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Choosing a Needle Gauge

Mr Dalvi Humzah and Anna Baker discuss the influence of needle design and dimension on pain experience during botulinum toxin injection

One of the main treatment goals of any aesthetic procedure is to prevent complications using safe and appropriate techniques.[1] Pain and complications are key concerns for patients and their perception of treatment outcomes. These factors should be considered and discussed during the consultation and consent process.[2] Botulinum toxin A (BoNT-A) remains one of the most popular aesthetic non-invasive treatments, with an exponential rise in the approximate number of treatments performed each year.[3] The American Society for Aesthetic Plastic Surgeons reports a total of 4,267,038 botulinum toxin procedures undertaken in 2015, ranking as the most popular non-surgical treatment.[4] In light of these statistics, providing an optimum patient experience and selecting appropriate tools to administer treatment is an important factor. In this, we will examine the issue of the use of appropriate needle gauge as a factor.[5]

Needle design and dimensions: what does the current literature say?

A small body of literature suggests that cosmetic BoNT-A injections are principally performed with needle gauges ranging from 30G-33G.[2,6] A small blinded and randomised study with 20 subjects examined the difference in both pain and bruising between 30G Micro-Fine Plus needles and 33G TSK microneedles.[7] The results of the study demonstrated that the 33G needles offered superior comfort across three treated areas of the upper face (glabellar, forehead and crow's feet), with a statistically lower incidence of ecchymosis. This remains one of the few studies to specify the frequency with which the microneedle pierced the skin before it was changed (four to six injections).[7]

Alam *et al.,* (2015)[8] undertook a split-face, double-blinded randomised clinical trial, comprising 20 subjects with moderate glabellar and forehead wrinkles. One side of the subject's forehead was treated with BoNT-A in saline injected with a 32G needle, whilst the opposite side was treated with a 30G needle. In addition, each patient received randomised injections of saline to both upper inner arms with the same gauge needles. The level of discomfort was reported as greater with the 30G needles (40% of subjects), in comparison to 32G needles (15% of subjects). No difference was noted in the character of pain associated with needle bore for all comparisons. The authors concluded that BoNT-A may be better tolerated when administered with a 32G needle compared to a 30G needle.

Conversely, Price *et al.,* (2009),[9] report different findings in a similar study comprising 37 subjects whereby the right side of the face was treated at the crow's feet region with a 30G needle, and the left side was treated using a 32G needle. This was a single blind study and subjects were asked to rate injection pain on an 11-point numerical rating scale and to note any bruising. The study results indicated no statistically significant differences in the amount of discomfort from injection or the level of post-procedural pain and discomfort experienced. Rates of bruising were not statistically different; 27% of subjects reported bruising with the 32G needle, versus 29.7% with the 30G needle. The physician injector reported no preference with either needle size. The authors concluded with no recommendation to use 32G needles in place of 30G needles. However, little explanation was provided concerning the result, or discussion around the potential variables in the study design, in particular, how many injections each subject was administered, and the impact these may have had upon the results.

Yomtoob *et al.,* (2009)[5] concur with these findings, their study design included treating patients at the periocular region with

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benign essential blepharospasm. No rationale was provided for the chosen anatomical region or clinical presentation. A split face analysis was adopted with 30 subjects who received bilateral injections using 30G needles on one side of the face and 32G needles on the opposite side. The average pain score was 4.38=+/-2.02 for 30G needles and 3.90+/1.65 for 32G needles, however, this was not statistically significant. Therefore, the authors could not recommend a preferred needle gauge.

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Conversely, Arendt-Nielsen *et al.,* (2006)[10] argue that needle gauge is a significant parameter and consideration in analysing levels of patient discomfort. The authors performed a study using an automated needle injection system to perform a series of injections whereby the velocity, angle of insertion and depth of injection were controlled. The frequency of pain following needle injections (23, 27, 30 and 32 gauge) was recorded, together with the pain intensity (measured on a visual analogue scale), with the occurrence of bleeding and bruising. The results indicated that the needle gauge was positively and significantly correlated to the frequency of the injection pain: 63% of injections with 23G needles caused pain, 53% of injections with 27G and 31% of injections with the 32G needle caused pain. The authors reported that the 30G needles were found to be more uncomfortable when inserted into the abdomen, compared to the thigh. Yet, insertions into the abdomen were associated with fewer bleeding events (2.5% of insertions, independent of needle diameter). The authors did not analyse any potential correlation with this observation.

Outer needle diameter and gauge may not be the only features that may be important for evoked pain. Using thin wall technology, the inner bores of a needle can be made wider, which allows thinner needles to be used for the administration of various drugs. However, widening the inner diameter of the needle affects the needle wall, making it markedly thinner. Such needles are, therefore, more delicate and prone to bending.[11] The sharpness of a needle can be lost following a single skin injection[12] and blunted needles are more painful to inject requiring a higher extrusion force.[11] However this study is based upon analysing needles for diabetic patients, and has limited scope for comparison to cosmetic BoNT-A injections.

