present/ Absent)

SURGICAL TECHNIQUE

- Under GA, patient was positioned.
- Under all aseptic precaution, parts were painted and draped.
- The nasal cavity on the side to be operated was decongested with 2% lignocaine and 1:2 lac adrenaline.
- DNE was done to make note of the pre-operative findings.
- Local infiltration given over anterior part of axilla of middle turbinate. (**Figure 16**)
- Incision made on the lateral wall of nose starting 3mm above the axilla of the middle turbinate.
- Another incision made above the level of the upper border of inferior turbinate.
- The two incisions are joined by vertical incision.
- Posterior based flap elevated just anterior to axilla and frontal process of maxilla and lacrimal bone visualized. (**Figure 17**)
- Bone removed using the allotted instrument – CUSA ((**Figure 18**) or Kerrison's bone punch (**Figure 19**).
- Lacrimal sac visualized. Sac incised using keratome and medial wall of sac debrided. (**Figure 20**)
- Mucopurulent discharge was seen to be coming out of the sac in 18 cases out of the 20.
- Syringing done and free flow of fluid confirmed by syringing and patency of nasolacrimal duct established. (**Figure 21**)
- Haemostasis achieved. Merocel nasal packing done. Bolster applied.

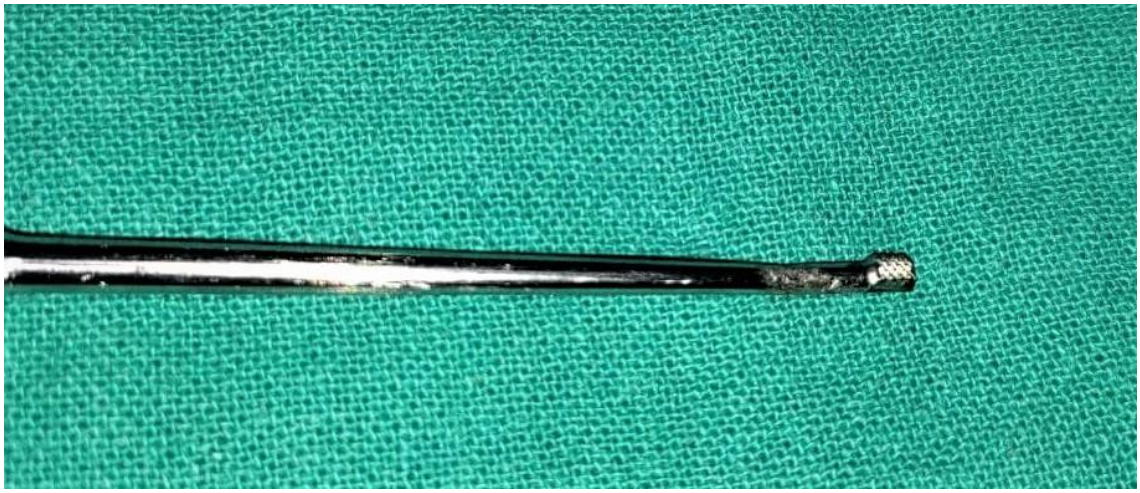


Figure 13: Bone tip of CUSA used in the CUSA group of the study

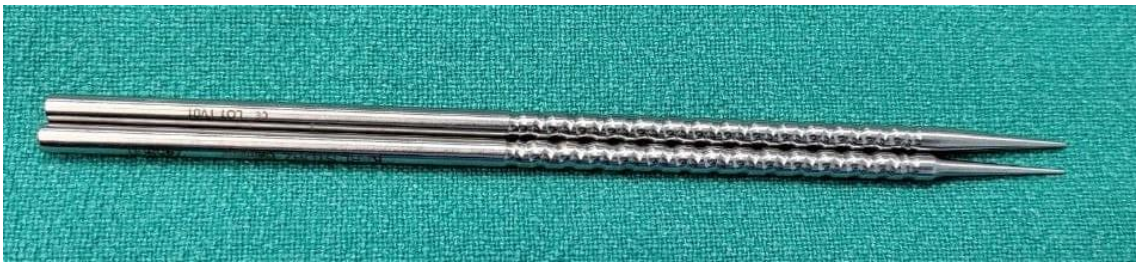


Figure 14: Punctum dilators of different sizes

Figure 15: Keratome used for opening the lacrimal sac

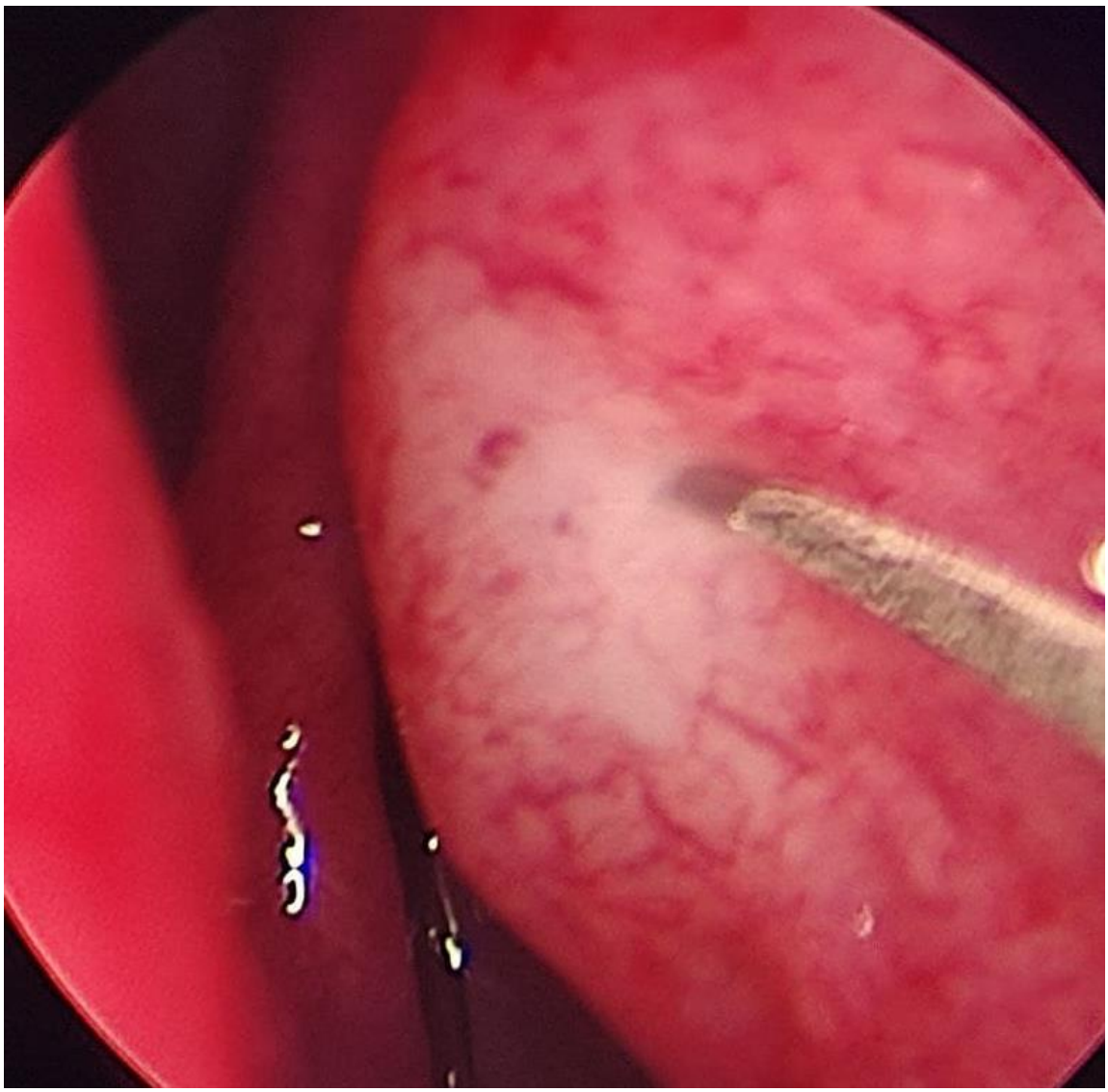


Figure 16: Local infiltration being given on the area anterior to the axilla of middle turbinate (Left)

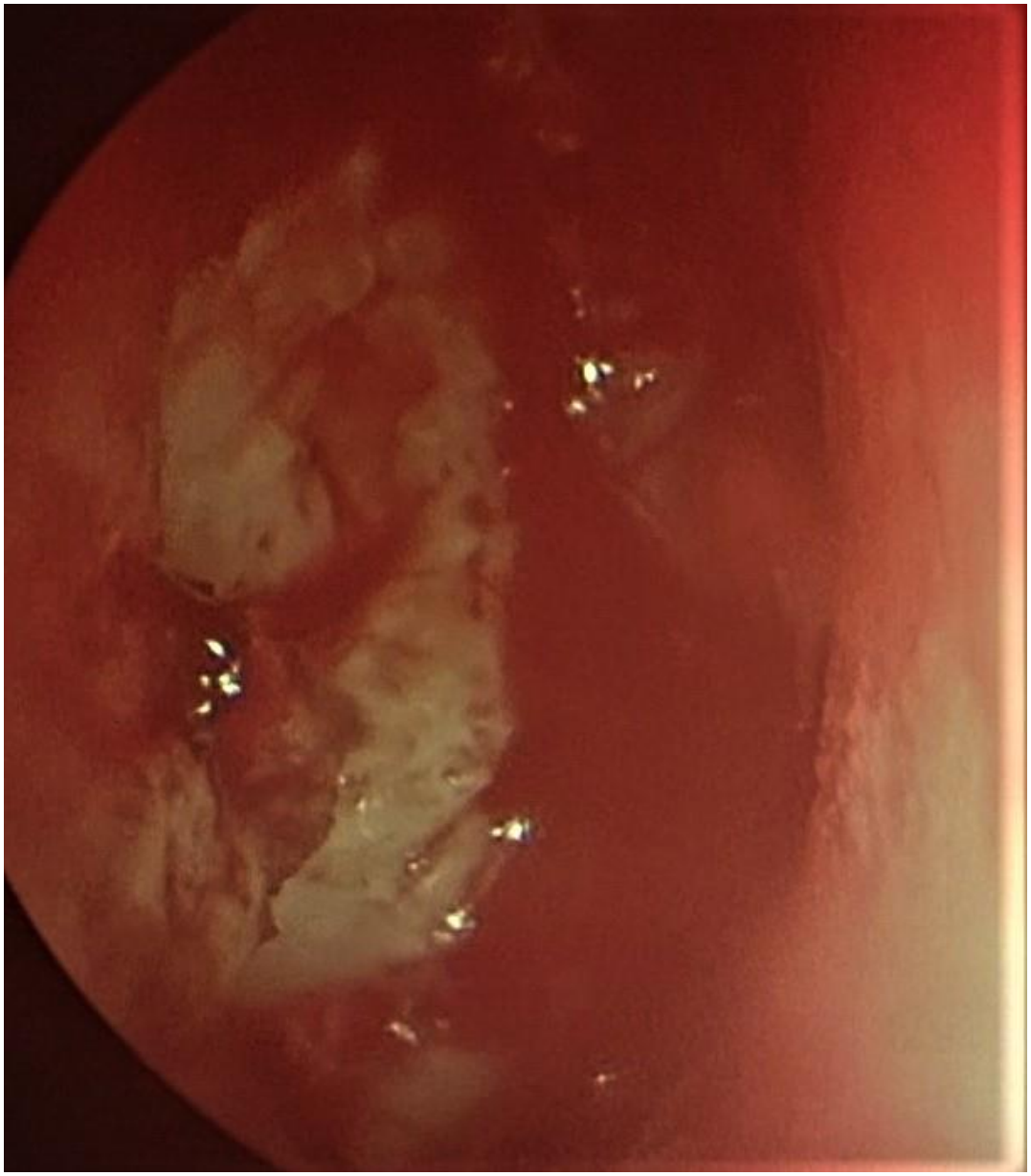


Figure 17: Frontal process of maxilla and lacrimal bone exposed after elevating nasal mucosal flap (Right)

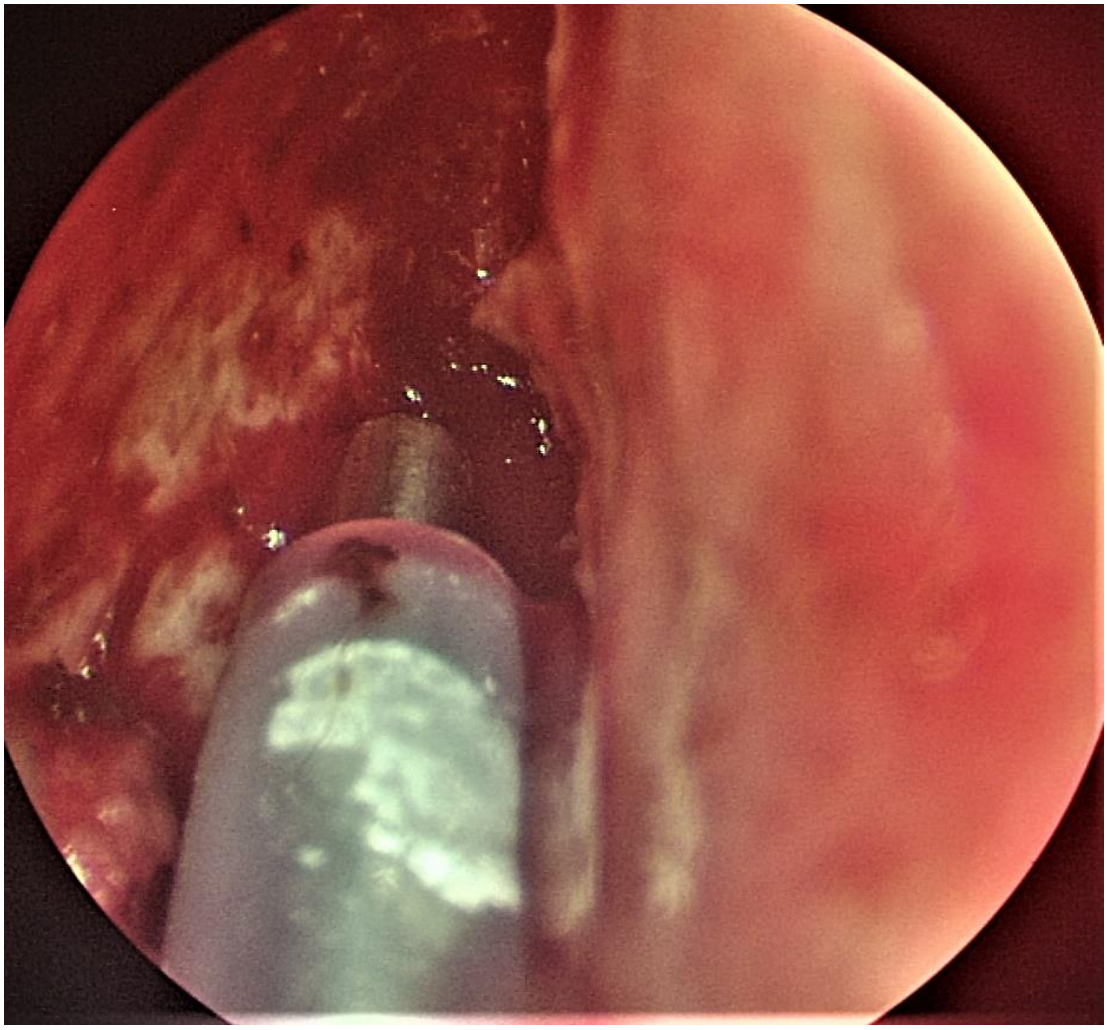


Figure 18: CUSA with the bone tip in use intra-operatively (Right)

