

# Insulin syringe for anaesthetic injection in ptosis surgery: A randomised controlled clinical study

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## Research Article

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# Abstract

**Background:** To evaluate the potential benefit of using insulin syringes for local anaesthesia in ptosis surgery.

**Methods:** Sixty patients (120 eyelids) were included in this randomised, fellow eye-controlled study at a university-based hospital. An insulin syringe was used on one eyelid and a conventional 30-gauge needle on the other. Patients were asked to score pain in both eyelids using a visual analogue scale (VAS) ranging from 0 (no pain at all) to 10 (unbearable pain). Ten minutes after the injection, an observer scored the degree of haemorrhage and oedema in both eyelids on a scale of 0 to 4.

**Results:** The VAS score was 5.17 in the insulin syringe group and 5.35 in the 30-gauge needle group ( $p=0.264$ ). Ten minutes after the anaesthesia, the haemorrhage score was 1.30 and 1.64 and eyelid oedema score was 1.50 and 1.80 in the insulin syringe and 30-gauge needle groups, respectively (haemorrhage,  $p=0.045$ ; eyelid oedema,  $p=0.023$ ).

**Conclusion:** Injecting local anaesthesia using an insulin syringe, compared to conventional 30-gauge needles, significantly reduces haemorrhage and eyelid oedema before skin incision but does not significantly reduce the injection pain. Using insulin syringes also presents fewer complications related to tissue penetration and lesser distortion of anatomical structures compared to conventional 30-gauge needles. We recommend using an insulin syringe for local anaesthesia in ptosis surgery.

**Trial registration:** registry – CRIS / registration number – KCT0005120 / date of registration: 12/06/2020 (retrospectively registered), <https://cris.nih.go.kr/cris/index.jsp>

## Background

Ptosis surgery is performed under local anaesthesia, which allows patients to cooperate during surgery and adjust the eyelid height, achieving better postoperative outcomes.<sup>1 2</sup> In most periorcular procedures, local anaesthesia is administered via an infiltrative technique using 25–30 gauge needles.<sup>3-5</sup> Anaesthetic methods, such as local nerve block, and intravenous and/or oral sedation, may be performed.<sup>6-13</sup> However, sedation techniques have risks of adverse events or complications, especially in older patients, and should be used after carefully considering the patient profile.

Anaesthesia is an essential part of eyelid surgery, but pain during anaesthesia is the most anxiety-provoking step during the procedure, and the differences in pain experienced by each individual can vary.<sup>3-5 14</sup> In general, it is recommended to use small diameter needles and to slowly inject the anaesthetic agent to reduce pain during the procedure.<sup>15-21</sup> Furthermore, various studies have reported factors that help minimise pain during local anaesthesia, which include the choice of the anaesthetic agent, dilution, buffering, and skin cooling.<sup>22</sup> Anaesthetic injections can also lead to tissue distortion and bleeding, which further distort the anatomical structures, making it more difficult to perform surgery accurately; thus, care should be taken to limit these.<sup>3 4 21</sup>

Various studies have been conducted to find factors that reduce the pain of anaesthetic injections.<sup>21 22</sup> However, only one study has examined the difference in pain caused by the type of needle.<sup>21 22</sup> Yu et al. reported that using 27-gauge blunt needles reduces pain and hematoma occurrence compared to using a 27-gauge conventional sharp needle during anaesthesia for upper blepharoplasty.<sup>21</sup> This type of blunt needle has been introduced in some

limited areas, such as interventional radiology, to avoid inadvertent penetration of vital structures, but it is not yet widely used in eyelid surgery.<sup>15</sup>

In contrast, insulin syringes, used primarily in the treatment to control blood glucose levels in diabetes management, are readily available. Recently, several studies used insulin syringes for arterial puncture and paediatric dental treatment, and showed that the pain reported was lower than that caused by conventional needles.<sup>23 24</sup> The insulin syringe does not have a dead space because its needle and syringe are not separated, and the silicone oil lubricant is coated to reduce friction during injection. Generally, the needle is 30- or 31-gauge, and 6–8 mm in length, much shorter than conventional needles (Figure 1). Since it is designed for subcutaneous injection, it can also be used to administer local anaesthesia in eyelid surgery.

