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ORIGINAL ARTICLE

Is constant needle motion during soft tissue filler injections a safer procedure? A theoretical mathematical model for evaluating patient safety

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Abstract

Background: The safety rationale behind the constant needle motion injection technique is based on the assumption that due to the constant needle motion and simultaneous soft tissue filler material administration a smaller amount of product per area may be injected into an artery if an artery within the range of the moving needle is inadvertently entered.

Objective: To perform mathematical calculations for determining the probability for causing intra-arterial product administration when constantly moving the needle during facial aesthetic soft tissue filler injections.

Methods: This study was designed as a theoretical investigation into the probabilities for causing adverse events due to intravascular injection of soft tissue filler material when constantly moving a 27-G needle during facial soft tissue filler administration.

Results: It was revealed that with a higher number of conducted injection passes a greater soft tissue area can be covered by the needle. The odds of encountering an artery within the covered soft tissue volume and the odds of injecting any volume greater than zero into the arterial blood stream increases with the number of performed injection passes. This increase is greatest between 1 and 10 performed injection passes.

Conclusion: This model demonstrates that the constant needle motion technique increases the probability of encountering an artery within the treatment area and thus increases the odds for intra-arterial product administration. The constant needle motion technique does not increase safety but rather may increase the odds of causing intra-arterial product administration with the respective adverse consequences for the patient.

KEYWORDS
facial anatomy, facial vasculature, mathematical modeling, patient safety, soft tissue filler injections

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1 | INTRODUCTION

The number of facial soft tissue filler injections performed in the United States is continuously increasing according to the annual report released by The Aesthetic Society.[1] At a similar rate, the number of soft tissue filler reversal procedures is likewise increasing with 23031 corrective procedures performed in 2021.[1] This reflects on the increased need for corrective measures which includes the administration of hyaluronidase with or without ultrasound guidance to treat nodules, inflammatory reactions, facial overfilled syndromes, various stages of tissue loss (from livedo reticularis to necrosis), and impending injection-related visual compromise (IRVC).[2–6] The success rate is unfortunately highly variable with more severe cases (IRVCs) having poorer outcomes.[7,8]

To avoid adverse events from occurring and to account for factors resulting in poor aesthetic outcomes, various precautionary measures have previously been recommended. Some of these measures include: performing pre-injection aspiration,[9] injecting with low plunger pressure and slow injection speed,[10] injecting small amounts of material during bolus injections,[11,12] and continuous needle motion within the facial soft tissues during product application.[13]

The rationale underlying the latter safety measure is as follows: when a needle is inserted into facial soft tissue there is a risk for the tip to enter an artery. If the needle position remains stable and the injection is performed, 100% of the product is injected into the arterial blood stream with potentially disastrous clinical consequences (as performed during a bolus technique). Alternatively, if the needle remains in constant motion, even if the tip becomes intra-arterial at some point, only a small percentage of the total product administered will be injected intra-arterially. The contrary aspect of this hypothesis is that constant needle motion enhances the chances of intra-arterial product administration by encountering the artery due to the continuous needle motion during the injection process (as if the injector is searching to target the artery within the covered soft tissue volume). This subsequently increases the risk for adverse vascular events with tissue loss or IRVC. Additionally, it has to be noted that currently no threshold for a tolerable amount of intra-arterial product administration is available despite recent research has provided some values for the intra-arterial ophthalmic artery volume.[11,12] Therefore, it has to be assumed that any amount greater than zero can cause adverse vascular events; this is understandable when the arterial vascular system is viewed as a tubular system with decreasing internal lumina toward a capillary bed.

These competing lines of thought result in a dilemma for the injector with respect to injection techniques when using a needle, especially in higher risk areas. To aid the injector in the decision process whether to constantly move the needle during facial aesthetic injectable procedures, a mathematical model is needed to compute statistical probabilities and to approximate the potential outcome of the constant needle motion injection technique during aesthetic treatments. A theoretical mathematical model is more accurate and superior to a cadaveric model which reflects only on the sample investigated, the facial region targeted, the ethnic group available for testing, and on the facial arterial vasculature evaluated.

Therefore, the objective of this study is to perform mathematical calculations for determining the probability of intra-arterial injection when constantly moving the needle during facial aesthetic soft tissue filler injections.

2 | MATERIALS AND METHODS

2.1 | Study setup

This study was designed as a theoretical investigation into the probabilities of intra-arterial injection associated with the constant needle motion injection technique during facial soft tissue filler injections. The calculations were conducted between July and December 2022 at the REDACTED by the first author (REDACTED).