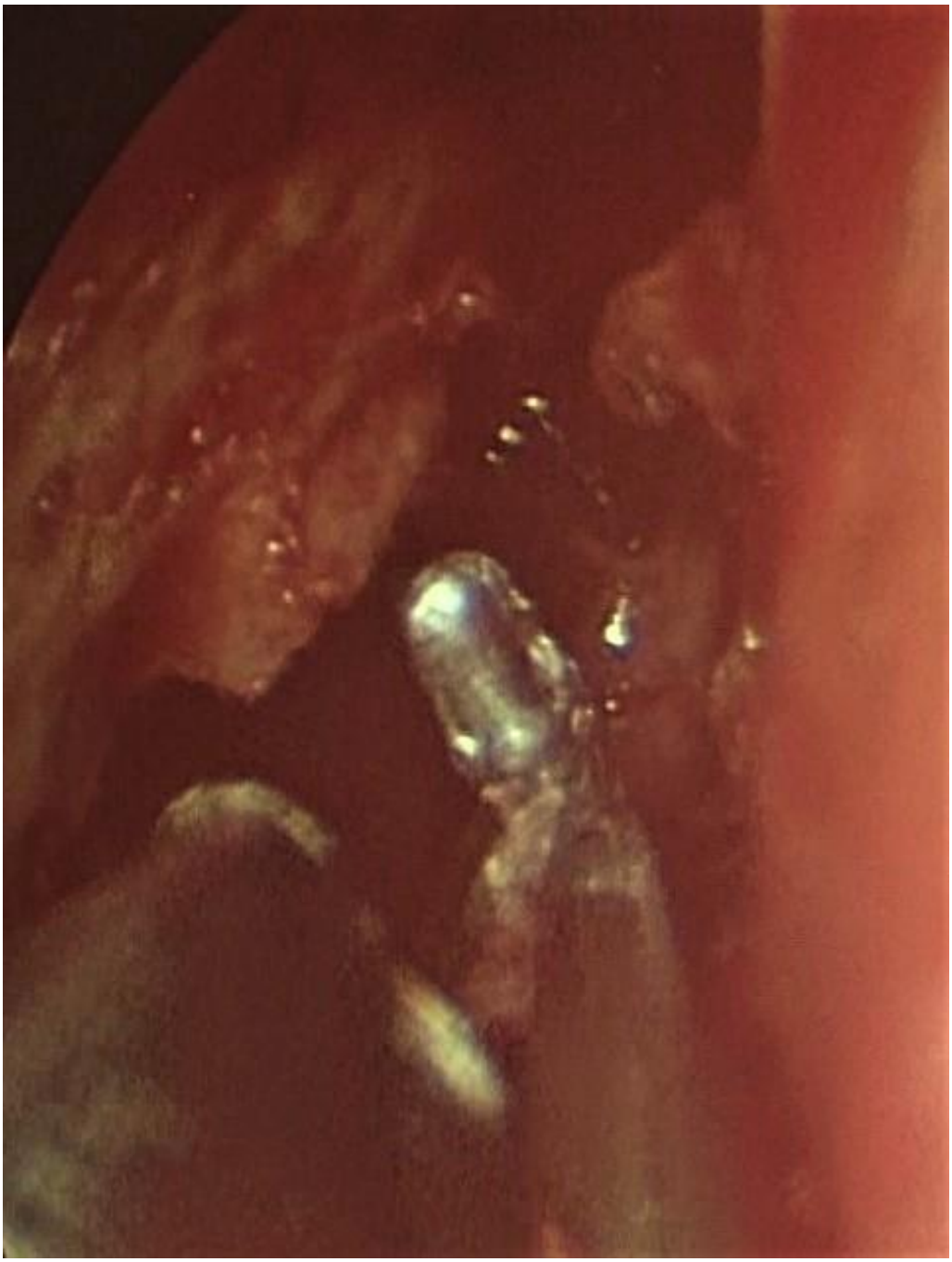


Figure 19: Kerrison's bone punch in use intra-operatively (Right)

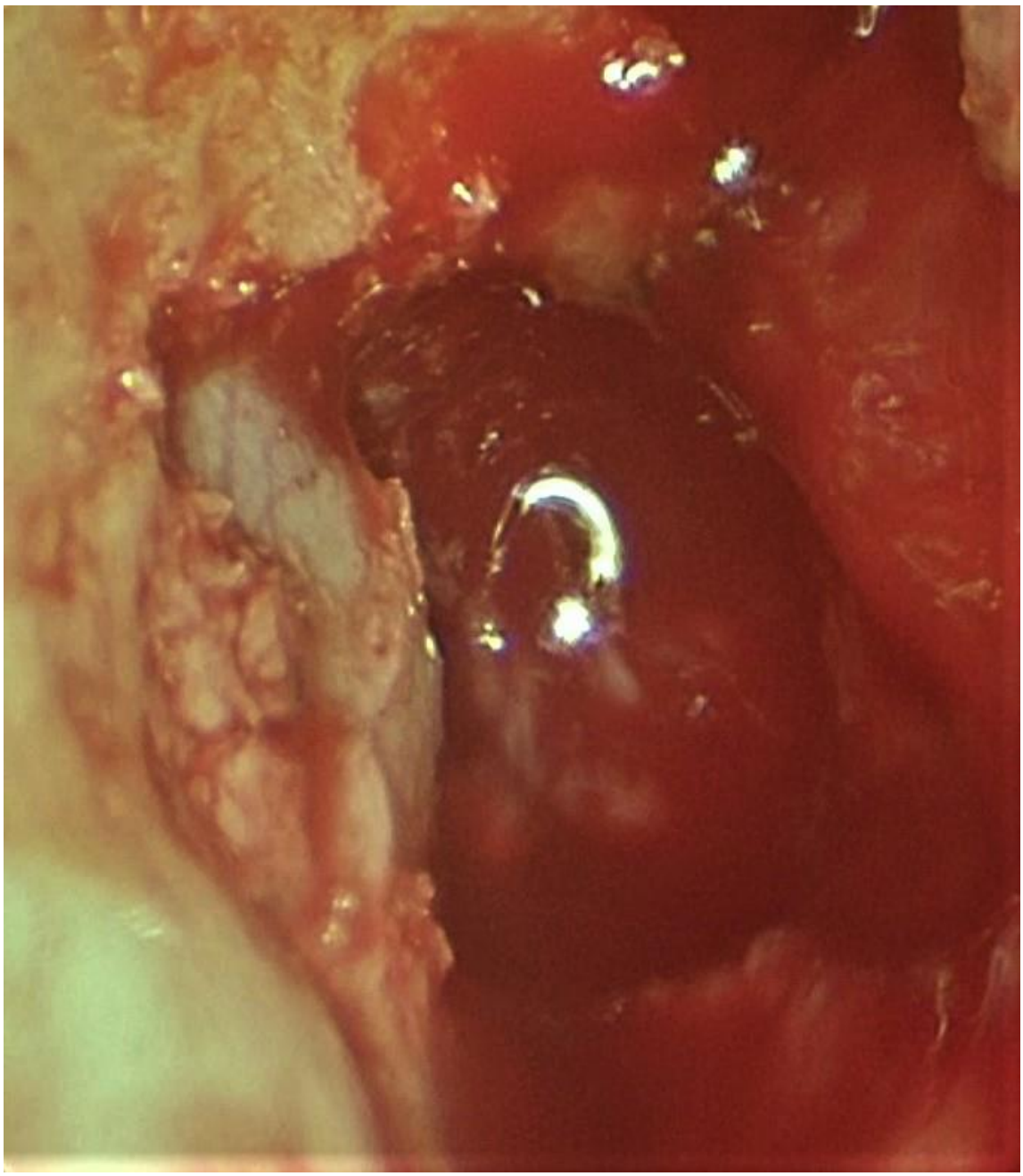


Figure 20: Lacrimal sac exposed (Right)

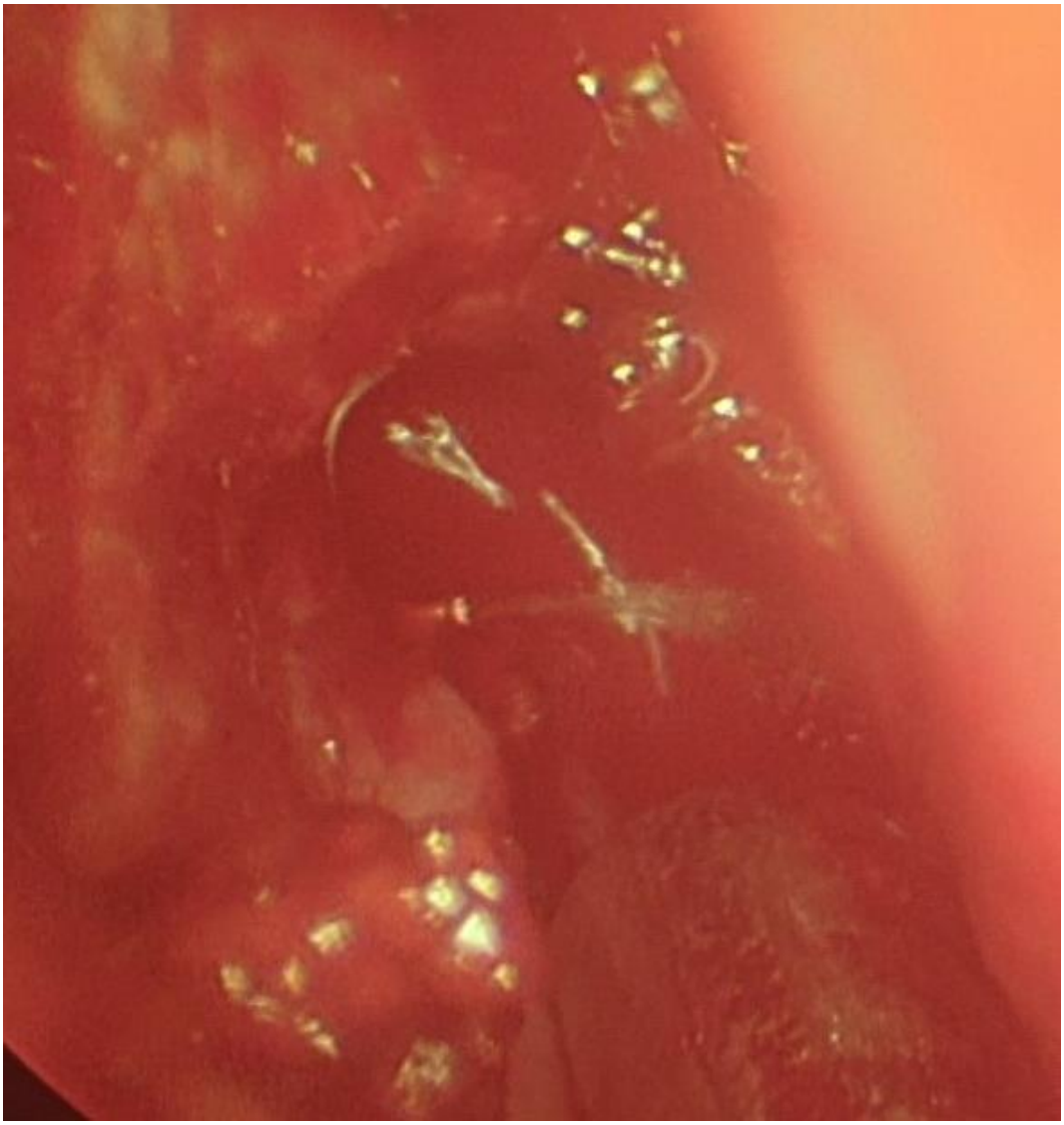
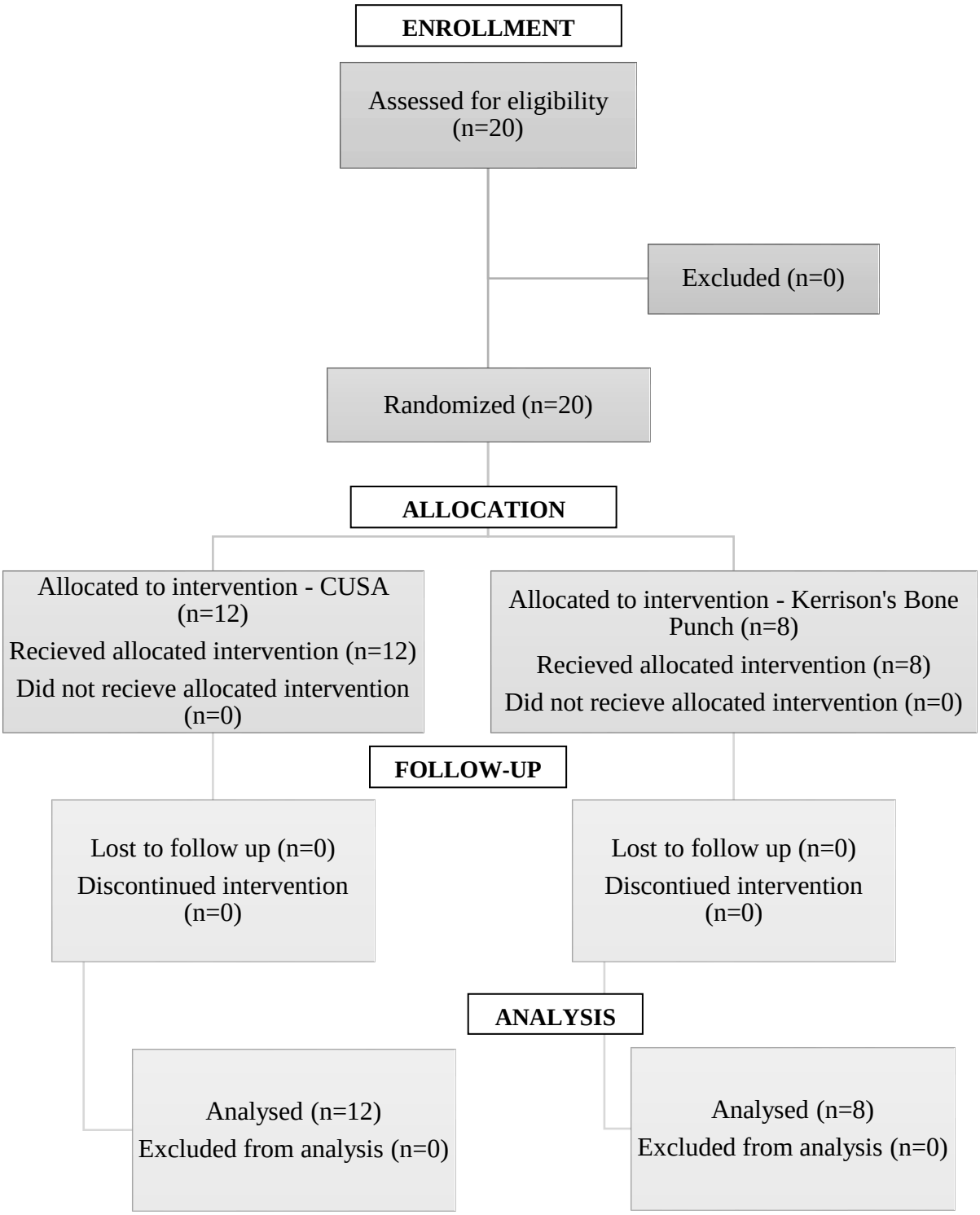


Figure 21: Free flow on syringing confirming patency of nasolacrimal duct being established

Figure 22: Consolidated Standards of Reporting Trials (CONSORT) figure representing the enrolment and analysis of data:



STATISTICAL ANALYSIS

All data collected was tabulated in an excel spread-sheet and was analysed using Statistical Package for Social Sciences (SPSS) IBM software version 23 (IBM SPSS Advanced Statistics, Chicago, IL, USA). Results of the categorical measurements were presented in numbers, or ratio

Results of quantitative variables were presented as median (95% confidence interval) or mean ± SD.Mann-Whitney U test was applied for comparing qualitative (categorical) data, and Unpaired Student's t test was applied for comparing quantitative (continuous) data.