This study sought to evaluate whether there is any benefit of using the smaller gauge insulin syringe to administer local anaesthesia during ptosis surgery with respect to the pain score. We also evaluated whether the insulin syringe reduced haemorrhage and oedema of the eyelid due to needle penetration, as clinical indicators of tissue injury, compared to that caused by conventional needles.

## Methods

This prospective, observer-blinded, randomised controlled clinical study was performed on 120 eyelids from 60 patients who underwent bilateral levator aponeurosis repair or levator muscle resection surgery for the management of bilateral ptosis from July 2017 to September 2020. Sample size calculation was based on the results of a previous study comparing pain across different needle types, with a difference of 0.84, between 5.48 (SD=1.59) and 4.64 (SD=1.67), on the pain visual analogue scale (VAS) score considered to be clinically relevant.<sup>21</sup> With a power ( $\beta$ ) of 0.80 and two-sided significance level ( $\alpha$ ) of 0.05, 60 patients and 120 eyelids were recruited to this study (G-power 3.1 was used for sample size calculations). The exclusion criteria were: previous surgery on the upper eyelids; severe asymmetric ptosis that required treatment using different surgical methods; and asymmetric bilateral eyelid skin conditions, such as scar formation or skin disease. This study adheres to the Helsinki Declaration and was approved by the Institutional Review Board of the Kangdong Sacred Heart Hospital.

Local anaesthesia was done using subcutaneous injection of 2% lidocaine and 1:100,000 epinephrine, which are commonly used in periorbital surgery. A 1-cc syringe with a 30-gauge needle (BD Precision Glide Needle, Franklin Lakes, New Jersey, USA) was used on one eyelid and an insulin syringe (BD Ultra-Fine 6-mm Insulin Syringe, Franklin Lakes, New Jersey, USA) was used on the other eyelid (Figure 1). Since the patients closed their eyes during the injection, they did not know which needle was used during anaesthesia. Anaesthesia was performed in the right eye first, and the needle type for each eyelid was assigned randomly using an Excel software to minimise the psychological effect of the anaesthetic sequence on pain. The amount of anaesthetic agent was different for each patient according to the degree of excision of the eyelid skin, but the amount of anaesthesia administered to both eyes was the same and not more than 2 mL per eye. The injection rate was 0.1 mL/s and was performed by one surgeon (YJC).

To evaluate the difference in pain, patients were asked to score the pain in both upper eyelids using a VAS ranging from 0 (no pain at all) to 10 (unbearable pain). Ten minutes after the anaesthesia injection, an observer who did not participate in the anaesthesia procedure scored the degree of haemorrhage and oedema of both eyelids from 0 to 4 (0=no, 1=minimal, 2=moderate, 3=severe, 4=very severe). For haemorrhage scores, standard photographs were obtained and scored (Supplement 1). The eyelid oedema was scored according to the subjective evaluation of the

observer, because it was difficult to standardise the extent of tissue swelling based on a two-dimensional photograph.

In an additional analysis, we investigated the amount of anaesthesia administered to each patient and the number of additional anaesthetic injections. We also analysed whether sex, age, underlying comorbidities (diabetes, hypertension), and medication history that might alter bleeding (aspirin, warfarin, clopidogrel, etc.) affected the difference in pain, haemorrhage, and oedema during the anaesthetic procedure.

Differences in pain, haemorrhage, and oedema caused by the two syringes were assessed using the Wilcoxon signed rank test, and differences in these factors depending on the presence or absence of diabetes, hypertension, and medication history causing an increase in bleeding tendency were assessed using the Mann-Whitney test. The Wilcoxon signed rank test was used to analyse the amount of anaesthetic agent and number of injections performed after the first anaesthesia. All analyses were performed using SPSS 19.0 (IBM Corporation) and GraphPad Prism 5 (GraphPad Software Inc) software.