2.2 | Mathematical modeling

2.2.1 | Covered soft tissue volume

The covered volume calculations are based on the assumptions that after the needle is inserted into the facial soft tissues the dermal access point remains stable, but the tip of the needle is moving. Those movements occur in deep and superficial directions (= in and out) as well as in all directions (= left and right, up and down) covering ultimately three dimensions. The covered area by the needle is shaped like a cone with the tip of the cone being the dermal access point. (Figure 1) A 27-G needle with a length of ½ inch (=12.7 mm) and an external diameter of 0.41 mm was used for the calculations, and it was assumed that the minimal length of insertion (l_{min}) was 3 mm whereas the maximal length of insertion (l_{max}) was 12 mm whereas the number of injection passes (n) varied from 1 to 50 times. In can be shown that the covered volume per n injection passes ($V_{in}(n)$) follows a scaled Irwin–Hall distribution.[14] Its average volume can be calculated as follows:

$$\mathbb{E}\left(V_{\text{in}}(n)\right) = \frac{\pi d^2}{4}\frac{n\left(l_{\max} + l_{\min}\right)}{2}.$$

The respective standard deviation is given as follows:

$$\sigma_{V_{\text{in}}} = \sqrt{\mathbb{V}\left(V_{\text{in}}(n)\right)} = \frac{\pi d^2}{4}\left(l_{\max} - l_{\min}\right)\sqrt{\frac{n}{12}}.$$

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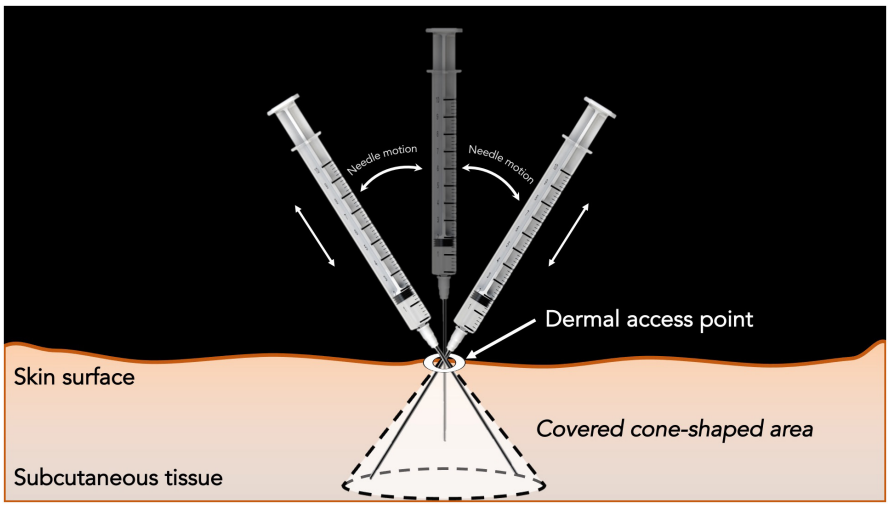

FIGURE 1 Illustration showing the covered soft tissue volume during the constant needle motion injection technique. Movements occur in all three dimensions forming a cone-shaped soft tissue area covered by the needle and the tip of the cone being the dermal access point.

2.3 | Encounter of an artery within the covered soft tissue volume

To calculate the risk that a needle is in contact with an artery during the injection process the following assumptions are established a priori: (1a) the probability (p) for arterial encounter is the same for each injection pass, and (1b) the events during each injection pass are independent of each other. Additionally, (1c) due to the unpredictability of the arterial course within the covered soft tissue volume resulting from anatomic two- and three-dimensional variations, variable arterial diameter, facial side differences of the arterial vascular system, demographic, anthropometric, and dispositional data of the patient (gender, age, height, body mass index, etc.) the probability of an arterial encounter is stable but unknown for each injection process and is therefore regarded as a constant factor. The probability of arterial encounter during k out of n (1–50) injection passes can be calculated following a Binomial distribution $\mathrm{Bin}(n,p)$[15]:

$$\Pr(k) = \Pr(k \text{ damaging passes out of } n) = \binom{n}{k} p^k (1-p)^{n-k}$$

where $\binom{n}{k}$ is a binomial coefficient. Therefore, probability of encountering at least one artery is equal to:

$$\Pr(1 \text{ or more damaging passes}) = 1 - \Pr(0) = 1 - (1-p)^n.$$

To quantify the change of this probability in relation to the number of injection passes, the odds ratio (when compared to a single injection pass) is computed according to the following formula:

$$OR_n = \frac{\frac{1-(1-p)^n}{(1-p)^n}}{\frac{p}{1-p}} = \left(\frac{1}{(1-p)^n} - 1\right)\left(\frac{1}{p} - 1\right).$$

It can be shown that for small $p \to 0$ the following approximation is applicable: $OR_n \approx n$.