Level of significance was taken as 5% with p value < 0.05, being considered as significant.

ETHICS APPROVAL

Approval to conduct this study was taken from the Institution Ethics Committee (IEC), AIIMS, Jodhpur (**IEC Reg. No. AIIMS/IEC/2019-20/982** – attached in Appendix-A) and registration was done with Clinical Trail Registry - India (**CTRI Registration No. CTRI/2020/03/024297 obtained on 27/03/2020**). Informed and written consent in a language the patient understands was obtained from the subjects before their participation in the study. There were reasonable ethical implications in this study:

1. All subjects had provided a written informed consent (attached as Appendix B).
2. There were no added costs to the patient.
3. Patient had to meet the aforementioned study inclusion criteria.

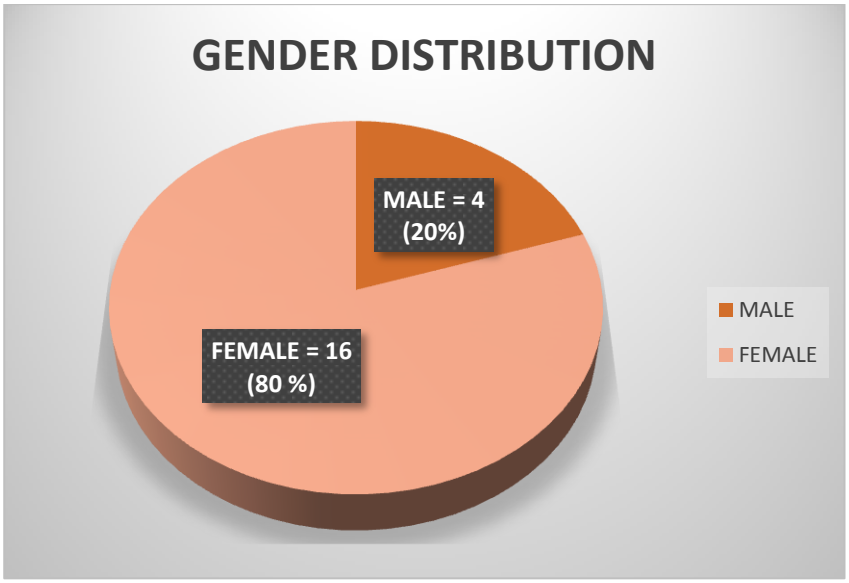
REQUIREMENTS

Schirmer test strips and Fluorescein dye were required for the study which were made available with the help of Department of Ophthalmology and utilized for routine follow up of patients in our department.

RESULTS

GENDER DISTRIBUTION:

Figure 23: Gender distribution in the study population:



The above figure depicts the gender-wise distribution of the included subjects. There was a female preponderance with percentage of females included being 80.0% and males 20.0%.

Table 1: Comparison of gender distribution between the study groups:

Gender	CUSA (n=12) n (%)	Kerrison's bone punch (n=8) n (%)	p-value
Male	2 (16.67%)	2 (25.0%)	0.648077
Female	10 (83.33%)	6 (75.0%)	

The above table shows the gender distribution of patients between CUSA and Kerrison's bone punch groups. There were 2 (16.67%) males and 10 (83.33%) females in the CUSA group vs 2 (25.0%) males and 6 (75.0%) females in the Kerrison's bone punch group. The chi-square test was applied and the corresponding p-value was 0.6480; which was statistically non-significant i.e., both the study groups were comparable with respect to the gender of patients enrolled.

AGE:

Table 2: Comparison of mean age between study groups:

Age (in years)	CUSA (n=12)	Kerrison's bone punch (n=8)	p-value
Mean ± SD	48.83 ± 13.89	44.88 ± 17.16	0.576

The Mean age in CUSA group and Kerrison's bone punch group was (48.83 ± 13.89) years and (44.88 ± 17.16) years, respectively (p-value = 0.576).

The unpaired student 't' test was used to compare the age between study groups, which showed a p-value of 0.576, which was statistically non-significant i.e., both the study groups were comparable with respect to the age. (Table 2)

EPIPHORA:

Table 3: Comparison of post-operative epiphora in the study population:

	POST OPERATIVE EPIPHORA	CUSA (n=12) n (%)	KERRISON'S BONE PUNCH (n=8) n (%)	p-value
POD- 0 (n=20)	Present	1 (8.3%)	0 (0.0%)	1.000
	Absent	11 (91.7%)	8 (100.0%)	
POD- 1 WEEK (n=20)	Present	1 (8.3%)	0 (0.0%)	1.000
	Absent	11 (91.7%)	8 (100.0%)	
POD- 4 WEEKS (n=20)	Present	2 (16.7%)	1 (12.5%)	1.000
	Absent	10 (83.3%)	7 (87.5%)	
POD- 12 WEEKS (n=20)	Present	1 (8.3%)	1 (12.5%)	1.000
	Absent	11 (91.7%)	7 (87.5%)	
Fisher's Exact Test was used				

The above table shows the **absence of epiphora in majority** of the patients in the post-operative period. The difference was not statistically significant (p-value – 1.000)

- At post-operative day 0 and 1 week, **recurrence of epiphora** was seen in 1 patient (8.3%) in the CUSA group. The Kerrison's bone group showed no recurrence up to 1 week post-operatively.
- At 4 weeks post-operative day, recurrence of epiphora was seen in 2 patients (16.7%) with CUSA and in 1 patient (12.5%) with Kerrison's bone punch.
- At 12 weeks post-operative day, there was persistence of recurrence in 1 patient (8.3%) in the CUSA group and also 1 patient (12.5%) in the Kerrison's bone punch group.

PAIN:

Table 4: Comparison of post-operative pain by the Visual Analogue Scale in the study population:

BY VISUAL ANALOGUE SCALE (VAS)				
	POST OPERATIVE PAIN	**CUSA (n=12) n (%)**	**KERRISON'S BONE PUNCH (n=8) n (%)**	**p-value**
POD-0 (n=20)	MILD PAIN (Scores 1,2)	10 (83.3%)	8 (100.0%)	0.495
	NO PAIN (Score 0)	2 (16.7%)	0 (0.0%)	
POD- 1 WEEK (n=20)	MILD PAIN (Scores 1,2)	2 (16.7%)	0 (0.0%)	1.000
	NO PAIN (Score 0)	10 (83.3%)	7 (87.5%)	
POD- 4 WEEKS (n=20)	MILD PAIN (Scores 1,2)	2 (16.7%)	1 (12.5%)	1.000
	NO PAIN (Score 0)	10 (83.3%)	7 (87.5%)	
POD- 12 WEEKS (n=20)	MILD PAIN (Scores 1,2)	1 (8.3%)	1 (12.5%)	1.000
	NO PAIN (Score 0)	11 (91.7%)	7 (87.5%)	
Fisher's Exact Test was used				

The above table shows the comparison of post-operative pain in terms of the Visual analogue scale scores as experienced by the patients on post-operative day 0, 1 week, 4 weeks and 12 weeks which is comparable in both the groups (p-value = 0.495 and p-value = 1.000).

- On post-operative day 0, majority of the patients reported mild pain – 83.3% patients in the CUSA group and 100.0% patients in the Kerrison group.

- However, there was no pain in majority of the patients in both the groups on follow-up.

Table 5: Comparison of post-operative pain by the FACES Scale in the study population:

BY FACES SCALE				
	POST OPERATIVE PAIN	**CUSA (n=12) n (%)**	**KERRISON'S BONE PUNCH (n=8) n (%)**	**p-value**
POD-0 (n=20)	Hurts little bit - Hurts little more	8 (66.7%)	7 (87.5%)	0.603
	No hurt	4 (33.3%)	1 (12.5%)	
POD- 1 WEEK (n=20)	Hurts little bit - Hurts little more	2 (16.7%)	1 (12.5%)	1.000
	No hurt	10 (83.3%)	7 (87.5%)	
POD- 4 WEEKS (n=20)	Hurts little bit - Hurts little more	1 (8.3%)	1 (12.5%)	1.000
	No hurt	11 (91.7%)	7 (87.5%)	
POD- 12 WEEKS (n=20)	Hurts little bit - Hurts little more	1 (8.3%)	1 (12.5%)	1.000
	No hurt	11 (91.7%)	7 (87.5%)	
Fisher's Exact Test was used				

The above table shows the comparison of post-operative pain in terms of the FACES scale as experienced by the patients on post-operative day 0, 1 week, 4 weeks and 12 weeks which is comparable in both the groups (p-value = 0.603 and p-value = 1.000).

- On post-operative day 0, majority of the patients reported pain as "Hurts little bit" to "Hurts little more" – 66.7% patients in the CUSA group and 87.5% patients in the Kerrison group.
- However, majority of the patients reported that there was "No hurt" in both the groups on follow-up.

LACRIMAL QUESTIONNAIRE SCORE (LAC-Q SCORE):

Table 6: Comparison of Lacrimal questionnaire scores in the study population:

LAC-Q SCORES MEAN ± SD	CUSA (n=12) n (%)	KERRISON'S BONE PUNCH (n=8) n (%)	p-value
PRE-OPERATIVE	15.92 ± 0.289	15.88 ± 0.354	0.776
POD-0 (n=20)	4.42 ± 0.515	4.38 ± 0.518	0.862
POD- 1 WEEK (n=20)	0.25 ± 0.452	0.13 ± 0.354	0.519
POD- 4 WEEKS (n=20)	0.25 ± 0.622	0.38 ± 1.061	0.742
POD- 12 WEEKS (n=20)	0.58 ± 1.443	0.63 ± 1.768	0.954
Independent 't' test was used			

The above table shows the comparison of the lacrimal questionnaire scores in pre-operative versus post-operative day 0, 1 week, 4 weeks and 12 weeks as experienced by the patients.

There has been reduction in mean LAC-Q scores in the post-operative period as compared to the pre-operative scores, from (15.92 ± 0.289) to (4.42 ± 0.515) in the CUSA group and from (15.88 ± 0.354) to (4.38 ± 0.518) in the Kerrison's group on post-operative day 0.

The scores have reduced to <1 on follow-up.

SCHIRMER'S TEST:

Table 7: Comparison of Schirmer's Test in the study population in the pre and post-operative period:

SCHIRMER'S TEST	PRE-OPERATIVE	POD-0 (n=20)	POD- 1 WEEK ((n=20)	POD-4 WEEKS (n=20)	POD- 12 WEEKS (n=20)
NORMAL (≥15 mm)	19	19	19	19	19
MILD (14-9mm)	1	0	0	0	0
MODERATE (8-4mm)	0	1	1	1	1
SEVERE (<4mm)	0	0	0	0	0

The above table shows the comparison of pre and post-operative Schirmer's test in the patients on post-operative day 0, 1 week, 4 weeks and 12 weeks.

Schirmer's test was found to be normal (≥15mm) in 19 patients, pre-operatively and post-operatively. Only one patient had moderate wetting of the Schirmer's test strip.

FLUORESCEIN DYE DISAPPEARANCE TEST (FDDT):

Table 8: Comparison of post-operative Fluorescein dye disappearance test in the study population between the study groups:

	FDDT GRADES (0-3)	CUSA (n=12) n (%)	KERRISON'S BONE PUNCH (n=8) n (%)	p-value
POD- 1 WEEK (n=20)	Normal	2 (16.7%)	1 (12.5%)	1.000
	Abnormal	10 (83.3%)	7 (87.5%)	
POD- 4 WEEKS (n=20)	Normal	3 (25.0%)	3 (37.5%)	0.642
	Abnormal	9 (75.0%)	5 (62.5%)	
POD- 12 WEEKS (n=20)	Normal	4 (33.3%)	2 (25.0%)	1.000
	Abnormal	8 (66.7%)	6 (75.0%)	
Fisher's Exact Test was used				

The above table shows the FDDT grades as observed on post-operative day 1 week, 4 weeks and 12 weeks.

- Pre-operatively, all the patients had Abnormal FDDT grade (Grades 2, 3) suggestive of abnormal lacrimal drainage function.
- On follow-up, at POD- 1 week and at POD-12 weeks, the CUSA group shows to have normal lacrimal drainage (Grades 0,1) in higher number of patients (16.7% and 33.3% patients respectively) as compared to the Kerrison's group (12.5% and 25.0%).

However, the difference is not statistically significant.

ROPLAS:

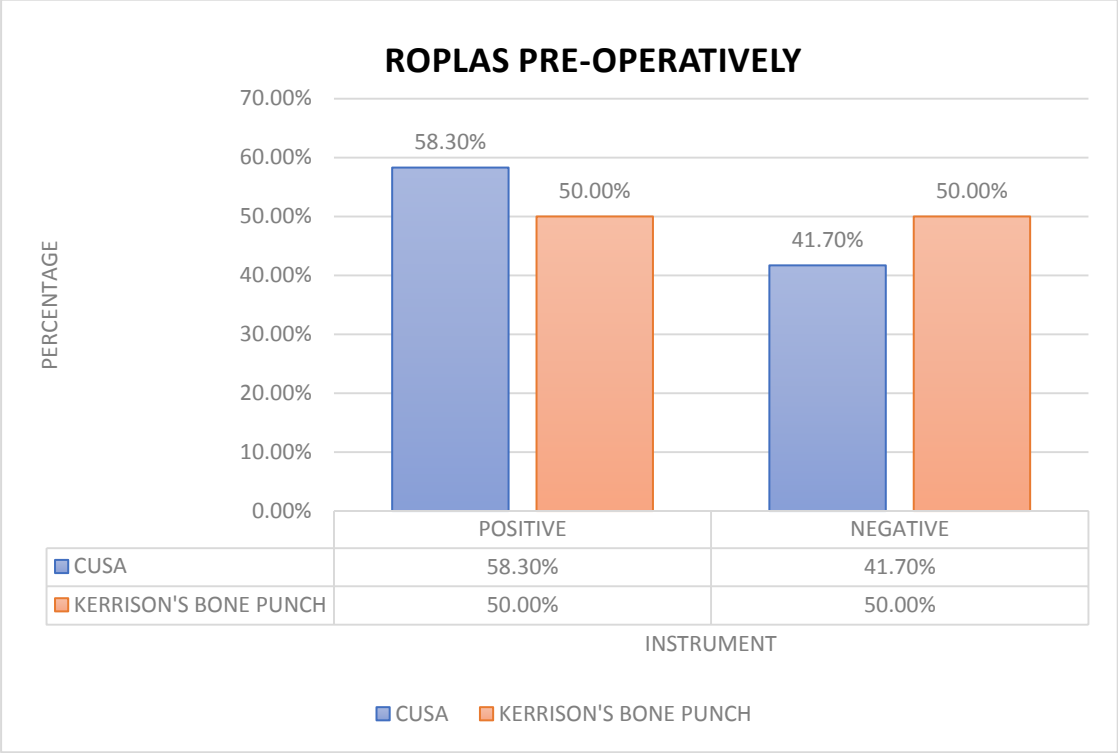


Figure 24: Comparison of ROPLAS pre-operatively in both the study groups.

