

Randomized Control Trial to Compare Minimally Invasive Strabismus Surgery Versus Traditional Limbal Approach Regarding Postoperative Ocular Inflammation in Suez Canal University Hospital

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Running title: Invasive strabismus surgery versus traditional limbal approach regarding postoperative ocular inflammation.

Abstract

Purpose: To achieve a successful postoperative ocular alignment in strabismus surgery with the least postoperative ocular inflammation using two different surgical techniques; the minimally invasive approach (MISS) and the traditional limbal approach.

Methods: This study included 22 patients divided into 2 groups, group A (15 eyes of 11 patients) operated by MISS and group B (18 eyes of 11 patients) operated using the traditional limbal approach. Alignment and ocular inflammation as well as complications were recorded at the 1st day, 1st week and the 1st month postoperatively. Postoperative ocular inflammation scored and compared to a published score scale to grade the conjunctival swelling and redness in the University Eye Clinic in Giessen, Germany”.

Results: postoperative ocular inflammation was less pronounced in group A than in group B, both groups showed no difference in postoperative ocular alignment and no scleral perforation or other serious complications were observed in both groups.

Conclusions: This study indicates that MISS induces less postoperative ocular inflammation compared to the traditional limbal approach.

Keywords: Minimally invasive approach strabismus surgery (MISS), traditional limbal approach, postoperative ocular alignment and postoperative ocular inflammation.

Introduction

In many fields of ophthalmology, minimal access surgery has gained popularity such as, phacoemulsification, sutureless vitrectomies, noninvasive eyelid operation and new mini- stents and implants in glaucoma operations. These procedures are considered minimally invasive surgical treatments that allow for early rehabilitation. Also in strabismus surgery, minimally invasive approach may provide a valuable alternative and can offer more postoperative comfort and equally successful results compared to conventional squint surgery. One of the important steps in strabismus surgery is the choice of conjunctival incision.

Several approaches have been described, which provide convenient access and preferred exposing to the eye muscles¹⁻⁶.

The first technique in conjunctival incision which was described by Swan and Talbott¹ is an incision just behind the insertion of the rectus muscles. However, it is nowadays used only for the vertical rectus muscles, especially the superior one, to keep conjunctival tissue for possible future operations (e.g., trabeculectomy). Strabismus operation is not different. One of the main factors influencing patient quality of life, cosmeses and the function of the operated muscle is the size of the conjunctival incision made during strabismus surgery. As such, some

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surgeons have attempted to limit the size of the incision in order to enhance postoperative outcomes⁷.

The second technique is a limbal approach which was first described by Harms,² and later popularized by Von Noorden.³ The majority of surgeons still use it in squint surgery. This approach allowed full visualization of the operated muscle and avoided bleeding and immoderate scarring over the muscle tendon. But this technique can lead to some of common complications after surgery like bulbar conjunctival redness, discomfort, corneal dellen, and prolapse of the Tendon's capsule.

The third technique is an alternative fornix approach which was described by Parks⁴ Although this technique has less postoperative discomfort, but we cannot perform it in children due to their notable capsule of Tenon, especially in cases of large pre-existing scarring, and in elderly patients with inflexible conjunctiva.

The fourth technique is single snip with the incision placed in a radial shape which was described by Velez⁵, while Gobin and Bierlaagh⁶ developed later, the fifth approach is two snip radial incisions for exposing the rectus muscle, one along the upper muscle margin and the other along the lower muscle margin to perform hang-back recessions. This technique further modified by Mojon in 2007, who nominates it as minimally invasive strabismus surgery (MISS)⁷. Then further adaptation and development for this technique have occurred to allow performing all types of strabismus surgeries.⁷⁻¹⁰

Kaup et al., in (2011) evaluated which factors lead to an intraoperative conversion to the usual limbal approach in MISS from 2003 to 2007. Nine hundred eighty two eyes that were included in the study were operated by one surgeon. The overall conversion rate decreased over time, from 8.4% in 2003 to 0.4% in 2007 with increasing surgical experience. He found that the higher conversion rate was in muscle resection surgery; while the age, the motility of eye and revision surgery had no significant influence on an intraoperative conversion.⁹ So it is rapidly becoming the norm in medicine.¹⁰