2.4 | Product injected during continuous needle motion

To calculate the smallest amount of product inadvertently injected into the arterial blood stream the following assumptions are established a priori (in addition to aforementioned assumptions 1b and 1c): (2a) needle motion occurs at the same and constant speed (u) in all injection passes; (2b) product administration occurs at the same and constant volumetric flow rate (Q) in all injection passes; (2c) the depth of the injection L (= reflected by the needle length) is the same in all passes. Then the expected volume administered into the arterial blood stream in a single injection pass denoted as $\overline{V}_1$ can be computed according to the formula: $\overline{V}_1 = \bar{l}_D Q/u$, where $\bar{l}_D$ is an average distance that needle tip travels in the arterial lumen, while total product volume injected is $V_1^{\mathrm{tot}} = LQ/u$.

After k (1 to 50) injection passes the total product volume (V_k^{tot}) equals:

$$V_k^{\mathrm{tot}} = \frac{kLQ}{u} = kV_1^{\mathrm{tot}}.$$

The expected value $\overline{V}_k$ of the volume injected into the arterial blood stream throughout k passes is computed according to the following equation:

$$\overline{V}_k = k\bar{l}_D Q/u = k\overline{V}_1 > \overline{V}_1.$$

The critical volume for causing serious averse vascular events (IRVCs) has to be assumed to be any volume greater than zero and is denoted by v. The probability (Pr) to inject any volume greater than zero into the arterial blood stream is computed as:

$$\Pr(V_k \geq v) = 1 - \Pr(V_k < v).$$

Since $\Pr(V_k < v) \leq \Pr(V_1 < v)^k$, denoting $\Pr(V_1 \geq v) = p(v)$, the lowest probability possible can be calculated as:

$$\Pr(V_k \geq v) \geq 1 - (1-p(v))^k.$$

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With multiple injection passes ($k > m$) the following formula is applicable: $\Pr(V_k \geq v) \geq \Pr(V_m \geq v) \geq p(v)$, indicating that with more injection passes, the greater is the probability of injecting any volume greater than zero into the arterial blood stream.

The odds ratio to inject any volume greater than zero in k injection passes (when compared to a single injection pass) is greater than the following expression:

$$OR_k(v) \geq \left(\frac{1}{(1-p(v))^k} - 1\right)\left(\frac{1}{p(v)} - 1\right).$$

2.5 | Numerical computation

All calculations were performed by hand and visualization of the results was made via Python (Python Software Foundation).

3 | RESULTS

3.1 | Covered soft tissue volume

The calculations were conducted based on the increment of two injection passes starting from 1 to 50 passes (see Figure 2) and based on 1, 2, 4, 10, 22, and 50 injection passes for computing a probability density function (see Figure 3). It was revealed that with a higher number of conducted injection passes a greater soft tissue volume is penetrated by the needle (e.g., the soft tissue cone affected by the needle becomes larger with each additionally performed injection pass). Fifty injection passes result in a covered volume of 0.05 cc whereas 10 passes result in a covered volume of 0.01 cc. A greater soft tissue volume covered by a constantly moving 27-G needle indicates a higher risk for encountering an artery within that respective soft tissue cone.

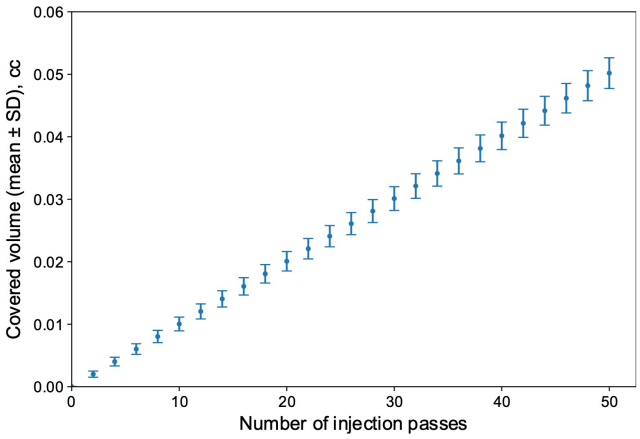

FIGURE 2 Graph showing the covered soft tissue volume (mean ± SD) in cc depending on the number of performed injection passes as performed during the constant needle motion technique. Here at 27-G ½ inch (= 12.7 mm) needle was used for mathematical modeling.