ROPLAS was found to be positive in 58.3% (n=7) patients and negative in 41.7% (n=5) in the CUSA group. It was positive in 50% patients in the Kerrison's bone punch group pre-operatively.

On subsequent follow-up, at 12 weeks post-operatively, 1 patient in each group was found to be having ROPLAS positive; that is recurrence of symptoms.

INTRA-OPERATIVE DURATION:

Table 9: Comparison of mean intra-operative duration between the study groups:

INTRA-OPERATIVE DURATION (in mins)	CUSA (n=12) (in mins)	KERRISON'S BONE PUNCH (n=8) (in mins)	p-value
Mean ± SD	119.17 ± 33.496	106.38 ± 37.992	0.438[a]
Median (Q_1, Q_3)	117.7 (102.5, 138.75)	114.00 (76.25, 132.00)	0.487[b]
[a] Independent 't' test [b] Mann-Whitney U test			

The above table shows the comparison of Mean ± SD for the time taken for the surgery using the two instruments CUSA and Kerrison's bone punch. The mean ± SD of the intra-operative duration in the CUSA group and Kerrison's bone punch group was 119.17±33.496 minutes and 106.38±37.992 minutes, respectively. The unpaired student 't' test was used to compare intra-operative duration between the study groups, which showed a p-value of 0.438, which was statistically non-significant, i.e., both the study groups were comparable with respect to time taken for the operation between the study groups.

The median of the intra-operative duration in the CUSA group and Kerrison's bone punch group was 117.5 minutes and 114.0 minutes, respectively. The Mann-Whitney U test was used to compare intra-operative duration between the study groups, which showed a p-value of 0.487, which was statistically non-significant, i.e., both the study groups were comparable with respect to time taken for the operation between the study groups.

PER-OPERATIVE ADEQUACY OF LACRIMAL SAC EXPOSURE:

There was **adequate exposure** of the lacrimal sac in *all the subjects operated (100%)* using both the CUSA or the Kerrison's bone punch.

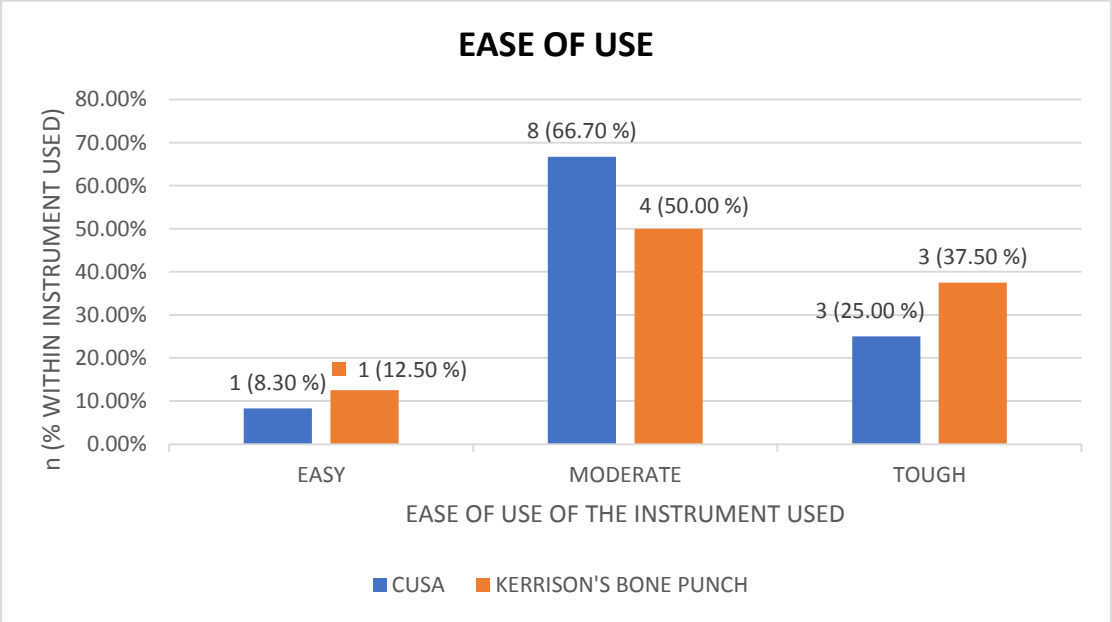
EASE OF USING EACH OF THE INSTRUMENTS:

Table 10: Comparison of ease of using the two instruments in the surgical procedure:

Ease of use of instrument (1-10)	CUSA (n=12) n (%)	KERRISON'S BONE PUNCH (n=8) n (%)	p-value
EASY (1-3)	1 (8.3%)	1 (12.5%)	0.723
MODERATE (4-7)	8 (66.7%)	4 (50.0%)	
TOUGH (8-10)	3 (25.0%)	3 (37.5%)	
Mann Whitney U test was used.			

The above table shows the ease of using the two instruments CUSA and Kerrison;s bone punch in terms of grades marked by the operating surgeon after performing the surgery with either of the instruments. They are divided into 3 groups as Easy (grade 1-3), Moderate (grade 4-7), Tough (grade 8-10). In majority of the cases (60.0%) the surgeons had Moderate difficulty with either of the instruments. Using the CUSA, in 66.7% cases the surgeons experienced Moderate difficulty whereas only 50% of the surgeons graded similar difficulty using the Kerrison's bone punch.

Figure 25: Comparison of Ease of using the instrument in the surgical procedure:



The above figure shows the comparison of the ease of using the individual instruments CUSA versus Kerrison's bone punch in the surgery.

INDIVIDUAL SURGEON'S EXPERIENCE WITH EACH INSTRUMENT:

Table 11: Comparison of time and ease of use with each instrument group between the operating surgeons in the study:

Instrument parameters	Surgeon No.	CUSA	KERRISON'S BONE PUNCH	p-value
TIME TAKEN FOR SURGERY (in minutes)	SURGEON 1	108.57 ± 39.13	99.00 ± 36.29	0.925
	SURGEON 2	132.00 ± 20.80	113.75 ±43.66	0.539
EASE OF USE (1-10)	SURGEON 1	4.57 ± 1.51	4.50 ±1.91	1.000
	SURGEON 2	6.80 ± 1.79	7.50 ± 1.00	0.558
Mann-Whitney U Test was used				

The above table shows the individual experiences of the surgeons with each of the instruments. Overall, more time was taken for the surgery on operating with CUSA as compared to that taken with the Kerrison's bone punch by each individual surgeon, that is (108.57 ± 39.13) minutes with CUSA as compared to (99.00 ± 36.29) minutes with Kerrison, by Surgeon 1; and (132.00 ± 20.80) minutes with CUSA as compared to (113.75 ±43.66) minutes with the Kerrison by Surgeon 2.

Both CUSA and Kerrison's bone punch showed similar Ease of use in case of Surgeon 1 (4.57 ± 1.51 with CUSA and 4.50 ±1.91 with Kerrison's bone punch)
CUSA showed a slightly better Ease of use (6.80 ± 1.79) than Kerrison's bone punch (7.50 ± 1.00) in Surgeon 2.
However, there was no statistical difference between the two groups (p-value> 0.05)

INTRA-OPERATIVE COMPLICATIONS:

Table 11: Comparison of complications faced with each of the two instruments in the surgical procedure:

Intra-operative complications	CUSA (n)	KERRISON'S BONE PUNCH (n)
Difficulty in removal of superior part of bone	0	1
Difficulty in identifying sac	3	0
External skin wound inferior to medial canthus	3	0

The above table shows the comparison of the complications faced by the surgeons intra-operatively with each of the instruments.

- With CUSA there was difficulty in identifying the sac and external skin wound at the area of the medial canthus in 3 patients each.

- In 1 patient being operated with the Kerrison's bone punch there was difficulty in removal of the superior part of the bone.

There was **requirement of septoplasty** in 1 patient in each group.

SURGICAL SUCCESS RATES:

The operation was classified as successful by the subjective disappearance of patient symptoms (absence of epiphora/ ROPLAS negative) at 3 months follow-up.

Table 12: Comparison of Surgical success using the two instruments in endoscopic endonasal DCR:

		CUSA (n=12)	KERRISON'S BONE PUNCH (n=8)	p-value
SURGICAL SUCCESS	YES	11 (91.7%)	7 (87.5%)	1.000
	NO	1 (8.3%)	1 (12.5%)	
Fisher's Exact Test was used				

Both CUSA and Kerrison's bone punch groups showed recurrence of symptoms (presence of epiphora and ROPLAS positive) and thereby failure of surgery in 1 patient each.

So endoscopic endonasal DCR using CUSA demonstrated a success rate of 91.67% (successful in 11 out of 12 patients) whereas endoscopic endonasal DCR using Kerrison's bone punch showed a success rate of 87.5% (successful in 7 out of 8 patients). However, the results were not statistically significant. (p-value = 1.000)

DISCUSSION

Nasolacrimal duct obstruction (NLDO) prevents the drainage of tears from the eye to the nose, leading to epiphora. It could range from an occasional trickle to chronic overflowing of tears. Hence there is a disruption of the balance between tear production and drainage. Permanent obstruction of the nasolacrimal duct constitutes Chronic Dacryocystitis. (5)

Conservative treatments only aid in temporary relief of symptoms. Hence, surgery is considered as the treatment of choice for patients with nasolacrimal duct obstruction. Dacryocystorhinostomy (DCR) is a surgical procedure wherein the drainage of tears is established by creating a bypass between the lacrimal sac and the nasal cavity. (114)

Numerous studies have emphasized the benefits of endoscopic endonasal dacryocystorhinostomy technique as compared to the external dacryocystorhinostomy. There have been excellent results due to significant advances in technique, instruments and deeper understanding of endoscopic surgical anatomy. (71) Absence of external skin incision and scar, protection of the pumping mechanism of the orbicularis oculi muscle, shorter operative duration and the wider knowledge of the endoscopic nasal anatomy are among few of the advantages of endoscopic DCR as compared to the external DCR. (115), (116) The principles of endoscopic sinus surgery in endonasal endoscopic DCR are targeted towards the minimalist goal of restoring the function of the area primarily responsible for the presenting symptoms. (117)

In our research, we aimed at comparing the outcomes of using two different instruments (Cavitron Ultrasonic Surgical Aspirator, CUSA versus Kerrison's bone punch), in performing endoscopic endonasal DCR in adult patients with nasolacrimal duct obstruction. We also assessed the surgeon's perspective regarding use of each of the two instruments for performing the surgery. Our key purpose was to decipher if the use of CUSA provided a better outcome than the outcomes with the Kerrison's bone punch in patients with chronic dacryocystitis undergoing Endonasal Endoscopic Dacryocystorhinostomy.

Tests of normality were used to assess the distribution of the data. According to the Shapiro-Wilk test the variables of age and intra-operative duration were normally distributed (p-value > 0.05) while rest of the data were not normally distributed.

In our study, **gender** distribution showed that most of the patients (n=16) were females i.e. 80% of the study population, while only 20% were males (n=04). Each of the study groups showed a female preponderance too. In the CUSA group, there were 10 (83.33%) females and 2 (16.67%) males. In the Kerrison's bone punch group there were 6 (75.0%) females and only 2 (75.0%) males. The chi-square test was applied and the corresponding p-value came as 0.6480. This was statistically non-significant and hence both the study groups were comparable with respect to the gender of patients enrolled. This finding was comparable to the study done by Gur. *et al*, (118) in which 89.1% of all cases included in the study were females. This finding was also similar to the study performed by David *et al* (64) which had 81.2% females undergoing endonasal DCR. Female preponderance was also observed in the study done by Ingale *et al.* in 2018. (119)

The mean **age** of the patients enrolled in the study was (48.83 ± 13.89) years in the CUSA group and (44.88 ± 17.16) years in the Kerrison's bone punch group, which was comparable (p-value-0.576) as calculated using the unpaired student 't' test. This finding was consistent with the study done by Herzallah *et al.* (22) where the mean age of the study population was 45 years. This was also similar to the study done by David *et al.* (64) which showed the mean age in patients undergoing endonasal dacryocystorhinostomy to be (41.9 ± 15.8) years.

Epiphora was found to be absent in the majority of the patients post-operatively. At post-operative day 0 and 1 week, recurrence of epiphora was seen in 1 patient (8.3%) in the CUSA group while the Kerrison's bone group showed no recurrence up to 1 week post-operatively. At 4 weeks post-operative day, recurrence of epiphora was seen in 2 patients (16.7%) with CUSA and in 1 patient (12.5%) with Kerrison's bone punch. At 12 weeks post-operative day, there was persistence of recurrence in 1 patient (8.3%) in the CUSA group and also 1 patient (12.5%) in the Kerrison's bone punch group. However, there was no statistically significant difference between the two groups as assessed by the Fisher's exact test. The presence of post-operative epiphora could be attributed to the fact that few patients had improper compliance to

alkaline nasal douching, which was evident by post-operative diagnostic nasal endoscopy of the surgical site showing presence of crusting blocking the operated area.

At post-operative week 12, on follow-up, intra-nasal synechiae formation was seen on nasal endoscopy at the operated site in 1 patient in each group, who were having recurrence of symptoms, that is 8.3% patients in the CUSA group compared to 12.5% patients in the Kerrison's bone punch group. This could also be attributed to the fact that the CUSA group had more number of subjects as compared to the Kerrison's bone punch group. The synechiae formation could also be a cause leading to persistence of epiphora. Among the 3 patients with post-operative recurrence of symptoms, one patient underwent septoplasty along with DCR, which could have also led to synechiae formation.

Comparison of post-operative pain in terms of the **Visual Analogue Scale (VAS) scores** as experienced by the patients on post-operative day 0, 1 week, 4 weeks and 12 weeks was comparable in both the groups (p-value = 0.495 and p-value = 1.000) as assessed by the Fisher's exact test. On post-operative day 0, the majority of the patients reported "Mild pain" – 83.3% patients in the CUSA group and 100.0% patients in the Kerrison group. However, there was "No pain" in the majority of the patients in both the groups (83.3% patients to up to 91.7% patients in the CUSA group and 87.5% patients in the Kerrison's bone punch group) on follow-up.