MISS can be used to perform all types of strabismus surgery, namely rectus muscle recessions, resections, plication's, transpositions, adjustable sutures, retroequatorial myopexy, oblique muscle recessions, reoperations, or plication's even in the presence of limited motility.¹⁰⁻²²

Asproudis et al., in (2017) reviewed the principles and different techniques employed to perform minimally invasive strabismus surgeries (MISS). In these procedures, squint operation is implemented through keyhole openings, thus minimizing the risk of corneal complications after surgery, reducing patients discomfort and maintaining better muscle function.¹⁰

To switch from traditional strabismus surgery performed with magnifying glasses to MISS with the operating microscope, Surgeons should first only switch to the operating microscope then after mastering the use of microscope, they can switch to MISS, Starting with primary horizontal rectus muscle displacements of 4 mm or less. The age of patients should be between 14 and 40 years. In younger age, surgery will be more difficult due to the thick Tenons capsule; also, in older patients the risk of conjunctival tear will be increased due to reduced conjunctival elasticity, while introducing or manipulation instruments through the keyhole openings.¹⁹

Another advantage of MISS approach is greatly reduced the risk of ischemia in anterior segment of the eye after surgery comparison the traditional approach that dissects the limbal conjunctiva.⁽¹⁵⁾ Of note, no randomized clinical trials were conducted to compare results of eye alignment results with MISS versus traditional approaches. Thus, to determine the exact role and value of MISS in squint operations, more controlled evidence is still needed.¹⁰

This study was conducted to compare the new MISS and the traditional limbal approach strabismus surgery in correction of horizontal strabismus regarding postoperative ocular alignment and ocular inflammation.

Patients and Methods

The study involved 22 patients came to Suez Canal University hospital with concomitant horizontal strabismus from 1/6/2018 to 30/6/2019.

Inclusion criteria included patients with only concomitant horizontal strabismus (congenital or acquired) for surgical intervention. The range of patient s age was from 1 to 35 year. *Exclusion criteria* included patients with concomitant horizontal strabismus fully corrected by glasses, patients with paralytic strabismus, patients with previous strabismus surgery on the muscles planned to be operated, patients who need retro-equatorial fixation sutures or muscle transpositions, simultaneous vertical rectus or oblique muscle surgery, patients with allergic conjunctivitis, dry eyes or other conjunctival inflammatory disorders and patients with bleeding tendencies.

Patients and/or who are responsible for them signed an informed consent after complete discussion of the procedure before participation in the study conformed to local laws and in compliance with the principles of the Declaration of Helsinki. The research protocol was approved by the Faculty of Medicine Ethics Committee, Suez Canal University, Ismailia, Egypt.

The patients who have fulfilled the inclusion criteria were listed then randomly allocated through blocking (6 blocks) into two groups according to the surgical technique performed; patients who underwent MISS and patients who underwent limbal approach strabismus surgery. Under general anesthesia, all patients were operated by using the surgical microscope. Patients of the two groups were submitted for follow up visits at 1st day, 1st week, and 1st month to evaluate postoperative ocular alignment and ocular inflammation.

In patients with central fixation angles of the strabismus were measured with the alternating cover test, otherwise, angles the strabismus were determined by centralizing the corneal reflex with using prisms in front of the fixating eye (Krimsky test) or by Hirschberg test in uncooperative patients. Successful postoperative motor alignment was defined as esodeviation

between 1 and 10 ΔD, orthotropia or exodeviation between 1 and 10 ΔD during the follow-up, at the 1st month postoperatively.¹³

Postoperative ocular inflammation including lid swelling, conjunctival injection and swelling were graded to" Grade 0 "hardly visible" Redness and swelling of eyelid and conjunctiva are not visible from 1 meter, Grade 1 "discrete" minimal redness or swelling of conjunctiva is not visible from 1 meter or ptosis of not more than 1 mm, Grade 2 "moderate" immediate visibility of redness from 1 meter or ptosis of more than 1mm, Grade 3 "severe" conjunctival chemosis or subconjunctival hemorrhage, ptosis of more than 3mm or lid hemorrhage".^{14,15}