## Results

The mean age of the subjects was  $68.35 \pm 13.24$  years. The injection volume during the first anaesthetic injection was the same in both eyelids with a mean injection volume of  $1.56 \pm 0.21$  mL. There were 14 patients (23.3%) with diabetes, 35 (58.3%) with hypertension, and 22 (36.6%) were taking drugs that cause an increased tendency to bleed (Supplement 2).

In the insulin syringe and 30-gauge needle groups, the number of additional anaesthetic injections after the first anaesthetic injection was 0.59 and 0.53, respectively ( $p=0.346$ ). The time before re-injection of anaesthetics was 50.34 and 50.96 min, respectively; there was no significant difference between the two groups ( $p=0.848$ ). The amount of anaesthetic administered at re-injection was 0.25 mL and 0.30 mL, respectively; not significantly different between the groups ( $p=0.631$ ). Therefore, the type of needle used for the initial anaesthetic injection did not affect the duration of anaesthesia or the amount of additional anaesthesia injected (Supplement 3).

Pain scores (VAS) were lower in the insulin syringe group (5.17) than in the 30-gauge needle group (5.35); however, the difference was not statistically significant ( $p=0.264$ ). After 10 minutes of anaesthesia, the haemorrhage score was significantly lower in the insulin than in the 30-gauge needle group (1.30 and 1.64, respectively;  $p=0.045$ ). Also, the score for eyelid oedema was significantly lower in the insulin syringe group (1.50 and 1.80, respectively,  $p=0.023$ ) (Figure 2). The distribution of the haemorrhage and oedema scores in each group is shown in Figure 3.

We then examined whether there were significant differences in pain, haemorrhage, and oedema according to the presence of diabetes mellitus, hypertension, and use of medications causing increased bleeding between the two groups. Under the same systemic conditions, the insulin syringe group had lower pain, bleeding, and oedema scores than the 30-gauge needle group (Table 1). When subgroup analysis was performed, the insulin syringe group did not show any difference in pain, haemorrhage, or oedema scores with respect to diabetes, hypertension, and medication history status. In the 30-gauge needle group, diabetes and hypertension did not affect pain; haemorrhage, oedema scores, and the medication history had no significant relationship with pain, but had a significant relationship with haemorrhage ( $p=0.018$ ) and oedema ( $p=0.004$ ). Detailed data and statistics are presented in Table 1.

**Table 1. Pain, haemorrhage, and oedema assessment scores according to systemic conditions in each group.**

		DM (n=14)	No DM (n=36)	p	HTN (n=35)	No HTN (n=25)	p	Med. (n=22)	No Med. (n=38)	p
<b>Insulin syringe group</b>	Pain (Mean ± SD)	4.00±2.19	5.28±1.22	0.237	4.66±1.78	5.31±1.29	0.879	4.23±1.82	5.42±1.27	0.165
	Haemorrhage (Mean ± SD)	1.45±1.03	1.43±0.98	0.082	1.58±1.10	1.26±0.80	0.266	1.52±1.00	1.38±0.98	0.170
	Oedema (Mean ± SD)	1.73±0.64	1.59±0.61	0.085	1.70±0.62	1.42±0.60	0.445	1.64±0.60	1.53±0.64	0.159
<b>30-gauge needle group</b>	Pain (Mean ± SD)	4.90±2.62	5.37±1.33	0.767	5.29±2.03	5.21±1.31	0.896	5.08±2.27	5.38±1.29	0.789
	Haemorrhage (Mean ± SD)	1.81±0.87	1.62±0.75	0.664	1.83±0.86	1.47±0.61	0.987	2.00±0.93	1.46±0.58	<b>0.018*</b>
	Oedema (Mean ± SD)	2.27±0.46	1.65±0.54	0.305	1.95±0.62	1.63±0.49	0.501	2.17±0.52	1.57±0.50	<b>0.004*</b>