The post-operative pain in terms of the **FACES scale** as experienced by the patients on post-operative day 0, 1 week, 4 weeks and 12 weeks, was comparable in both the groups (p-value = 0.603 and p-value = 1.000) by the Fisher's exact test. On post-operative day 0, the majority of the patients reported pain as "Hurts little bit" to "Hurts little more" as per the FACES scale – that was 66.7% patients in the CUSA group and 87.5% patients in the Kerrison group. However, on post-operative day 1 week and 4 weeks, the majority of the patients i.e 83.3% patients and 91.7% patients respectively in the CUSA group and 87.5% patients in the Kerrison's bone punch group reported that there was "No hurt" on follow-up. Hence, immediate post-operative pain is slightly more in patients undergoing surgery with the Kerrison's bone punch as compared to the CUSA (p-value = 0.603). However, the difference is

not statistically significant. No similar studies have been found comparing these two instruments in terms of their post-operative pain, earlier.

Comparison of the **lacrimal questionnaire scores** in pre-operative versus post-operative day 0, 1 week, 4 weeks and 12 weeks as experienced by the patients show that there has been reduction in the mean LAC-Q scores in the post-operative period as compared to the pre-operative scores. Pre-operative LAC-Q score of (15.92 ± 0.289) reduced to (4.42 ± 0.515) in the CUSA group and from (15.88 ± 0.354) to (4.38 ± 0.518) in the Kerrison's group on post-operative day 0. On subsequent follow-up at post-operative 1 week, 4 weeks and 12 weeks, the scores were reduced to <1 in both the groups. However, the difference in either group is not statistically significant (p-value > 0.05) as obtained by applying the independent 't' test. Previously studies have been done to show the reduction in post-operative LAC-Q scores as compared to the pre-operative scores. (120), (121) However, no studies have been done previously to compare these two instruments in terms of their surgical outcomes using the Lacrimal questionnaire.

Schirmer's test was done to rule out the component of dry eye leading to increased lacrimation in the patients. ≥15mm wetting of the Schirmer's test strip was considered Normal. 14-9mm was Mild, 8-4mm was Moderate and <4mm was Severe dry eyes. In 19 patients in both pre-operative and post-operative period, the Schirmer's test was normal ruling out the possibility of dry eye in those patients. Only one patient had moderate wetting of the Schirmer's test strip but had successful surgical outcome on follow-up.

The **Fluorescein dye disappearance test** (FDDT) was done in the study population both pre and post-operatively to assess improvement in the lacrimal drainage function. Pre-operatively, all the patients had abnormal FDDT grade (Grade 2, 3) suggestive of abnormal lacrimal drainage function. On follow-up, at POD- 1 week and at POD-12 weeks, the CUSA group shows to have normal lacrimal drainage (Grades 0,1) in higher number of patients (16.7% and 33.3% patients respectively) as compared to the Kerrison's group (12.5% and 25.0%). However, the difference is not statistically significant (p-value > 0.05) as assessed by the Fisher's exact test applied.

ROPLAS was found to be positive in 58.3% (n=7) patients and negative in 41.7% (n=5) in the CUSA group pre-operatively while it was positive in 50% of the patients in the Kerrison's bone punch group. ROPLAS positivity before the operation has been considered as a good prognostic sign since old times. The presence of lacrimal regurgitation through the punctum by pressure on the sac indicates patency of the canaliculi and presence of a dilated non-shrunken sac which indicates better prognosis. (63). Post-operatively on follow up at 12 weeks, ROPLAS was found to be positive in 2 patients (1 in each group), signifying recurrence of symptoms. Among these two patients, one had ROPLAS positive pre-operatively also.

Among the two patients undergoing septoplasty along with DCR in the study, the one with ROPLAS positive finding pre-operatively, had no recurrence and was operated with CUSA. However, the other patient who had ROPLAS negative finding pre-operatively, ended up with recurrence after septoplasty with DCR with Kerrison's bone punch.

The mean ± SD of the **intra-operative duration** in the CUSA group and Kerrison's bone punch group was (119.17±33.496) minutes and (106.38±37.992) minutes, respectively. The intra-operative duration between both groups were comparable (p-value - 0.438) by the Independent 't' test. On the contrary, a study done by Herzallah *et al.*(22) has shown the mean operating time as 75 minutes using Kerrison's bone punch. . Mean surgery time for unilateral complex cases using Sonopet Ultrasonic aspirator was 85.1 minutes in a study by Chappell *et al.* (39) Hence, in our study the results of intra-operative duration were more as compared to the studies done previously which could be attributed to the fact that the surgeons in training and often wearing personal protective equipments (PPEs) performed the surgeries.

There was adequate **exposure of the lacrimal sac** in all the subjects operated (100%) using both the CUSA or the Kerrison's bone punch. However, the surgeons reported facing difficulty in identifying the lacrimal sac in 3 patients in the CUSA group, while none in the Kerrison's bone punch group. This could be attributed to the fact that surgeon's had lesser previous experience in using the ultrasonic aspirator.

The **ease of use** with either instrument, from the surgeon's perspective, was divided into 3 groups: Easy (grade 1-3), Moderate (grade 4-7) and Tough (grade 8-10). In the majority of the cases (60.0%) the surgeons had Moderate difficulty with either of the instruments. Using the CUSA, in 66.7% cases the surgeons experienced Moderate difficulty whereas only 50% of the surgeons graded similar difficulty in using the Kerrison's bone punch. Using the Mann Whitney U test in either group, the ease of use was found to be comparable as there was no statistically significant difference. (p-value=0.723)

On comparing the **individual experiences of the surgeons** with each of the instruments, overall, more time was taken for the surgery on operating with CUSA as compared to that taken with the Kerrison's bone punch by each individual surgeon, that is (108.57 ± 39.13) minutes with CUSA as compared to (99.00 ± 36.29) minutes with Kerrison, by Surgeon 1; and (132.00 ± 20.80) minutes with CUSA as compared to (113.75 ±43.66) minutes with the Kerrison by Surgeon 2. Both CUSA and Kerrison's bone punch showed similar Ease of use in case of Surgeon 1 (4.57 ± 1.51 with CUSA and 4.50 ±1.91 with Kerrison's bone punch) whereas CUSA showed a slightly better Ease of use (6.80 ± 1.79) than Kerrison's bone punch (7.50 ± 1.00) in Surgeon 2. However, there was no statistical difference between the two groups (p-value> 0.05). Previously no studies have been done comparing these two instruments from the surgeon's point of view.

There were increased number of **intraoperative complications** reported with the CUSA group like- difficulty in identifying sac (n=3) and external skin wound occurring inferior to the medial canthus (n=3). There was requirement of septoplasty in one patient in the CUSA group which was assessed pre-operatively using nasal endoscopy. In the Kerrison's bone punch group, there was a requirement of septoplasty and difficulty in removal of the superior part of the bone in 1 patient unlike that in the CUSA group. The difficulty faced in removing the superior part of the bone using Kerrison's bone punch is consistent with the study done by Chappell *et al.,* (39) which states that conventional rongeurs are difficult to use in the superior part due to limited working space and tight angulation within the nose.

The **surgical success rates** were determined and operation was classified as successful by the subjective disappearance of patient symptoms (absence of epiphora/ ROPLAS negative) at 3 months follow-up. This was taken as the end point of primary treatment by us. Similar end-points have been used in other studies such as the one by Ragab et al (36). Both CUSA and Kerrison's bone punch groups showed recurrence of symptoms (presence of epiphora and ROPLAS positive) and thereby failure of surgery in 1 patient each.

So endoscopic endonasal DCR using CUSA demonstrated a success rate of 91.67% (successful in 11 out of 12 patients) whereas endoscopic endonasal DCR using Kerrison's bone punch showed a success rate of 87.5% (successful in 7 out of 8 patients). However, the results were not statistically significant using the Fisher's exact test. (p-value = 1.000)

CONCLUSION

Nasolacimal duct obstruction (NLDO) leading to chronic dacryocystitis in patients, is more commonly seen in middle aged females. The CUSA and the Kerrison's bone punch are comparable instruments for use in endoscopic endonasal DCR as evident from the assessment of their surgical outcomes.

However, since our study is pilot study with a relatively small sample size, the results are limited in reaching at a generalization. As none of the variables had statistical significance, further randomised controlled trials with a larger sample size and longer duration are advisable for establishing a significant correlation.

There is need for more multi-centric trials before reaching any conclusion.

STRENGTHS AND LIMITATIONS

Strengths of the study:

1. All patients underwent DCR by the endoscopic endonasal technique at an apex institution.
2. Only two surgeons were the primary surgeons performing DCR.
3. Same pre-operative, intra-operative and post-operative protocol was followed in all.
4. The pre-operative and post-operative assessments were done using a single blinded observer who was not a part of the study.
5. The patients were blinded in the study and hence subjective evaluation from the patients could be considered as unbiased.
6. All the patients were under regular follow- up.

Limitations of the study:

1. Small sample size – Due to by the ongoing COVID-19 Pandemic because of which the elective operations were put on hold.
2. Short duration of study- We propose a longer duration of the study with follow up for further validation of our points or to look for any contrasting evidence.
3. Blinding of the surgeon was not possible.
4. Single-centre study.

BIBLIOGRAPHY

1. Woog JJ, Kennedy RH, Custer PL, Kaltreider SA, Meyer DR, Camara JG. Endonasal Dacryocystorhinostomy. 2001;108(12):9.

2. Salami A, Dellepiane M, Salzano FA, Mora R. Piezosurgery in endoscopic dacryocystorhinostomy. Otolaryngol Head Neck Surg [Internet]. 2009 Feb [cited 2019 Nov 8];140(2):264–6. Available from: http://journals.sagepub.com/doi/10.1016/j.otohns.2008.11.019

3. Jawaheer L, MacEwen CJ, Anijeet D. Endonasal versus external dacryocystorhinostomy for nasolacrimal duct obstruction. Cochrane Database Syst Rev. 2017 Feb 24;2:CD007097.

4. Duwal S, Saiju R. Outcomes of external dacryocystorhinostomy and endoscopic endonasal dacryocystorhinostomy in the management of nasolacrimal duct obstruction. Nepal J Ophthalmol. 2015 Jun;7(1):39–46.

5. SAVINO G, BATTENDIERI R, TRAINA S, CORBO G, D'AMICO G, GARI M, et al. External vs. endonasal dacryocystorhinostomy: has the current view changed? Acta Otorhinolaryngol Ital [Internet]. 2014 Feb [cited 2021 Sep 25];34(1):29–35. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3970232/

6. Steele TO, Wilson M, Strong EB. Ultrasonic bone aspirator assisted endoscopic dacryocystorhinostomy. American Journal of Otolaryngology [Internet]. 2016 May [cited 2019 Nov 8];37(3):202–6. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0196070916000181

7. Burkat CN, Lucarelli MJ. Anatomy of the Lacrimal System. In: Cohen AJ, Mercandetti M, Brazzo BG, editors. The Lacrimal System [Internet]. Springer New York; 2006 [cited 2022 Jan 4]. p. 3–19. Available from: http://link.springer.com/10.1007/978-0-387-35267-1_1

8. Machiele R, Lopez MJ, Czyz CN. Anatomy, Head and Neck, Eye Lacrimal Gland. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 [cited 2021 Dec 29]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK532914/

9. de la Cuadra-Blanco C, Peces-Peña MD, Mérida-Velasco JR. Morphogenesis of the human lacrimal gland. J Anat [Internet]. 2003 Nov [cited 2022 Jan 4];203(5):531–6. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1571187/

10. Ozanics V, Jakobiec F. Ocular anatomy, embryology, and teratology. Philadelphia, Harper & Row; 1982. 11–96 p.

11. Schaeffer J. The genesis and development of the nasolacrimal passages in man. Am J Anat. 1912;(13):1–23.

12. Jones LT, Wobig JL. Congenital anomalies of the lacrimal system. In: Surgery of the Eyelids and Lacrimal System. Birmingham, AL: Aesculapius; 1976. p. 157–73.

13. Hurwitz JJ. Embryology of the lacrimal drainage system. In: The Lacrimal System. Philadelphia: Lippincott-Raven; 1996. p. 9–13.

14. Bylsma LM, Gračanin A, Vingerhoets AJJM. The neurobiology of human crying. Clin Auton Res. 2019 Feb;29(1):63–73.

15. Kawakita T. Regeneration of Lacrimal Gland Function to Maintain the Health of the Ocular Surface. Invest Ophthalmol Vis Sci [Internet]. 2018 Nov 27 [cited 2021 Dec 29];59(14):DES169. Available from: http://iovs.arvojournals.org/article.aspx?doi=10.1167/iovs.17-23576

16. Tiffany JM. Tears in health and disease. Eye [Internet]. 2003 Nov [cited 2021 Dec 29];17(8):923–6. Available from: http://www.nature.com/articles/6700566

17. Stern ME, Beuerman RW, Fox RI, Gao J, Mircheff AK, Pflugfelder SC. The Pathology of Dry Eye: The Interaction Between the Ocular Surface and Lacrimal Glands. Cornea [Internet]. 1998 Nov [cited 2021 Nov 22];17(6):584. Available from: https://journals.lww.com/corneajrnl/Abstract/1998/11000/The_Pathology_of_Dry_Eye__The_Interaction_Between.2.aspx

18. Holly FJ, Lemp MA. Tear physiology and dry eyes. Survey of Ophthalmology [Internet]. 1977 Sep [cited 2021 Dec 29];22(2):69–87. Available from: https://linkinghub.elsevier.com/retrieve/pii/003962577790087X

19. Zarbin M, Chu D. DIAGNOSTIC AND SURGICAL TECHNIQUES. :12.

20. Weber RK, editor. Atlas of lacrimal surgery. Berlin ; New York: Springer; 2007. 158 p.

21. Cokkeser Y, Evereklioglu C, Er H. Comparative external versus endoscopic dacryocystorhinostomy: results in 115 patients (130 eyes). Otolaryngol Head Neck Surg. 2000 Oct;123(4):488–91.

22. Herzallah I, Alzuraiqi B, Bawazeer N, Marglani O, Alherabi A, Mohamed SK, et al. Endoscopic Dacryocystorhinostomy (DCR): a comparative study between powered and non-powered technique. J of Otolaryngol - Head & Neck Surg [Internet]. 2015 Dec [cited 2019 Nov 11];44(1):56. Available from: http://www.journalotohns.com/content/44/1/56

23. Sheikh S, Vaze VV, Bajaj A, . B. Merits of Kerrisons punch over powered drill in endonasal DCR. Int J Otorhinolaryngol Head Neck Surg [Internet]. 2019 Feb 23 [cited 2022 Jan 5];5(2):387. Available from: https://www.ijorl.com/index.php/ijorl/article/view/1230

24. Antisdel JL, Kadze MS, Sindwani R. Application of ultrasonic aspirators to endoscopic dacryocystorhinostomy. Otolaryngol Head Neck Surg [Internet]. 2008 Oct [cited 2019 Nov 8];139(4):586–8. Available from: http://journals.sagepub.com/doi/10.1016/j.otohns.2008.07.001

25. Rai A, Jain A, Nagarkar N, Khan M. Use of Kerrison Rongeur for safe and effective removal of bone in temporomandibular joint ankylosis. Oral Maxillofac Surg [Internet]. 2018 Mar [cited 2021 Nov 7];22(1):115–6. Available from: http://link.springer.com/10.1007/s10006-018-0671-4

26. Buraimoh M, Basheer A, Taliaferro K, Shaw J, Haider S, Graziano G, et al. Origins of eponymous instruments in spine surgery. Journal of Neurosurgery: Spine. 2018 Sep 14;29:1–8.