Briefly, MISS was performed "by applying a limbal traction suture to rotate the eye, 2 small radial cuts of about 1 mm less than the planned muscle displacement are performed, one parallel to the superior and the other parallel to the inferior muscle margin. With blunt Wescott scissors, the episcleral tissue is divided from the muscle sheath and the sclera. After preparation of the muscle margins and dissection of the check ligaments, the muscle is hooked. To perform a recession, 2 sutures (Vicryl 6-0) are applied to the superior and inferior borders of the muscle tendon close to the insertion. After detachment of the tendon using Wescott scissors the tendon is reattached with the 2 sutures to the sclera at the desired distance. To perform recession: Vicryl sutures (6-0) are placed at the upper and lower poles of the muscle insertion, locked and secured. The muscle is cut at the insertion and the muscle is carefully resutured at sclera at the planned position after measuring the distance with caliber. To perform resection: Vicryl sutures (6-0) are passed at the upper and lower pole of the muscle at the planned position for resection, locked and secured. The muscle is divided in front of the suture level for resection. To perform a plication, 2 sutures (Vicryl 6-0) are applied to the upper and lower borders of the muscle at the desired distance from the insertion. The sutures are passed at the superior and inferior tendon insertions, respectively, and the muscle is plicated over an iris spatula inserted between the tendon and the

sutures. Finally, the Tenon capsule and conjunctiva are closed by 2 sutures (Vicryl 8-0) at each cut".¹⁶

Traditional limbal approach was performed by applying a limbal traction suture to rotate the eye, a limbal opening with two radial relaxing incisions of 3 mm is performed. With blunt Wescott scissors the episcleral tissue is separated from the muscle sheath and the sclera. When the borders of the muscles have been identified, the muscle is hooked. Then, a meticulous dissection of the check ligaments and intramuscular membrane is performed. Then, a recession, resection or plication is performed in the same manner as described for the MISS technique. The surgical procedure is finished by readapting the conjunctiva, applying four to six sutures (Vicryl Rapid 8-0, Ethicon, Switzerland).^{3&7}

At the end of surgery, TobraDex ointment was applied. No eye patch was used. For the first 2 weeks after surgery, application of TobraDex suspension three times daily and TobraDex ointment in the evening was prescribed.

Statistical Methods

Data were entered into the Statistical Package for Social Sciences (SPSS, version 24, SPSS, Chicago, IL, U.S.A.) The correlation between proportion variables was calculated by using the Chi Square χ^2 test and the student's t-test for means variables in 2 groups with 95 % confidence level and P value <0.05.

Results

The mean age of the study population who underwent minimally invasive strabismus surgery was 13.1 ± 10.17 years ranging from 2 years to 35 years, while the mean age of the study population who underwent limbal approach strabismus surgery was 9.9 ± 6.45 years ranging from 1 year to 23 years.

The study involved both male (50%) and female (50%) patients. (72.1%) of the male patients were operated using the limbal approach and (27.9%) were operated using the MISS, while (72.1%) of the female patients were operated using MISS and (27.9%) were operated using the limbal approach.

45.5% of patients underwent limbal approach strabismus surgery were complaining of alternating esotropia, 18.2% alternating exotropia and 36.4% were complaining of right exotropia, while 18.2% of patients underwent MISS were complaining of alternating esotropia, 27.3% alternating exotropia, 9.1% left esotropia, 27.3% left exotropia and 18.2% were complaining of right esotropia.

The mean amount of ocular deviation in patients who underwent Limbal approach strabismus surgery was $41.63 \pm 13.18 \Delta D$ ranging from 18-50 ΔD , which was less than the mean amount of ocular deviation in patients underwent MISS that was $42.91 \pm 12.37 \Delta D$ ranging from 20-50 ΔD .

The mean time of surgical procedure in patients who underwent Limbal approach strabismus surgery was 35 ± 20 minutes ranging from 30-70 minutes, which was less than the mean time of surgical procedure in patients underwent MISS that was 38 ± 18 minutes ranging from 35-75 minutes. The difference in the surgical time between both techniques was statistically insignificant ($P > 0.05$).

There was no statistical difference in postoperative ocular alignment between the 2 groups, as 10 patients (90.9%) who underwent limbal approach strabismus surgery had successful postoperative alignment, and only one patient (9.1%) had a residual angle $>10 \Delta D$; it was the same with patients who underwent MISS (Figure 1).