Pain: VAS score (1-10), Haemorrhage: score (0-4), Oedema: score (0-4)

DM: Diabetes mellitus, HTN: Hypertension, Med: use of medication that increases bleeding tendency, SD: standard deviation

\*p<0.05

## Discussion

The ideal local anaesthesia should have a quick anaesthetic effect, long duration time, cause little pain on injection, and have little effect on the surgical procedure. There have been numerous studies examining which anaesthetic protocol provides an optimal anaesthesia in eyelid surgery. Recently, a systematic review including 23 randomised controlled trials investigated local anaesthesia in periocular procedures.<sup>22</sup> Only one of these studies examined the needle type as an equipment factor.<sup>21</sup> Forty four patients (mean age=31) undergoing blepharoplasty used a blunt 27-gauge needle, which has the same thickness as a conventional sharp needle, to compare pain, bruising, and hematoma formation. Blunt needle use led to a significantly lower pain score than conventional sharp needle use (VAS score 5.48 vs 4.64), and the incidence of hematoma was also significantly lower.

Theoretically, the blunt tip needle may be an alternative choice as an anaesthetic injection tool, because it can lower the probability of direct blood vessel puncture. However, there are some points to be considered for its use in ptosis surgery. First, it is not easily obtainable because it is used in other procedures (interventional radiology, procedures on spinal lesions, etc.) to avoid penetrating blood vessels or vital organs. Second, unlike in the young or middle-aged patients undergoing blepharoplasty, the age of the patients undergoing ptosis surgery is usually higher (average age in this study, 68.35±13.24 years). The penetration of blunt tip needles through the relatively thin, inelastic, and dry skin of the eyelids of older patients may not be as easy as in younger patients.

In this study, we tried an insulin syringe, which is relatively easy to obtain, as an anaesthetic injection tool for ptosis operations. Compared with the 27–30-gauge needles commonly used for inducing local anaesthesia in the eyelids, the insulin syringe needle is thinner (31-gauge) and shorter (6–8 mm), making it more suitable for subcutaneous injection; in this study, a 6 mm needle was used. In addition, the sharpness of the needle tip is blunt compared to that of the conventional 30-gauge needle (Figure 1). Therefore, the insulin syringe was expected to

reduce injection pain relative to the use of the conventional 30-gauge needle, and reduce haemorrhage and oedema by reducing tissue damage and vascular penetration. However, there was no statistically significant difference in the pain score between the insulin syringe and the 30-gauge needle groups (VAS 5.17 and 5.35, respectively). The insulin syringe group did show significantly lower scores for haemorrhage and oedema than the 30-gauge needle group.

The similarity in pain scores may simply be because the needle thickness (1 gauge) and needle tip bluntness did not differ significantly between the two needle groups. Another possible explanation is that elderly patients are less sensitive to pain stimuli; therefore, the pain caused by the two needles may not be distinguished.<sup>25 26</sup> It is important to note that haemorrhage and oedema, which are indicators of tissue damage caused by needle injury, were significantly lower in the insulin syringe group. This may be because the insulin syringe needle is thinner and the needle tip is blunt, but, above all, the main factor is thought to be the shorter needle length of the insulin syringe than that of the conventional 30-gauge needle (6 mm vs 13 mm). In a study with diabetic children who used insulin injections using 8 mm and 12.7 mm needles with various insulin syringes, 8 mm needles significantly lowered the incidence of intramuscular penetration compared to 12.7 mm long needles.<sup>20</sup> Insulin injection in diabetic patients and anaesthetic injection in eyelid surgery require different depths and angles of penetration making direct comparison difficult. However, the length of the 30-gauge needle is much longer; therefore, there is a greater tissue damage caused by the long subcutaneous or intramuscular tract created in the skin. Furthermore, as the skin, subcutaneous tissue, and muscle layers become thinner with age, the chance of the needle penetrating deeper tissues after skin penetration increases. For this reason, it is believed that the scores of haemorrhage and oedema in the 30-gauge needle group were significantly higher than those in the insulin syringe group.