27. Ledderose GJ. Use of an ultrasonic aspirator in transnasal surgery of tumorous lesions of the anterior skull base. Interdisciplinary Neurosurgery. 2019;4.

28. Sivak-Callcott JA, Linberg JV, Patel S. Ultrasonic bone removal with the Sonopet Omni: a new instrument for orbital and lacrimal surgery. Arch Ophthalmol. 2005 Nov;123(11):1595–7.

29. Hadeishi H, Suzuki A, Yasui N, Satou Y. Anterior Clinoidectomy and Opening of the Internal Auditory Canal Using an Ultrasonic Bone Curette. Neurosurgery [Internet]. 2003 Apr 1 [cited 2021 Nov 23];52(4):867–71. Available from: https://academic.oup.com/neurosurgery/article/52/4/867/2734038

30. Henzi S, Krayenbühl N, Bozinov O, Regli L, Stienen MN. Ultrasonic aspiration in neurosurgery: comparative analysis of complications and outcome for three commonly used models. Acta Neurochir [Internet]. 2019 Oct 1 [cited 2022 Jan 10];161(10):2073–82. Available from: https://doi.org/10.1007/s00701-019-04021-0

31. SonaStar [Internet]. [cited 2022 Jan 6]. Available from: https://misonix.com/wp-content/uploads/2021/04/SonaStar_IFU.pdf

32. Metson R, Woog JJ, Puliafito CA. Endoscopic laser dacryocystorhinostomy. Laryngoscope. 1994 Mar;104(3 Pt 1):269–74.

33. Massaro BM, Gonnering RS, Harris GJ. Endonasal laser dacryocystorhinostomy. A new approach to nasolacrimal duct obstruction. Arch Ophthalmol. 1990 Aug;108(8):1172–6.

34. Gonnering RS, Lyon DB, Fisher JC. Endoscopic laser-assisted lacrimal surgery. Am J Ophthalmol. 1991 Feb 15;111(2):152–7.

35. Doğan M, Alizada A, Yavaş GF, Kahveci OK, Bakan O. Laser-assisted dacryocystorhinostomy in nasolacrimal duct obstruction: 5-year follow-up. Int J Ophthalmol [Internet]. 2018 Oct 18 [cited 2022 Jan 6];11(10):1616–20. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6192962/

36. Ragab SM, el-Koddousy MS, Badr M. Endocanalicular, high-pressure balloon catheter, endoscopic dacryocystorhinostomy: a randomized controlled trial. Otolaryngol Head Neck Surg. 2011 Oct;145(4):683–8.

37. Silbert DI, Matta NS. Outcomes of 9 mm Balloon-Assisted Endoscopic Dacryocystorhinostomy: Retrospective Review of 97 Cases. Orbit [Internet]. 2010 Jun 1 [cited 2022 Jan 10];29(3):131–5. Available from: https://doi.org/10.3109/01676830.2010.480924

38. Vinciguerra A, Indelicato P, Giordano Resti A, Bussi M, Trimarchi M. Long-term results of a balloon-assisted endoscopic approach in failed dacryocystorhinostomies. Eur Arch Otorhinolaryngol [Internet]. 2021 Jul 12 [cited 2022 Jan 10]; Available from: https://link.springer.com/10.1007/s00405-021-06975-3

39. Chappell MC, Moe KS, Chang S-H. Learning Curve for use of the Sonopet Ultrasonic Aspirator in Endoscopic Dacryocystorhinostomy. Orbit [Internet]. 2014 Aug [cited 2019 Nov 8];33(4):270–5. Available from: http://www.tandfonline.com/doi/full/10.3109/01676830.2014.904377

40. Lee JJ, Lee HM, Lim HB, Seo SW, Ahn HB, Lee SB. Learning Curve for Endoscopic Endonasal Dacryocystorhinostomy. Korean J Ophthalmol. 2017 Aug;31(4):299–305.

41. Hirschberg J. The renaissance of Ophthalmology in the 18th century. In: The history of Ophthalmology_vol 1. Belgium: Wayenborg Publications; 1984. p. 11.

42. Jasim DrAD, Ahmed DrAAQ, Khaleel DrMA. Transcanalicular laser dacryocystorhinostomy as a recent approach for treating nasolacrima duct obstruction at Al-Mosul teaching centre. Int J Surg Sci [Internet]. 2019 Jul 1 [cited 2022 Jan 6];3(3):313–7. Available from: http://www.surgeryscience.com/archives/2019.v3.i3.f.187

43. Hirschberg J. The renaissance of Ophthalmology in the 18th century. In: The history of Ophthalmology_vol3. Belgium: Wayenborg Publications; 1984. p. 250–5.

44. Ali MJ. Lacrimal disorders and surgery: historical perspectives. docksci.com [Internet]. [cited 2022 Jan 6]; Available from: https://docksci.com/lacrimal-disorders-and-surgery-historical-perspectives_5a9114ecd64ab27ef09de8eb.html

45. Galen. De Canmpos Medicam.

46. Hughes SM. The history of lacrimal surgery. Adv Ophthalmic Plast Reconstr Surg. 1986;5:139–68.

47. Eginetoe P, Pauli, Eginetoe P. Chirurgie de Paul d'Égine [Internet]. calameo.com. [cited 2021 Nov 1]. Available from: https://www.calameo.com/read/000107044315db0b8f132

48. Fallopius. Observ. Anatom. in Oper. Omn. Franco furti. 1584. 478 p.

49. Jan AM. Traite des maladies de l'oeil. 1701.

50. Chandler PA. Dacryocystorhinostomy. Trans Am Ophthalmol Soc [Internet]. 1936 [cited 2021 Oct 31];34:240–63. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1315579/

51. Montaigne. Gaz. m6d. de Paris. 1836. 692 p.

52. Bowman. Ann. d'ocul., xxix. 1851;52.

53. Andrew. Brit. M. J. 1883.

54. Killian. Versamml. sikddtsch. Laryngologen. 1899;

55. Toti A. Nuovo metodo conservatore di cura radicale delle suppurazioni croniche del sacco lacrimale (dacriocistorinostomia). Clin Moderna (Firenza) [Internet]. 1904 [cited 2021 Nov 1];10:385. Available from: https://www.scienceopen.com/document?vid=c1820472-c5f6-478a-892b-1fa434971739

56. West. Tr. Am. Ophth. Soc., xii, pt. ii. 654 p.

57. Polyak. Ztschr. f. Augenh., xxvi. 1911. 92 p.

58. Corbett JJ. Plastic Dacryorhinostomy. American Journal of Ophthalmology [Internet]. 1928 Oct [cited 2022 Jan 6];11(10):774–8. Available from: https://linkinghub.elsevier.com/retrieve/pii/S000293942892841X

59. Dupuy-Dutemp L, Bourguet M. Note preliminaire sur en procede de dacryocystorhinostomie. Ann Ocul. 1920;(157):445.

60. Dupuy-Dutemp L, Bourguet M. Procede plastíque de dacryocystorhinostomie et ses resultats. Ann Ocul. 1921;(158):241.

61. Mosher. Ann. Otol. Rhin. & Laryng.,. 1923;

62. Arruga H, Gifford SR. SURGICAL TREATMENT OF LACRIMATION. Archives of Ophthalmology [Internet]. 1938 Jan 1 [cited 2022 Jan 11];19(1):9–21. Available from: http://archopht.jamanetwork.com/article.aspx?articleid=613340

63. Girgis IH. Dacryocystorhinostomy. The Journal of Laryngology & Otology [Internet]. 1968 Feb [cited 2021 Oct 31];82(2):149–52. Available from: https://www.cambridge.org/core/journals/journal-of-laryngology-and-otology/article/abs/dacryocystorhinostomy/0DEC558499F5F811283C41E228756AE4

64. David S, Raju R, Job A, Richard J. A comparative study of external and endoscopic endonasal dacryocystorhinostomy — a preliminary report. Indian J Otolaryngol Head Neck Surg [Internet]. 1999 Dec [cited 2022 Jan 2];52(1):37–9. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3451228/

65. Zengin MÖ, Eren E. The return of the jedi: comparison of the outcomes of endolaser dacryocystorhinostomy and endonasal dacryocystorhinostomy. Int Forum Allergy Rhinol. 2014 Jun;4(6):480–3.

66. Caldwell GW. Two new operations for obstruction of the nasal duct with preservation of the canaliculi. Am J Ophthalmol. 1893;(10:b6).

67. Stammberger H. Endoscopic endonasal surgery--concepts in treatment of recurring rhinosinusitis. Part II. Surgical technique. Otolaryngol Head Neck Surg. 1986 Feb;94(2):147–56.

68. Kennedy DW. Functional endoscopic sinus surgery. Technique. Arch Otolaryngol. 1985 Oct;111(10):643–9.

69. Marcet MM, Kuk AKT, Phelps PO. Evidence-based review of surgical practices in endoscopic endonasal dacryocystorhinostomy for primary acquired nasolacrimal duct obstruction and other new indications. Curr Opin Ophthalmol. 2014 Sep;25(5):443–8.

70. McDonogh M, Meiring JH. Endoscopic transnasal dacryocystorhinostomy. J Laryngol Otol. 1989 Jun;103(6):585–7.

71. Ben Simon GJ, Joseph J, Lee S, Schwarcz RM, McCann JD, Goldberg RA. External versus endoscopic dacryocystorhinostomy for acquired nasolacrimal duct obstruction in a tertiary referral center. Ophthalmology. 2005 Aug;112(8):1463–8.

72. Yüce S, Akal A, Doğan M, Uysal İÖ, Müderris S. RESULTS OF ENDOSCOPIC ENDONASAL DACRYOCYSTORHINOSTOMY. J Craniofac Surg [Internet]. 2013 Jan [cited 2021 Nov 3];24(1):e11–2. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3556382/

73. Levin PS, StormoGipson DJ. Endocanalicular laser-assisted dacryocystorhinostomy. An anatomic study. Arch Ophthalmol. 1992 Oct;110(10):1488–90.

74. Silkiss RZ, Axelrod RN, Iwach AG, Vassiliadis A, Hennings DR. Transcanalicular THC:YAG dacryocystorhinostomy. Ophthalmic Surg. 1992 May;23(5):351–3.

75. Pearlman SJ, Michalos P, Leib ML, Moazed KT. Translacrimal transnasal laser-assisted dacryocystorhinostomy. Laryngoscope. 1997 Oct;107(10):1362–5.

76. Fay AM, Michalos P, Rubin PA. Endocanalicular Nd: YAG laser dacryocystorhinostomy. Int Ophthalmol Clin. 1999;39(1):177–84.

77. Mirza S, Jones N. Laser-Assisted Dacryocystorhinostomy. :13.

78. Javate RM, Campomanes BS, Co ND, Dinglasan JL, Go CG, Tan EN, et al. The endoscope and the radiofrequency unit in DCR surgery. Ophthalmic Plast Reconstr Surg. 1995 Mar;11(1):54–8.

79. Ullrich K, Malhotra R, Patel BC. Dacryocystorhinostomy. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 [cited 2022 Feb 4]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK557851/

80. Allen K, Berlin AJ. Dacryocystorhinostomy failure: association with nasolacrimal silicone intubation. Ophthalmic Surg. 1989 Jul;20(7):486–9.

81. Green R, Gohil R, Ross P. Mucosal and lacrimal flaps for endonasal dacryocystorhinostomy: a systematic review. Clin Otolaryngol. 2017 Jun;42(3):514–20.

82. Tsirbas A, Wormald PJ. Endonasal dacryocystorhinostomy with mucosal flaps. Am J Ophthalmol. 2003 Jan;135(1):76–83.

83. Trimarchi M, Giordano Resti A, Bellini C, Forti M, Bussi M. Anastomosis of nasal mucosal and lacrimal sac flaps in endoscopic dacryocystorhinostomy. Eur Arch Otorhinolaryngol. 2009 Nov;266(11):1747–52.

84. Mahendran S, Stevens-King A, Yung MW. How we do it: the viability of free mucosal grafts on exposed bone in lacrimal surgery - a prospective study. Clin Otolaryngol. 2006 Aug;31(4):324–7.

85. Codère F, Denton P, Corona J. Endonasal dacryocystorhinostomy: a modified technique with preservation of the nasal and lacrimal mucosa. Ophthalmic Plast Reconstr Surg. 2010 Jun;26(3):161–4.

86. Sathiamoorthi S, Frank RD, Mohney BG. Incidence and clinical characteristics of congenital nasolacrimal duct obstruction. Br J Ophthalmol [Internet]. 2019 Apr [cited 2022 Jan 11];103(4):527–9. Available from: https://bjo.bmj.com/lookup/doi/10.1136/bjophthalmol-2018-312074

87. Saniasiaya J, Abdullah B, Husain S, Wang DY, Wan Mohammad Z. Primary endoscopic endonasal dacryocystorhinostomy for pediatric nasolacrimal duct obstruction: A systematic review. Am J Rhinol Allergy. 2017 Sep 1;31(5):328–33.

88. Gupta AK, Bansal S. Primary endoscopic dacryocystorhinostomy in children -- analysis of 18 patients. Int J Pediatr Otorhinolaryngol. 2006 Jul;70(7):1213–7.

89. Pavlíková G, Foltán R, Horká M, Hanzelka T, Borunská H, Šedý J. Piezosurgery in oral and maxillofacial surgery. International Journal of Oral and Maxillofacial Surgery [Internet]. 2011 May 1 [cited 2021 Nov 5];40(5):451–7. Available from: https://www.sciencedirect.com/science/article/pii/S0901502710005060

90. Labanca M, Azzola F, Vinci R, Rodella LF. Piezoelectric surgery: twenty years of use. Br J Oral Maxillofac Surg. 2008 Jun;46(4):265–9.

91. Bruggers S, Sindwani R. Evolving Trends in Powered Endoscopic Sinus Surgery. Otolaryngologic Clinics of North America [Internet]. 2009 Oct 1 [cited 2021 Nov 5];42(5):789–98. Available from: https://www.sciencedirect.com/science/article/pii/S0030666509001315

92. Chang HS, Joko M, Song JS, Ito K, Inoue T, Nakagawa H. Ultrasonic bone curettage for optic canal unroofing and anterior clinoidectomy. Technical note. J Neurosurg. 2006 Apr;104(4):621–4.

93. Morishita Y, Konishi I, Noda Y, Mori T. [Usage of the CUSA (cavitron ultrasonic surgical aspirator) in radical surgery of cervical carcinoma of the uterus]. Gan To Kagaku Ryoho. 1987 May;14(5 Pt 2):1494–500.