As shown in Table 1, 2 and 3, ocular inflammation at the follow up visits was found to be more profound in patients who underwent limbal approach strabismus surgery as compared to MISS (comparison of ocular inflammation; $p < 0.05$ for MISS vs. limbal opening plication), (Figure 2A & 2B).

No serious intraoperative or postoperative complications were observed in both groups.

Table1: Post-operative ocular inflammation at 1st day.

| Inflammation score | MISS (n = 15 eyes) | Limbal (n =18 eyes) | P |
|--------------------|--------------------|---------------------|-------|
| 0 | 0 | 0 | <0.05 |
| 1 | 4 | 0 | |
| 2 | 7 | 8 | |
| 3 | 4 | 10 | |

Table2: Post-operative inflammation at 1st week.

| Inflammation score | MISS (n = 15 eyes) | Limbal (n =18 eyes) | P |
|--------------------|--------------------|---------------------|-------|
| 0 | 3 | 0 | <0.05 |
| 1 | 8 | 6 | |
| 2 | 4 | 12 | |
| 3 | 0 | 0 | |

Table3: Post-operative ocular inflammation at 1st month.

| Inflammation score | MISS (n = 15 eyes) | Limbal (n =18 eyes) | P |
|--------------------|--------------------|---------------------|-------|
| 0 | 14 | 9 | <0.05 |
| 1 | 1 | 7 | |
| 2 | 0 | 2 | |
| 3 | 0 | 0 | |