As insulin syringes are shorter in length, the effect of anaesthesia may not be sufficient, because the spread of anaesthetic solution is relatively limited, even if the same amount of anaesthetic is injected. However, the anaesthetic solution could spread evenly during mild compression of the eyelids for 1 min after injection, and an initial anaesthetic effect was found sufficient. We also found that the duration of the anaesthesia and amount of anaesthetic solution added after the initial anaesthetic injection did not differ between the two groups.

Some swelling will inevitably occur after injection because the injected anaesthetic agent is delivered to the subcutaneous or deeper tissue layer. In this study, since the subjects were elderly with an average age of 68 years, it is necessary to consider that dermatochalasis is usually present. After the injection of 2 mL or less of anaesthetic solution, mild compression was done for approximately 1 min for haemostasis. When the degree of eyelid oedema was observed 10 min after injection, it varied from grade 1 (minimal) to grade 4 (very severe) depending on the degree of dermatochalasis. In general, when the bleeding was severe, the degree of oedema worsened; however, in some cases, eyelid oedema was found to be relatively severe compared to the degree of haemorrhage. In contrast, in some patients with diffuse haemorrhage without hematoma, the degree of eyelid oedema was observed to be relatively less severe. For this reason, haemorrhage and eyelid oedema after anaesthesia injection were scored separately for analyses. Factors driving oedema include patient-related factors, such as patient age and underlying comorbidities, and treatment factors, such as the injection technique, rate and amount of injected anaesthetic agent, and degree of tissue damage caused by needle penetration.<sup>27</sup> Since the anaesthesia was performed on the two eyelids of the same patient by one operator using the same injection technique and same volume of anaesthetic agent, the degree of eyelid oedema reflected the degree of penetrative tissue damage caused by the difference in the instrument (needle) factor.

Subgroup analysis was performed to determine whether there were differences in pain, haemorrhage, and oedema according to patient factors, such as the underlying systemic disease or medication history. The insulin syringe group showed lower pain, bleeding, and oedema scores. In the insulin syringe group, there was no significant difference in pain, haemorrhage, or oedema scores according to comorbidities such as diabetes or hypertension, or history of medication that increases bleeding risk. However, the subgroup of patients using medications increasing bleeding tendency in the 30-gauge needle group had significantly higher haemorrhage and oedema scores than the patients who did not take the drugs. This may be an evidence of the reduction in haemorrhage and oedema of the eyelids when anaesthesia is performed using an insulin syringe rather than the conventional 30-gauge needle, especially in patients who use medication that increase bleeding risk. Since insulin syringe needles are thinner and shorter and the needle tip is relatively blunt, it can be useful in patients with increased bleeding risk because it can reduce the penetrative tissue damage caused by needle injection. It is known that oedema is associated with medications such as aspirin, NSAIDs, hormone treatments, calcium channel blockers, and certain vitamin supplements (vitamin E, ginger, ginseng, ginkgo biloba and garlic).<sup>27 28</sup> Although this study did not include and analyse all of these medications, patients undergoing ptosis surgery are typically older than other patients in the oculoplasty field; therefore, there is a greater likelihood of using these medications. Given that it is not always possible to confirm the use of all these medications and complementary medicines, an insulin syringe provides a good option for performing injections during ptosis surgery.