94. Salami A, Dellepiane M, Salzano FA, Mora R. Piezosurgery in the excision of middle-ear tumors: effects on mineralized and non-mineralized tissues. Med Sci Monit [Internet]. 2007 Dec 1 [cited 2021 Nov 5];13(12):PI25–9. Available from: https://www.medscimonit.com/abstract/index/idArt/563740

95. Salami A, Vercellotti T, Mora R, Dellepiane M. Piezoelectric bone surgery in otologic surgery. Otolaryngol Head Neck Surg [Internet]. 2007 Mar 1 [cited 2021 Nov 5];136(3):484–5. Available from: https://doi.org/10.1016/j.otohns.2006.10.045

96. Murchison AP, Pribitkin EA, Rosen MR, Bilyk JR. The Ultrasonic Bone Aspirator in Transnasal Endoscopic Dacryocystorhinostomy: Ophthalmic Plastic and Reconstructive Surgery [Internet]. 2013 [cited 2019 Nov 8];29(1):25–9. Available from: https://insights.ovid.com/crossref?an=00002341-201301000-00007

97. Ali MJ, Ganguly A, Ali MH, Naik MN. Time taken for superior osteotomy in primary powered endoscopic dacryocystorhinostomy: is there a difference between an ultrasonic aspirator and a mechanical burr? International Forum of Allergy & Rhinology [Internet]. 2015 [cited 2021 Nov 5];5(8):764–7. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/alr.21522

98. Feng Y, Yu JG, Shi JL, Huang JH, Sun YL and Zhao Y (2012). A meta-analysis of primary external dacryocystorhinostomy with and without mitomycin C. Ophthalmic epidemiology [Internet]. 2012 Dec [cited 2022 Feb 4];19(6). Available from: https://pubmed.ncbi.nlm.nih.gov/23171205/

99. Görgülü O, Ozdemir S, Görgülü FF, Altin A, Selçuk T, Akbaş Y. Adjunctive use of mitomycin C in endoscopic revision dacryocystorhinostomy. B-ENT. 2012;8(2):123–6.

100. Cheng S, Feng Y, Xu L, Li Y, Huang J. Efficacy of mitomycin C in endoscopic dacryocystorhinostomy: a systematic review and meta-analysis. PLoS One. 2013;8(5):e62737.

101. Sousa TTS, Schellini SA, Meneghim RLFS, Cataneo AJM. Intra-Operative Mitomycin-C as Adjuvant Therapy in External and Endonasal Dacryocystorhinostomy: Systematic Review and Meta-Analysis. Ophthalmol Ther. 2020 Jun;9(2):305–19.

102. Xue K, Mellington FE, Norris JH. Meta-analysis of the adjunctive use of mitomycin C in primary and revision, external and endonasal dacryocystorhinostomy. Orbit. 2014 Aug;33(4):239–44.

103. Nair AG, Ali MJ. Mitomycin-C in dacryocystorhinostomy: From experimentation to implementation and the road ahead: A review. Indian J Ophthalmol. 2015 Apr;63(4):335–9.

104. Dolmetsch AM. Nonlaser endoscopic endonasal dacryocystorhinostomy with adjunctive mitomycin C in nasolacrimal duct obstruction in adults. Ophthalmology. 2010 May;117(5):1037–40.

105. Raghuwanshi SK, Raghuwanshi S, Agarwal M, Batni G. Primary Endonasal DCR Without Stent: Our Experience and Case Series Analysis. Indian J Otolaryngol Head Neck Surg [Internet]. 2015 Sep [cited 2022 Jan 11];67(3):271–4. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4575663/

106. Chin J, Lam V, Chan R, Li CL, Yeung L, Law A, et al. Comparative study of stenting and ostium packing in Endoscopic Dacryocystorhinostomy for Primary

Acquired Nasolacrimal Duct Obstruction. Sci Rep [Internet]. 2020 Jan 8 [cited 2022 Feb 4];10(1):46. Available from: https://www.nature.com/articles/s41598-019-57019-0

107. Dalmia D, Sapre A, Katakdhond H, Patni P, Davange N, Goyal R, et al. Is Stenting Really Necessary in Primary Endonasal DCR—Our Experience. Indian Journal of Otolaryngology and Head & Neck Surgery. 2021 Jan 3;

108. Raghav. A comparative study of the results of endoscopic dacryocystorhinostomy with and without stent placement [Internet]. [cited 2022 Feb 4]. Available from: https://www.marinemedicalsociety.in/article.asp?issn=0975-3605;year=2018;volume=20;issue=2;spage=135;epage=137;aulast=Raghav

109. Mohamad S, Khan I, Shakeel M, Nandapalan V. Long-term results of endonasal dacryocystorhinostomy with and without stenting. Ann R Coll Surg Engl [Internet]. 2013 Apr [cited 2022 Feb 4];95(3):196–9. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4165244/

110. Nasolacrimal Stents: An Introductory Guide [Internet]. [cited 2022 Feb 4]. Available from: https://webeye.ophth.uiowa.edu/eyeforum/tutorials/Stents/index.htm

111. Callejas CA, Tewfik MA, Wormald P-J. Powered endoscopic dacryocystorhinostomy with selective stenting. The Laryngoscope [Internet]. 2010 [cited 2022 Feb 5];120(7):1449–52. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/lary.20916

112. Buchan J, Cazabon SJ, Morrell AJ, Woodhead J. Learning curve in endonasal dacryocystorhinostomy. American Journal of Ophthalmology [Internet]. 2003 Sep 1 [cited 2021 Oct 30];136(3):579–80. Available from: https://www.sciencedirect.com/science/article/pii/S0002939403004203

113. Thomas R, Thomas S, Braganza A, Muliyil J. Evaluation of the role of syringing prior to cataract surgery. Indian J Ophthalmol. 1997 Dec;45(4):211–4.

114. Penttilä E, Smirnov G, Tuomilehto H, Kaarniranta K, Seppä J. Endoscopic dacryocystorhinostomy as treatment for lower lacrimal pathway obstructions in adults: Review article. Allergy Rhinol (Providence) [Internet]. 2015 [cited 2022 Feb

5];6(1):e12–9. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4388871/

115. Nussbaumer M, Schreiber S, Yung MW. Concomitant nasal procedures in endoscopic dacryocystorhinostomy. J Laryngol Otol [Internet]. 2004 Apr [cited 2022 Jan 1];118(4):267–9. Available from: https://www.cambridge.org/core/product/identifier/S002221510400074X/type/journal_article

116. Kamel R, Gamal El-deen H, El-deen YS, El-hamshary M, Assal A, Farid M, et al. Manometric Measurement of Lacrimal Sac Pressure after Endoscopic and External Dacryocystorhinostomy. Acta Oto-Laryngologica [Internet]. 2003 Feb 1 [cited 2022 Jan 1];123(2):325–9. Available from: https://doi.org/10.1080/00016480310001196

117. Whittet HB, Shun-Shin GA, Awdry P. Functional endoscopic transnasal dacryocystorhinostomy. Eye (Lond). 1993;7 (Pt 4):545–9.

118. Gur MH, Yuca K, Cınal A, Kıroglu AF, Varsak YK, Cankaya H. The Clinical Results of Endoscopic Dacryocystorhinostomy. Electron J Gen Med [Internet]. 2012 Apr 10 [cited 2022 Jan 1];9(2). Available from: http://www.ejgm.co.uk/article/the-clinical-results-of-endoscopic-dacryocystorhinostomy-6958

119. Ingale MH, Shinde VV, Kumar AS, Singh HR. Clinical assessment and follow up of post-operative outcomes in endonasal dacryocystorhinostomy: our experience. Int J Otorhinolaryngol Head Neck Surg [Internet]. 2018 Aug 25 [cited 2022 Jan 2];4(5):1225. Available from: http://www.ijorl.com/index.php/ijorl/article/view/1082

120. Ali MJ, Iram S, Ali MH, Naik MN. Assessing the Outcomes of Powered Endoscopic Dacryocystorhinostomy in Adults Using the Lacrimal Symptom (Lac-Q) Questionnaire. Ophthalmic Plast Reconstr Surg. 2017 Feb;33(1):65–8.

121. Wk W, S D, S N. Comparison between endoscopic and external dacryocystorhinostomy by using the Lacrimal Symptom Questionnaire: A pilot study. American journal of rhinology & allergy [Internet]. 2018 Jan 1 [cited 2022 Jan 12];32(1). Available from: https://pubmed.ncbi.nlm.nih.gov/29336290/

ANNEXURES

Appendix – A

IEC Certificate

All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/2038 Date: 01/01/2020

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2019-20/982**

Project title: **"Surgical outcomes following the use of cavitron ultrasonic surgical aspirator (CUSA) versus the use of Kerrison's bone punch in patients with chronic dacryocystitis undergoing endoscopic endonasal dacryocystorhinostomy"**

Nature of Project:	**Research Project**
Submitted as:	**M.S. Dissertation**
Student Name:	**Dr.Sanchari Nandi**
Guide:	**Dr.Bikram Choudhary**
Co-Guide:	**Dr.Kavita Bhatnagar, Dr.Amit Goyal, Dr.Kapil Soni & Dr.Darwin Kaushal**

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on **23-12-2019** and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Enclose:
1. Annexure I

Annexure 1

Institutional Ethics Committee
All India Institution of Medical Sciences, Jodhpur

Meeting of Institutional Ethics committee held on **23-12-2019 at 10:00** AM at Committee Room, Admin Block AIIMS Jodhpur.

Following members were participated in the meeting:-

S/No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1.	Dr. F.S.K Barar	MBBS, MD (Pharmacology)	**Chairman**
2.	Justice N.N Mathur	LLB	Legal Expert
3.	Dr. Varsha Sharma	M.A (Sociology)	Social Scientist
4.	Mr. B.S.Yadav	B.Sc., M.Sc. (Physics), B.Ed.	Lay Person
5.	Dr. K.R.Haldiya	MD (General Medicine)	Clinician
6.	Dr. Arvind Mathur	MBBS, MS (General Medicine)	Clinician
7.	Dr. Surajit Ghatak	MBBS, MS (Anatomy)	Basic Medical Scientist
8.	Dr. Vijaya Lakshmi Nag	MBBS, MD (Microbiology)	Basic Medical Scientist
9.	Dr. Sneha Ambwani	MBBS, MD (Pharmacology)	Basic Medical Scientist
10.	Dr. Kuldeep Singh	MBBS, MD (Paediatric), DM (General Medicine)	Clinician
11.	Dr. Abhinav Dixit	MBBS, MD (Physiology), DNB (Physiology)	Basic Medical Scientist
12.	Dr. Pradeep Kumar Bhatia	MBBS, MD (Anaesthesiology)	Clinician
13.	Dr. Tanuj Kanchan	MBBS, MD (Forensic Medicine)	Basic Medical Scientist
14.	Dr. Pankaj Bhardwaj	MBBS, MD (CM&FM)	Clinician
15.	Dr. Praveen Sharma	M.Sc., Ph.D. (Biochemistry)	Member Secretary

Dr. Praveen Sharma

Member Secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Appendix-B

All India Institute of Medical Sciences, Jodhpur

Serial no._____

INFORMED CONSENT FORM

Subject: Consent for participation in study

Participant's registration number: _____.

I declare that on date ..... all the details of this information sheet given to me has been explained in my language. I am told that in this process, I am required to provide personal data to fill a Proforma that would be used for the study. This research is being done for studies and treatment. I understand that all information related to me in this research will be kept by the responsible person of AIIMS Jodhpur. I allow them to see all the information related to me. I have been told that all the information related to me will be kept confidential. I have also been told that the results of this research can be published in any book or journal and can be displayed in any conference. I have also been told that my name or any other identity will not be used without my consent. I know that I am participating in this research with my consent and I can refuse to participate in this research at any time without any reason.

I agree to participate in this research.

(Signature) Date:

Place:

Name of the Participant: _____

Son / Daughter / Spouse of: _____

Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

1) Witness – 1 2) Witness – 2

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Name: Name:

Address: Address:

Signatures of the principal investigator: Dr. Sanchari Nandi

Place:

Date:

Appendix-B

सीरीयल नम्बर।____

सू चत सहमति पत्र

अ खल भारतीय आयु र्वज्ञान संस्थान जोधपुर
वषय: अध्ययन में भागीदारी के लए सहमति
प्रतिभागी का पंजीकरण संख्या: _____।

मैं घोषणा करता हूं क ..... तारीख को मुझे दी गई यह सूचना पत्र मेरी भाषा में समझाया गया है। मुझे बताया गया है क इस प्र क्रया में मुझे एक प्रदर्शन को भरने के लए व्यक्तिगत डेटा प्रदान करने की आवश्यकता है जिसका उपयोग अध्ययन के लए कया जाएगा। यह शोध अध्ययन और उपचार के लए कया जा रहा है। मैं समझता हूं क इस शोध में मुझसे संबं धत सभी जानकारी एम्स जोधपुर के जिम्मेदार व्यक्ति द्वारा रखी जाएगी। मैं उन्हें मुझसे संबं धत सभी जानकारी देखने की अनुमति देता हूं। मुझे बताया गया है क मुझसे संबं धत सभी जानकारी गोपनीय रखी जाएगी। मुझे यह भी बताया गया है क इस शोध के परिणाम कसी पुस्तक या पत्रिका में प्रका शत कए जा सकते हैं और कसी भी सम्मेलन में प्रद र्शत कए जा सकते हैं। मुझे यह भी बताया गया है क मेरी सहमति के बिना मेरा नाम या कोई अन्य पहचान का उपयोग नहीं कया जाएगा। मुझे पता है क मैं इस शोध में अपनी सहमति से भाग ले रहा हूं और मैं बिना कसी कारण के कसी भी समय इस शोध में भाग लेने से इंकार कर सकता हूं।
मैं इस शोध में भाग लेने के लए सहमत हूं।

(हस्ताक्षर)

तारीख:

जगह:
प्रतिभागी का नाम: _____
पुत्र / बेटी / पति / पत्नी: _____
पूरा डाक पता: _____
यह प्रमा णत करना है क उपर्युक्त सहमति मेरी उपस्थिति में प्राप्त की गई है।

1) साक्षी - 1	2) साक्षी - 2
नाम:	नाम:
पता :	पता:

मुख्य जांचकर्ता के हस्ताक्षर: डॉ संचारी नंदी
जगह:
तारीख :

Appendix-C

Department of Otorhinolaryngology

All India Institute of Medical Sciences, Jodhpur

PATIENT INFORMATION SHEET

TITLE: Surgical Outcomes following the use of Cavitron Ultrasonic Surgical Aspirator (CUSA) versus the use of Kerrison's bone punch in patients with chronic dacryocystitis undergoing endoscopic endonasal dacryocystorhinostomy

This study requires your detailed information for the assessment to be done to proceed in this study. You will be subjected to detailed clinical assessment and routine workup and will be followed up till the commencement of confirmatory treatment. This study would require these details of illness and related factors that would contribute to measurement of the parameters. The expected duration of your stay in the Department of Otorhinolaryngology, AIIMS, Jodhpur will be about 4 days and you have to visit the Centre at mentioned follow up accordingly. You are expected to attend to all the questions put in front of you in depending on the mutual comfort of you and the investigator. There are no obvious, expected or known adverse effects to the patient due to this study. You have been invited to take part in a study, which will help us in better understanding the effects of your surgery/procedure. You are free to withdraw from the study at any time and this will not have any negative implication on you/your ward's future treatment in the hospital.