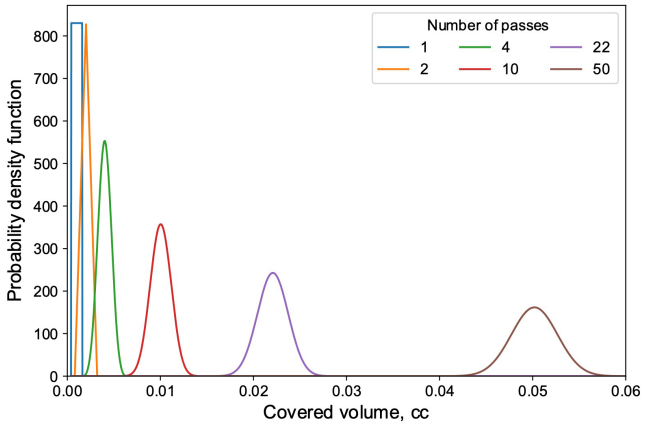

FIGURE 3 Graph showing the probability density function of the covered soft tissue volume distribution for a total number of 1, 2, 4, 10, 22, and 50 passes.

3.2 | Encounter of an artery within the covered soft tissue volume

The results of this computational model reveal that the probability to encounter an artery within the covered soft tissue area (cone) increases with the number of performed injection passes. Figure 4 shows this relationship for various scenarios of having an artery present within the covered volume; these various scenarios range from 0.1% probability to 50% probability for each conducted injection pass. The greatest increase in probability to encounter an artery was however observed below 10 injection passes which is the most likely clinical scenario.

The odds ratio increases with the number of performed injection passes creating a very strong dependency between the number of performed injection passes and the odds ratio (Figure 5). In other words: the more injection passes are performed, the higher the odds to encounter an artery within the targeted soft tissue area.

3.3 | Product injected during continuous needle motion

The results reveal that if the a priori assumption that all injection passes carry the same (but independent) risk of encountering an artery holds true, following the calculated formula $\overline{V}_k = k\overline{V}_1$, the average volume potentially injected into the arterial blood stream is proportional to the number of injection passes.

The lowest probability for injecting any volume greater than zero into the arterial blood stream increases with each performed injection pass. With more injection passes performed, more soft tissue material can be administered into an artery; the factor to determine the amount of product administered is that of the performed number of injection passes (k) (Figures 6 and 7).

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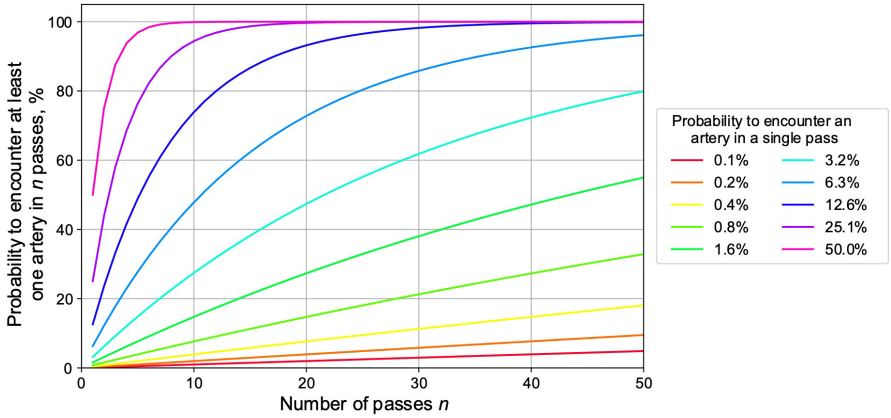

FIGURE 4 Graph showing the probability to encounter at least one artery with the injection area depending on the number of performed injection passes (*n*). Calculations were performed with different probabilities ranging from 0.1% to 50% for an artery being present within the within the injection area.