A limitation of this study is that eyelid oedema was scored according to the subjective judgment of the observer; thus, there may be some intra-observer variation between individual patients. However, since the main analysis of this study compares the difference between the two different needle groups in the same patient, we can conclude that comparing oedema in the two eyes of one patient sufficiently reflects the objective difference. Also, the evaluation of haemorrhage and oedema, which reflects the degree of penetrative tissue injury after anaesthetic infiltration, was not assessed serially over a long time. In this study, the time from anaesthetic agent injection to skin incision was 10 minutes; therefore, only haemorrhage and oedema 10 minutes after injection, just before skin incision, were evaluated. Bleeding or oedema inevitably occurs during the operation after the skin incision step; therefore, haemorrhage and oedema after skin incision are related to other factors in addition to the anaesthetic effect. As a result, haemorrhage and oedema after skin incision procedures were not evaluated in this study. The reason for setting the 10-minute time period in this study is that this is the time it takes for the surgeon to disinfect and drape after the actual anaesthesia injection. This is also a reflection of previous research that found that waiting 7 minutes before skin incision in eyelid surgery is enough to achieve a maximal haemostatic effect following the induction of local anaesthesia using epinephrine.<sup>29</sup>

## Conclusions

Using an insulin syringe to inject local anaesthetic in ptosis surgery significantly reduced haemorrhage and eyelid oedema at the time of skin incision, although it did not significantly reduce pain, compared to a conventional 30-gauge needle. Especially in patients who use medications that might affect the bleeding risk, the insulin syringe can contribute to reducing haemorrhage and oedema during surgery caused by the injection of anaesthetic agents. Patients undergoing ptosis surgery are relatively older and are more likely to take various drugs, supplements, and complementary medicines that affect bleeding and oedema; consequently, it is recommended to use an insulin syringe to inject local anaesthesia.

## List Of Abbreviations

VAS: Visual analogue scale

NSAIDs: Non-steroidal anti-inflammatory drugs

## Declarations

**Ethics approval and consent to participate:** This study adheres to the Helsinki Declaration and was approved by the Institutional Review Board (IRB) of the Kangdong Sacred Heart Hospital. (IRB file No.KANGDONG 2017-05-003). Written informed consent was obtained from all participants.

**Consent for publication:** Written informed consent for publication of identifying information/images in an online open-access publication was obtained from the participants

**Availability of data and materials:** All data generated or analysed during this study are included in this published article and its supplementary information files.

**Competing interests:** The authors declare that they have no competing interests.

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**Authors' contributions:** MJL and YJC contributed to the study conception and design. Material preparation, data collection and analysis were performed by WSS and YJC. The first draft of the manuscript was written by WSS and MJL commented on previous versions of the manuscript. All authors read and approved the final manuscript.