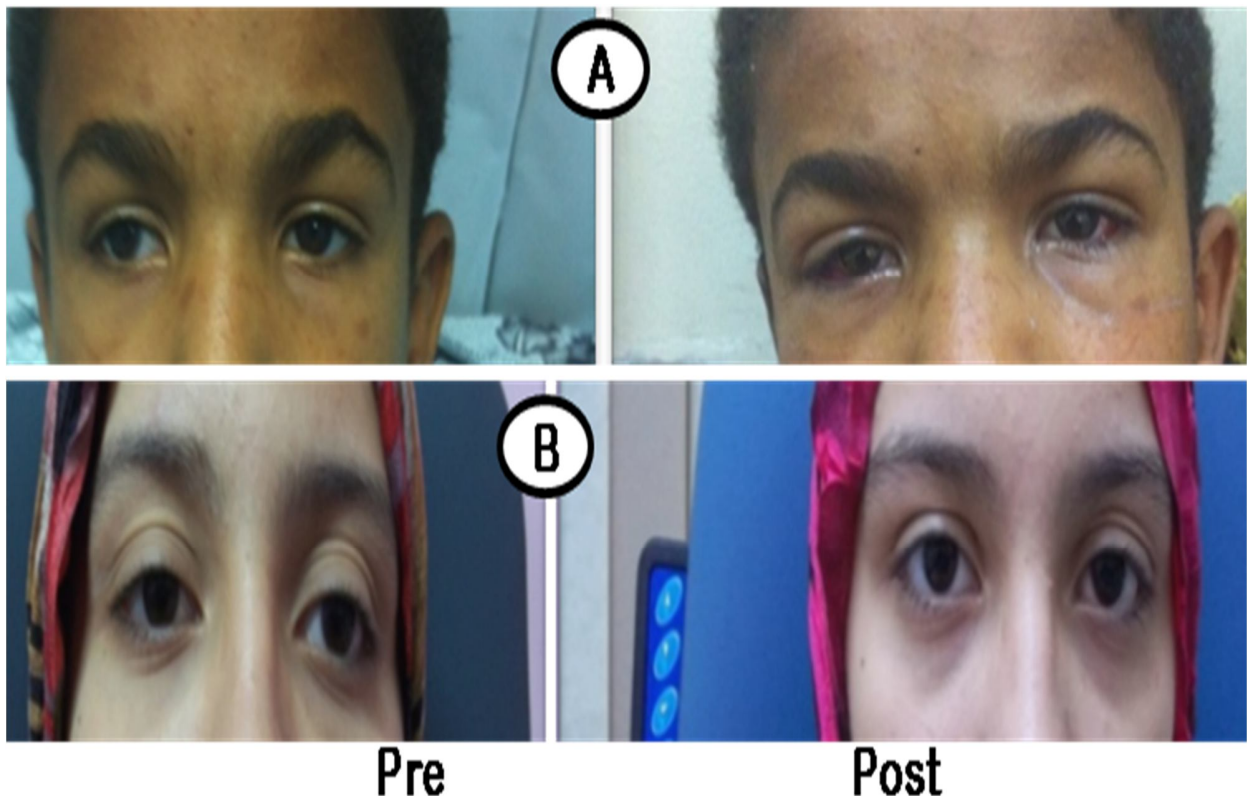


Figure 1: Pre- & post-operative ocular alignment. A) Limbal approach strabismus surgery (Pre- alternating exotropia 50 ΔD, Post-successfully aligned). B) Minimally invasive strabismus surgery (Pre- left exotropia 50 ΔD, Post- successfully aligned).

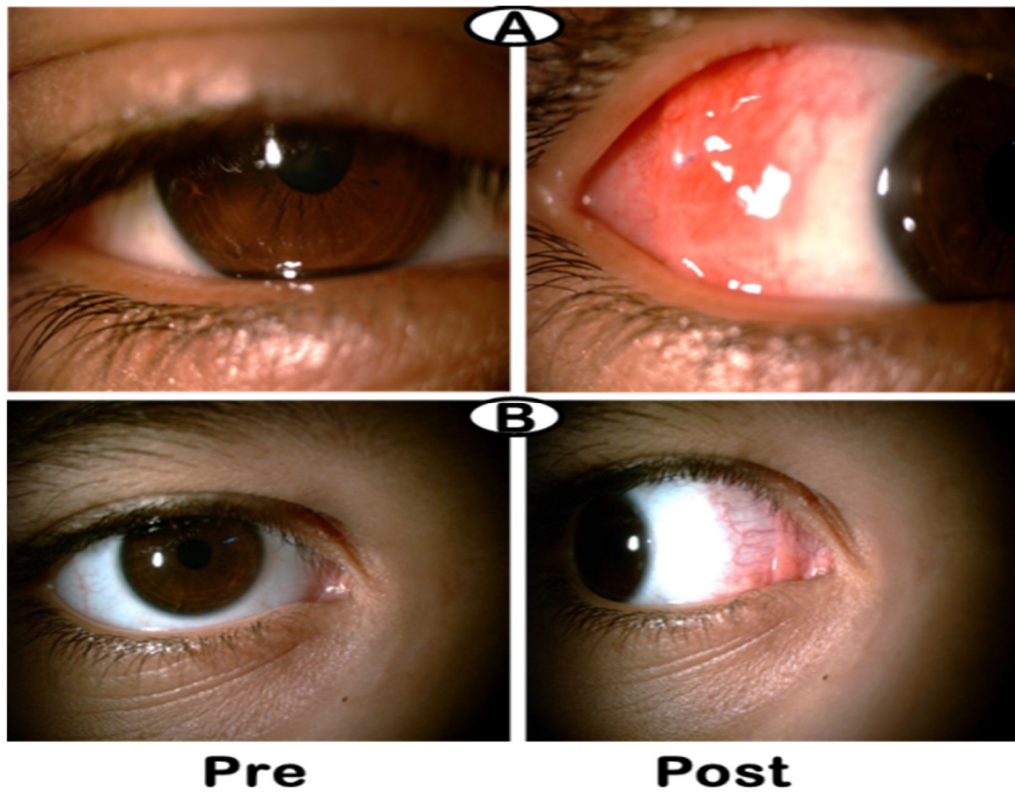


Figure 2: **A)** Post-operative ocular inflammation, 1 month post-limbal approach strabismus surgery (Grade 2). **B)** Post-operative ocular inflammation, 1 month post-minimally invasive strabismus surgery (Grade 0).

Discussion

Today, strabismus surgeons must use conjunctival openings as distant from the limbus as possible because the limbus is very vulnerable to surgical trauma. Permanent damages may occur, especially in the vessels around the limbus and stem cells. Also, if the surgeons avoid a limbal opening, this will decrease postoperative visibility of the surgical procedure, patient discomfort, scarring around the operated muscles, and reduce hospital stay and working disability.⁷⁻⁹

Switching to MISS at first will increase your surgical time. However, after a period of time, the surgery times will be shorter compared to traditional surgery. The marginal dissection technique in particular allows very fast performance of muscle reinforcements.^{12,19} From our experience, the ideal way before starting with a MISS technique is to spend a training period alongside an experienced MISS surgeon.