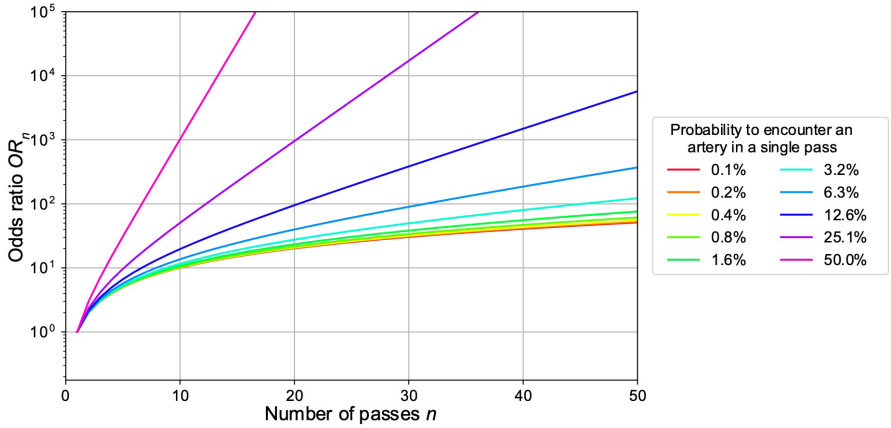

FIGURE 5 Graph showing the odds ratio to encounter at least one artery depending on the number of passes *n* (compared to a single injection pass). Calculations were performed with different probabilities ranging from 0.1% to 50% for an artery being present within the within the injection area.

4 | DISCUSSION

This study was conducted to evaluate the safety aspect of a frequently performed injection technique utilized during facial aesthetic soft tissue filler injections. This technique involves constant three-dimensional needle movements during product application after the needle tip penetrated the skin. The safety rationale behind this technique is based on the assumption that, due to the constant needle motion and simultaneous material administration, a smaller amount of product per area is injected into an artery if an artery is to be encountered within the range of the moving needle. An assumption underlying this model is that a smaller amount of intra-arterially administered product would subsequently result in a less severe vascular adverse event profile. This technique is therefore assumed to be safer when compared to a needle-based bolus injection technique which can inject 100% of the product intra-arterially if in that exact location the needle tip is located inside an artery. Following that line of thought and comparing the amount of product that could potentially end up intra-arterially, the constant needle motion technique (with more than 1 injection pass) may intuitively seem to be safer than the needle bolus technique.

Simplifying the arterial vascular system as a tubular system of decreasing diameters (from larger arteries to the capillary bed), it must be noted that adverse events following facial aesthetic procedures can occur with any amount of injected material that is greater than zero; with potentially larger amounts causing more severe adverse events. This is due to the characteristics of the arterial vascular system which becomes a capillary bed with diameter of several micrometers.[16–18] Additionally, scientific evidence is increasing that hyaluronidase alone might not be sufficient[19] to reverse tissue loss or IRVCs following hyaluronic acid-based filler injections whereas the addition of a thrombolytic agent (like urokinase) might be more efficacious.[20,21] This potentially indicates that intra-arterially injected hyaluronic acid-based soft tissue fillers have the ability to form blood clots which most likely add to the obstructive potential once reaching the blood stream and this event is most likely to happen at any given amount that is greater than zero. It is still subject to speculation whether the filler material itself or irritation of the vascular intima with subsequent clot formation is responsible for arterial occlusion following intra-arterial hyaluronic acid injection. As there is no clear evidence for a threshold amount of intra-arterially administered soft tissue filler product below which no adverse events can be expected, it has to be assumed that any amount greater than zero has the potential to cause adverse events including tissue loss and IRVCs. It needs therefore to be identified whether the constant needle motion technique can be classified as a mechanism to increase safety respecting that the intra-arterial volume has to be zero for any soft tissue filler injection.

To answer this question the present study was conducted based on the mathematical modeling of the constant needle motion injection technique. The results revealed that a greater number of conducted injection passes (here between 1 and 50) increases the soft tissue volume covered by the needle tip. This is plausible because a wider

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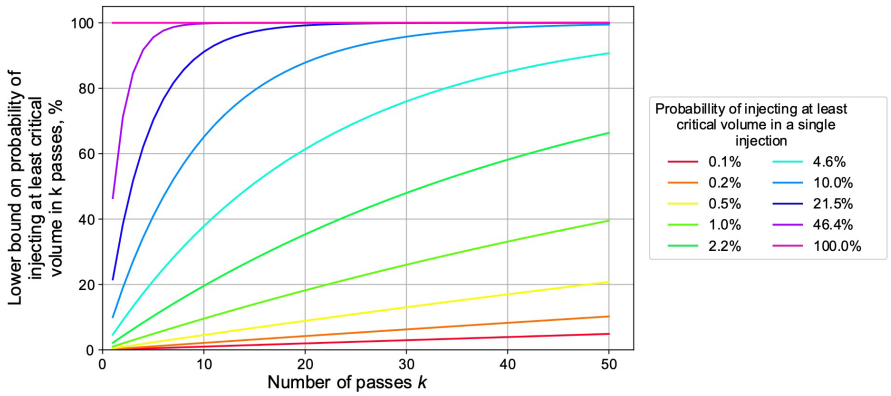