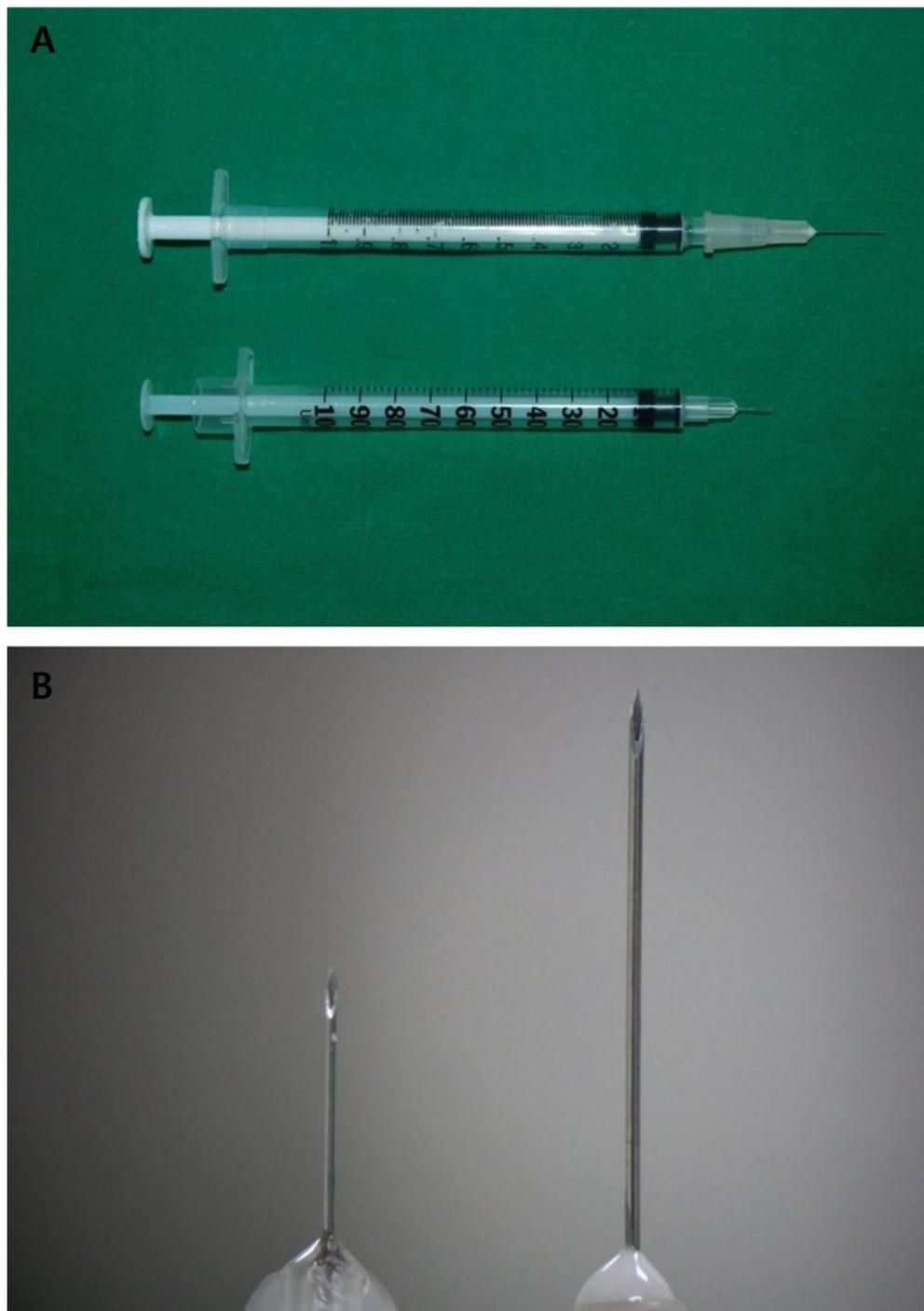
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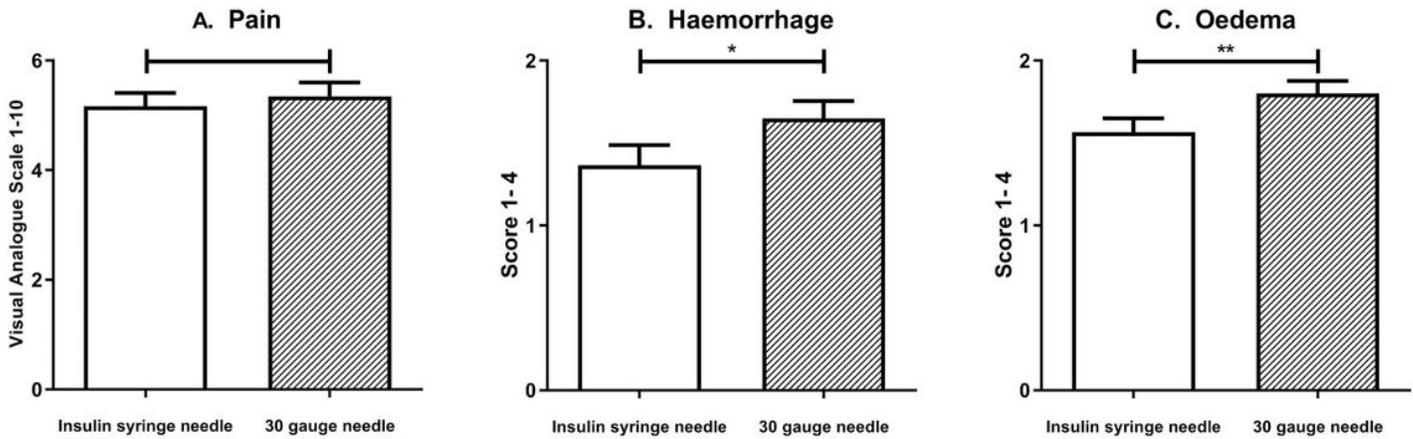
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## Figures