MISS was performed in (15) eyes of (11) patients (group A), while limbal approach was performed in (18) eyes of (11) patients (group B). All 22 patients underwent clinical assessment preoperatively and at 1st day, 1st week and 1st month postoperatively. The two groups underwent surgical correction using the surgical microscope in the operating theater under general anesthesia.

The present study revealed no significant difference between MISS and the traditional limbal approach for final ocular alignment ($P = 1.00$); both techniques achieved successful alignment in 90.9% of cases whereas they failed in 9.1% of cases. Although the current literature comparing results with MISS technique versus traditional technique, the study was in agreement with Mojon D who also found that there is no significant difference between the two approaches regarding postoperative ocular alignment.⁷ This demonstrates that the smaller conjunctival incisions of the minimally invasive

technique don't prevent good visualization and manipulation in operating horizontal extraocular muscles.^{14, 16}

There was no difference in both techniques regarding intraoperative complications like excessive hemorrhage, scleral perforation or slipped muscles. Also, Mojon.⁷ and Sharma et al.^{22,23} reported that no difference in both techniques regarding intraoperative complications.

The present study revealed significant statistical difference in the postoperative ocular inflammation (lid edema, conjunctival chemosis & injection) between the 2 groups for MISS at the 1st day, 1st week and 1st month postoperatively ($P < 0.05$). The study was in agreement with Sharma et al.²² who stated that MISS had milder redness ($P = 0.04$) and better total inflammatory score (TIS) ($P = 0.05$). In another study, the results showed that the MISS approach and the traditional fornix approach were equal in the period of operation and in the early postoperative visual acuity, and postoperative ocular inflammation.²¹ However, we cannot depend on these results because that study was retrospectively conducted on younger patients.

Ocular inflammation after strabismus surgery can be related to the operation time, conjunctival incision and exposure, tissue trauma, closure of conjunctiva, materials and instruments used and excessive manipulation and surgeon experience¹⁰⁻²⁰, in our study we found that MISS took the same operation time, same instruments and materials used of in the traditional limbal approach, but factors that made MISS superior than the traditional limbal approach in minimizing the postoperative ocular inflammation and better and thus faster healing of conjunctiva are smaller conjunctival incisions away from the limbus, lesser tissue trauma and conjunctival manipulation, preservation of most of perimuscular tissue and better closure of conjunctiva. Also the conjunctival incisions are remained covered by the eyelids in the forward gaze, and they heal completely within 2 to 4 weeks postoperatively leaving very minimal conjunctival linear scars that are hardly seen even with slit lamp examination.²²

MISS incisions are far away from the limbus so this technique significantly reduces the frequency and severity of corneal complications such as dry eye syndrome and dellen formation, and will allow earlier wearing of contact lenses earlier. The long-term benefits are to avoid increased visible conjunctival redness and reduce scarring of the perimuscular tissue, making it easier to repeat surgery - if needed.^{10,19,22,23}

In this study, we noticed unexplained postoperative mild subconjunctival hemorrhage in few cases of MISS that resolve spontaneously within few days postoperatively, we didn't know the exact cause, but we think that it may be because some blood escape through the conjunctival tunnel during surgery and we couldn't be able to remove it completely with the micro sponges.

MISS is a promising surgical approach that offers small conjunctival incisions with decreased surgical manipulation in a daily squint operation. It can enhance results and minimize postoperative complications by reducing tissue disruption and perilimbal vessels injuries. To become MISS technique the gold standard in strabismus surgery in the future, more exact evidence regarding outcomes of ocular alignment and postoperative ocular inflammation through randomized controlled clinical trials.

Conclusion

MISS is a good available alternative of the traditional limbal approach which achieves a successful ocular alignment with lesser postoperative ocular inflammation.

Conflict of Interest

Authors declare no conflicts of interest.

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Ethics declarations

Conflict of interest

Moawed EM, Kolkailah KA, Zaky KA, Ghobashy WA, all authors have no conflicts of interest that are directly relevant to the content of this review.

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