Gill and Prausnitz (2007)[13] observed that needle gauge has been shown to significantly affect the degree of pain during injections into the skin of human subjects with findings to indicate that use of a 27 or 28G needle had an approximate 50% chance of being reported as painful, which was significantly greater than with a 31G needle,

Discussion

One of the challenges in analysing the current literature in relation to consensus recommendation for needle size for BoNT-A injection is the lack of consistency in methodology and parameters between the small number of studies. Cohort numbers in the current literature rarely exceed 30 subjects and do not consistently compare the same anatomical areas, or cosmetic indications. The majority of the literature focuses upon analysing the pain score, whereas other crucial treatment outcomes, such as bruising and swelling, potential volume of product wastage, as well as the width of needle are not explored in sufficient detail. The narrow parameters in current literature do not definitively conclude an advantage in the use of 30G needles in comparison to available smaller sizes. In addition, the higher the number of injections per side, potentially the greater the chance of discomfort. In light of the increasing popularity of cosmetic BoNT-A injections, it seems prudent to recommend that future studies attempt to analyse broader parameters to guide clinicians with more clarity on the importance concerning appropriate needle size selection, as patient satisfaction rests not only on minimal discomfort but also successful treatment outcome. There is some non-statistical evidence to speculate that smaller gauge needles may reduce the risk of complications through a higher degree of accurate placement. Furthermore, the studies do not consistently use the same pain assessment tools so data must be interpreted cautiously and do not consistently stipulate which dilutant was used, or the significance of this, which we will discuss in a later review.

The effect of needle thickness on pain has been examined in various studies.[10,12,13] Current literature suggests that reducing needle diameter lowers pain and generally increases the patient's pain tolerance and satisfaction. Yet, most of the studies discussed were conducted in diabetic patients, with the goal of achieving higher compliance to insulin treatment. Thus, the areas of injection usually were the abdomen, deltoid, or thigh. A few studies have involved the forearm area of healthy volunteers, but these are challenging to make accurate comparisons to facial parameters. Although existing studies provide some insight, they are limited and clinically insufficient as a basis to consistently assess the effect of needle thickness in minimally-invasive facial procedures, as well as the number of injections to use a needle before changing to a new needle.

with a 39% chance of causing pain. Furthermore, the likelihood of bleeding was also observed to decrease with decreasing needle diameter. The authors also proposed that increasing needle length may increase pain but there are no robust studies to specifically demonstrate this effect.

Skiveren *et al.,* (2010)[14] concur with previously discussed findings from their randomised-controlled trial, analysing the influence of needle size for BoNT-A injection for axillary hyperhidrosis. They compared 27G needles and 30G needles in 38 patients, 50% of patients reported that the side which had been treated with 30G needles, were less uncomfortable, however this study addresses pain in axillary injections and may not be relevant to that perceived in facial injections. This also examined intradermal injection associated pain compared to other studies that look at subcutaneous injections. The average pain level in the present study was lower than that previously reported by Gill *et al.,* (2007), comprising multiple injections per site. The methodology in the Gill *et al.,* (2007) study used one injection administered to every 1cm^2 area of skin, the injection point in the present study was 1.5cm^2, suggesting that the injection area may be of some importance, yet this was not explored. The pain scores for the 27G and 30G needles peaked after 15 injections, which probably reflects local differences in pain sensitivity in the axilla.[14] These injections were administered to central parts of the axillae, where pain sensitivity appeared to be higher, although it was undisclosed if the needle was changed, or how many times it may have been changed, which potentially affects the study findings, depending upon how blunt the needle(s) were.
Kim *et al.,* (2013)[15] analysed the causative factors of adverse events associated with botulinum toxin injection, through a multi-department, retrospective study of 5,310 treatments, administered to 1,819 patients. Among their findings, the authors concluded that a needle gauge of <30G, is advisable to reduce the risk of unwanted spread. Council (2015)[16] concurs with this recommendation in context of BoNT-A treatments. Currently, the thinnest available needle in the UK – 'Invisible Needle' – is 14% thinner than conventional 33 gauge needles, with a low dead space needle hub designed to minimise product wastage.

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Conclusion

A variety of factors influence a patient's tolerance to pain during treatment with botulinum toxin, which include, the individual's perceived threshold of pain, the anatomical area being treated, as well as depth and technique of injection, needle gauge and width. These factors are not exhaustive, but are some of the most relevant considerations for the clinician. In an increasingly competitive market, patients are more likely to remember non-invasive procedures that were painful, potentially affecting retention. Fortunately, the design of injectable devices continues to evolve with needle lengths and widths becoming smaller and more sophisticated for increased accuracy and minimal wastage of product. Clinicians should consider these factors when choosing the most appropriate needle to deliver injectable treatments.

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