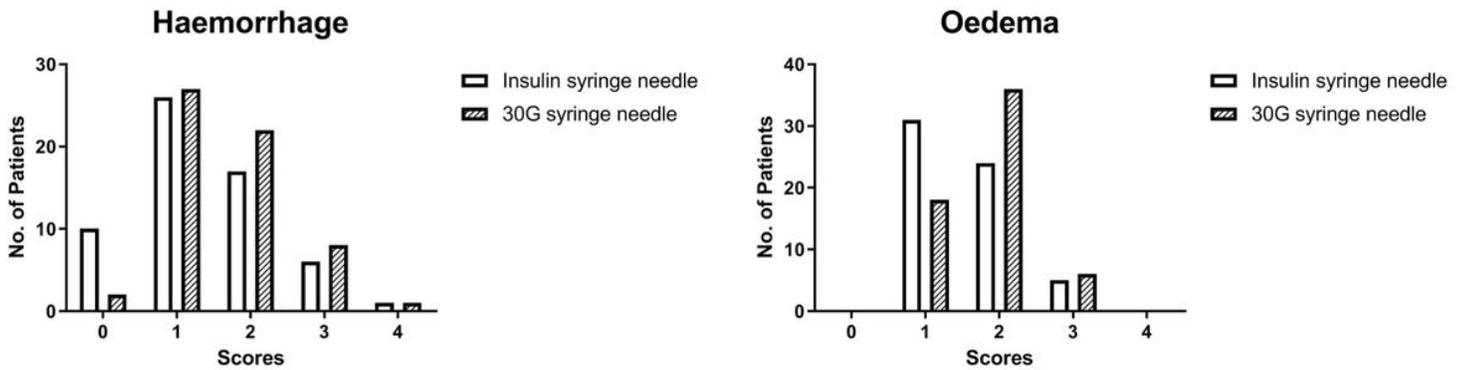
**Figure 1**

1 Photographs of an insulin syringe and a conventional 1-cc syringe with a 30-gauge needle. A. An overall view of the insulin syringe (bottom) and conventional 1-cc syringe with a 30-gauge needle (top) B. A detailed view of the insulin syringe needle (left: 31-gauge  $\times$  6 mm) and conventional 30-gauge needle (right: 30-gauge  $\times$  13 mm). The photo also shows that the needle tip of the insulin syringe is blunt compared to that of the conventional 30-gauge needle



**Figure 2**

Illustration of pain, haemorrhage, and oedema assessments following anaesthetic injection using an insulin syringe or conventional 30-gauge needle in ptosis surgery. A. The mean visual analogue scale pain scores were lower (5.17) in the insulin syringe group than in the 30-gauge needle group (5.35), but not significantly ( $p=0.264$ ). B. After 10 minutes of anaesthesia, the haemorrhage score was 1.30 and 1.64 in the insulin syringe group and 30-gauge needle group, respectively; this was significantly lower in the insulin syringe group ( $*p=0.045$ ). C. The score for eyelid oedema was 1.50 and 1.80, respectively, which was significantly lower in the insulin syringe group ( $**p=0.023$ )



**Figure 3**

Distribution of haemorrhage and oedema scores 10 minutes after anaesthetic injection using an insulin syringe or conventional 30-gauge needle in ptosis surgery (0=no, 1=minimal, 2=moderate, 3=severe, 4=very severe)

## Supplementary Files

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