Contact Person for further queries:

Dr.Sanchari Nandi

Appendix-C

ऑटोरहिनोलेरिंगोलोजी वभाग

अ खल भारतीय आयु र्वज्ञान संस्थान, जोधपुर

सूचनापत्र

टाइटल: क्रोनिक डॉक्रोसीसटाइटिस के मरीज़ में एन्डोस्कोपिक एन्डोनासाल डी. सी. आर की सर्जरी में कभित्रों अल्ट्रासोनिक सर्जिकल एस्पिरेटर (कुसा) और केरीसन बोन पंच के परिणामो के तुलना ।

इस अध्ययन में आगे बढ़ने के लए मूल्यांकन के लए इस अध्ययन के लए आपकी वस्तृत जानकारी और पछले उपचार की मांग की आवश्यकता है। आपको वस्तृत नैदानिक मूल्यांकन और निय मत कार्यप्रणाली के अधीन कया जाएगा और पुष्टि उपचार के शुरू होने तक इसका पालन कया जाएगा। इस अध्ययन में बीमारी और संबं धत कारकों के इन ववरणों की आवश्यकता होगी जो देरी के माप में योगदान देंगे। ओटोरिनोलैरिंजोलॉजी वभाग में आपके प्रवास की अपे क्षत अव ध, एम्स, जोधपुर लगभग **चार दिन** होगी और आपको तदनुसार उल्लि खत अनुवर्ती केंद्र में जाना होगा। आपको और जांचकर्ता के आपसी आराम के आधार पर आप के सामने रखे गए सभी प्रश्नों में भाग लेने की उम्मीद है। इस अध्ययन के कारण रोगी पर कोई स्पष्ट, अपे क्षत या ज्ञात प्रतिकूल प्रभाव नहीं हैं। आपको एक अध्ययन में भाग लेने के लए आमंत्रित कया गया है, जो हमें **इलाज /ऑपरेशन को** बेहतर समझने में मदद करेगा। आप कसी भी समय अध्ययन से वापस लेने के लए स्वतंत्र हैं और अस्पताल में आपके / आपके वार्ड के भ वष्य के उपचार पर इसका कोई नकारात्मक प्रभाव नहीं होगा।

अधिक प्रश्नों के लिए संपर्क करें

डॉ संचारी नंदी

Appendix-D

Department of Otorhinolaryngology

All India Institute of Medical Sciences, Jodhpur

INITIAL EVALUATIONS

A. PATIENT DETAILS:

1. **Name:**
2. **Age:**
3. **Sex:**
4. **Occupation:**
5. **Address:**

6. **Contact no.:**
7. **Date of examination:**

B. HISTORY:

C. PAST HISTORY:

D. PERSONAL HISTORY:

E. CLINICAL EXAMINATION:

I. GENERAL EXAMINATION:

i. **Built:**

ii. **Weight:**

iii. **Height:**

iv. **Pulse rate:**

v. **Blood pressure:**

vi. **Temperature:**

II. SYSTEMIC EXAMINATION:

i. **Cardiovascular System:**

ii. **Central nervous system:**

iii. **Gastrointestinal system:**

iv. **Respiratory system:**

F. OTHER RELEVANT POINTS:

Appendix-E

Department of Otorhinolaryngology

All India Institute of Medical Sciences, Jodhpur

PRE-OPERATIVE ASSESSMENT

1. **Schirmer's Test (pre-operative):**
2. **ROPLAS: Positive / Negative**
3. **Syringing:**
4. **Lacrimal symptom questionnaire (LAC-Q):**

Lac-Q - The Lacrimal Symptom Questionnaire **Name:** **Number:** **Date:**

Social and lifestyle impact of tear duct problem

Which of these five statements is true about the tear duct problem overall in the last eight weeks?
Please tick the box next to any true statement.

- Friends or family have commented about the watery eye problem. ☐
- The watery eye problem has caused embarrassment in company. ☐
- The watery / sticky eye problem has interfered with everyday activity, for example (underline each that applies):
  Reading .. Driving .. Wearing make-up
  Wearing glasses .. Hobbies
  Other activity (specify): ☐
- The vision is sometimes blurred because of the watery / sticky eye problem. ☐
- Medical attendance: visit to the family doctor's surgery, or the hospital eye clinic, because of tear duct problem. ☐

(Scoring: score one point for each box ticked, maximum score =5)

Total score for social impact: ☐

Problems with each eye separately

For each of the four problems (watery eye, pain, sticky eye or swelling), put a tick in the box next to the statement which best describes the situation over the last eight weeks.
Use the left hand column for the left eye, and the right hand column for the right eye.

	Left		Right
• Watery eye			
No watery eye problem	☐	0	☐
The eye waters occasionally, mainly outdoors	☐	1	☐
Troublesome watering of the eye, indoors and outdoors, some days	☐	2	☐
Troublesome watering of the eye most days	☐	3	☐
Troublesome watering of the eye every day	☐	4	☐
• Pain in or around the eye; soreness of eyelids			
No pain	☐	0	☐
Some pain or soreness, but has not sought medical advice or treatment	☐	1	☐
Pain or soreness, has used prescription eyedrops	☐	2	☐
Painful and swollen (lacrimal abscess), requiring antibiotics or surgical drainage	☐	4	☐
• Sticky eye			
No problem with sticky eye	☐	0	☐
The eye is sometimes sticky in the mornings	☐	1	☐
The eye is sticky every day in the mornings	☐	2	☐
The eye has sticky or mucous discharge throughout the day	☐	3	☐
There is infected discharge leaking through the skin of the lower eyelid (fistula)	☐	4	☐
• Swelling or lump at the medial canthus (mucocoele)			
No swelling or lump	☐	0	☐
Swelling present, but only intermittently	☐	1	☐
Swelling present all the time	☐	2	☐
(Scoring: use numbers in central column)	**Total scores for each eye:**		☐ ☐

Lac-Q score (sum of three total scores): ☐

Appendix-F

Department of Otorhinolaryngology

All India Institute of Medical Sciences, Jodhpur

PER-OPERATIVE ASSESSMENT

(SUREGON'S PROFORMA)

Surgeon's Post-operative Experience:

Evaluations	Surgical Approach By	
	CUSA	KERRISON'S BONE PUNCH
Intra-Operative duration (from time of incision to packing in minutes)		
Per-Op adequacy of lacrimal sac exposure	Adequate/ Inadequate	Adequate/ Inadequate
Ease of use		

Appendix-G

Department of Otorhinolaryngology

All India Institute of Medical Sciences, Jodhpur

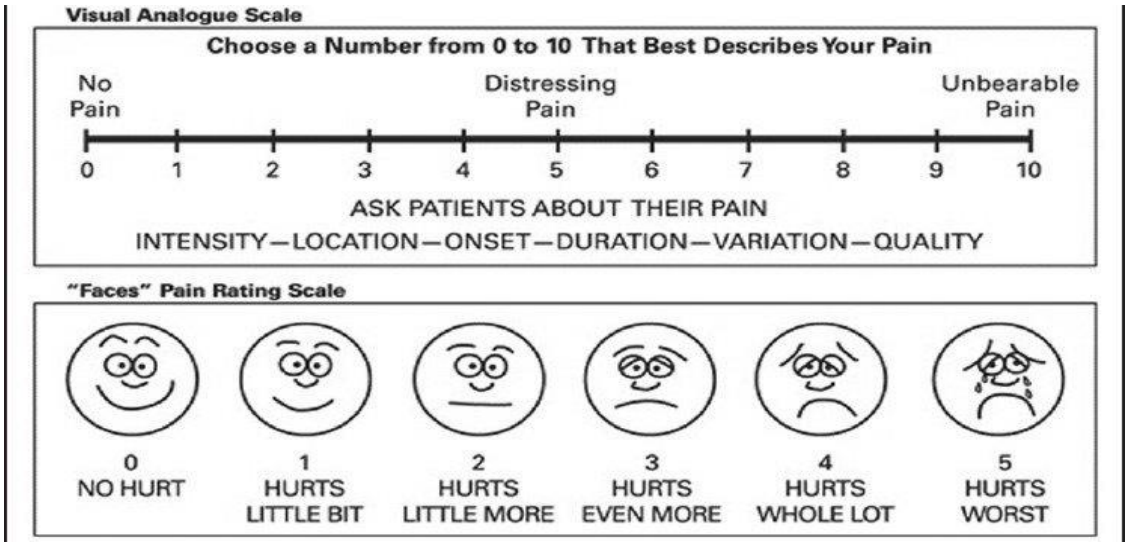
POST- OPERATIVE ASSESSMENT

Subjective Assessment:

1. **Pain:**

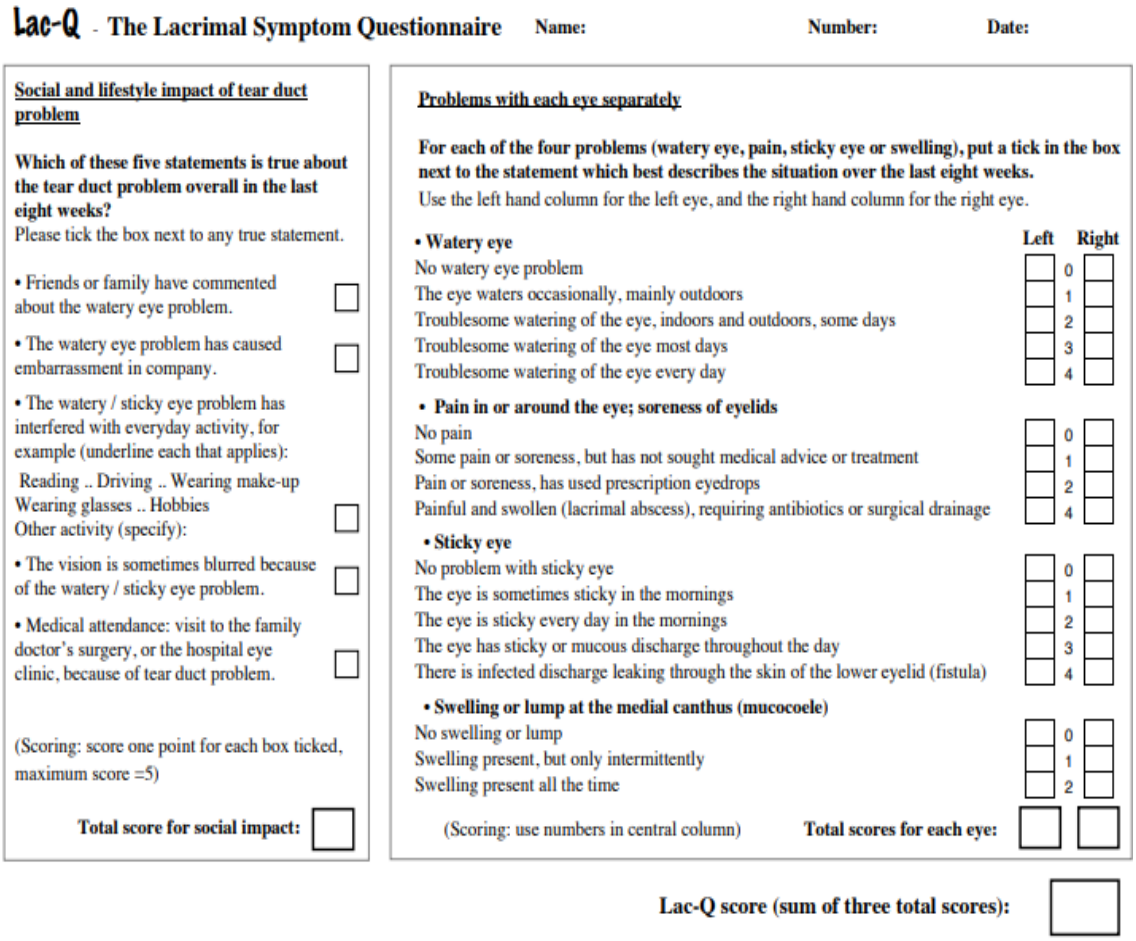
a) **Visual Analogue Scale:**

b) **"Faces" Pain Rating Scale:**



2. **Epiphora: Present / Absent**

3. LAC-Q questionnaire (post-operative)



Lac-Q - The Lacrimal Symptom Questionnaire **Name:** **Number:** **Date:**

Social and lifestyle impact of tear duct problem

Which of these five statements is true about the tear duct problem overall in the last eight weeks?
Please tick the box next to any true statement.

- Friends or family have commented about the watery eye problem. ☐
- The watery eye problem has caused embarrassment in company. ☐
- The watery / sticky eye problem has interfered with everyday activity, for example (underline each that applies):
  Reading .. Driving .. Wearing make-up
  Wearing glasses .. Hobbies
  Other activity (specify): ☐
- The vision is sometimes blurred because of the watery / sticky eye problem. ☐
- Medical attendance: visit to the family doctor's surgery, or the hospital eye clinic, because of tear duct problem. ☐

(Scoring: score one point for each box ticked, maximum score =5)

Total score for social impact: ☐

Problems with each eye separately

For each of the four problems (watery eye, pain, sticky eye or swelling), put a tick in the box next to the statement which best describes the situation over the last eight weeks.
Use the left hand column for the left eye, and the right hand column for the right eye.

	Left		Right
• Watery eye			
No watery eye problem	☐	0	☐
The eye waters occasionally, mainly outdoors	☐	1	☐
Troublesome watering of the eye, indoors and outdoors, some days	☐	2	☐
Troublesome watering of the eye most days	☐	3	☐
Troublesome watering of the eye every day	☐	4	☐
• Pain in or around the eye; soreness of eyelids			
No pain	☐	0	☐
Some pain or soreness, but has not sought medical advice or treatment	☐	1	☐
Pain or soreness, has used prescription eyedrops	☐	2	☐
Painful and swollen (lacrimal abscess), requiring antibiotics or surgical drainage	☐	4	☐
• Sticky eye			
No problem with sticky eye	☐	0	☐
The eye is sometimes sticky in the mornings	☐	1	☐
The eye is sticky every day in the mornings	☐	2	☐
The eye has sticky or mucous discharge throughout the day	☐	3	☐
There is infected discharge leaking through the skin of the lower eyelid (fistula)	☐	4	☐
• Swelling or lump at the medial canthus (mucocoele)			
No swelling or lump	☐	0	☐
Swelling present, but only intermittently	☐	1	☐
Swelling present all the time	☐	2	☐
(Scoring: use numbers in central column)	**Total scores for each eye:**	☐	☐

Lac-Q score (sum of three total scores): ☐

Objective Assessment:

1. **Schirmer's Test (post-operative):**

2. **Fluorescein Dye Dependent Test (FDDT):**

Appendix-H

OUTCOME VARIABLES:

	VARIABLES	POD-0	POD-7	1 MONTH POST OPERATIVE PERIOD	3 MONTH POST OPERATIVE PERIOD
SUBJECTIVE ASSESSMENT	Pain/ discomfort in the operated site	VAS: FACES pain rating scale:	VAS: FACES pain rating scale:	VAS: FACES pain rating scale:	VAS: FACES pain rating scale:
	Epiphora	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
	LAC-Q questionnaire				
OBJECTIVE ASSESSMENT	Schirmer Test				
	Fluorescein Dye Dependent Test (FDDT)				