FIGURE 6 Graph showing the lower bound of the probability of injecting any volume greater than zero into an artery depending on the number of performed injection passes *k*. Calculations were performed with different probabilities ranging from 0.1% to 100% for injecting at least critical volume (= any volume greater than zero) in a single injection.

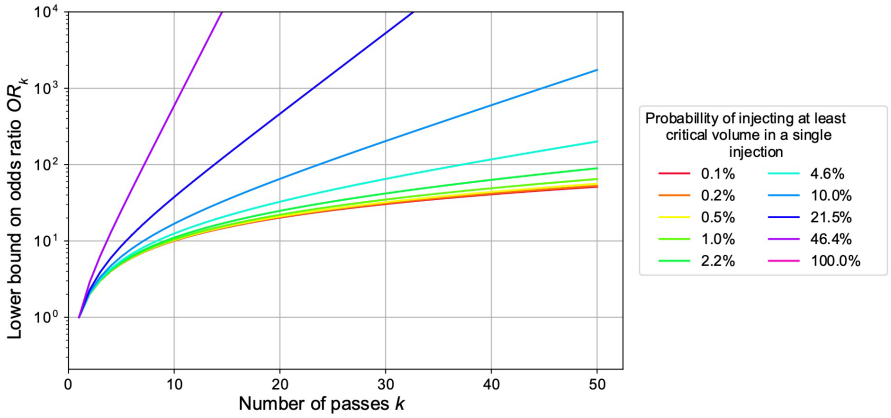

FIGURE 7 Graph showing the lower bound on odds ratio of injecting any volume greater than zero into an artery depending on the number of passes *k* . Calculations were performed with different probabilities ranging from 0.1% to 100% for injecting at least critical volume (= any volume greater than zero) in a single injection.

injection area can be reached with more injection passes performed. It must be noted that this model is based on the assumption that every injection pass is performed in a slightly different location and with every injection pass being variable and independent of each other. This corresponds to a real-life clinical scenario in which the injector is aiming each pass in a unique direction to minimize the amount of product placed in one single location thereby achieving more homogeneous product distribution and avoiding skin surface irregularities.

Despite best anatomic two- and three-dimensional knowledge the arterial vascular system is unpredictable, varies between facial sides, and is highly inconsistent between patients. A prediction model which might be able to provide information about the potential location of a vessel is therefore difficult to obtain. To circumvent this unknown parameter, the probability of an artery being present within the soft tissue volume (cone) covered by the needle tip was regarded as a constant factor of variable magnitude (here between 0.1% and 50%). The computations reveal that the more injection passes are performed, the greater the probability to encounter an artery is given. This relationship holds true for various probabilities of an artery being present within the soft tissue cone and increases in relation to the number of the performed injection passes. Clinically this means that every additionally performed injection pass increases the risk of encountering an artery and to potentially administer product into the arterial blood stream. This is especially important when considering that any amount greater than zero has the ability to cause adverse vascular events including tissue loss and IRVCs.

This study is not free of limitations. The proposed mathematical models are theoretical models which might deviate from a real-life clinical scenario. Due to ethical aspects of prospective comparative studies, a computational model is the most appropriate and therefore should be regarded as a guideline rather than an absolute clinical measure. The models calculated were based on the assumptions that the injector is moving the 27-G needle at a constant velocity throughout each and every injection pass and that the administered product leaves the needle tip at a constant and continuous volume following constant injection speed and plunger pressure. These assumptions are idealized but might be difficult to maintain in a clinical scenario where slight variations exist between needle motion and product application. Results could vary in both directions (faster vs. slower needle motion and higher vs. lower plunger pressure and injection speed) and an average might therefore be most representative.

It has to be emphasized that despite previous studies have measured the intra-arterial volume of the ophthalmic artery (between 0.1 and 0.2 cc),[11,12] no threshold value for soft tissue filler injections is currently available. No study to date has clinically or theoretically investigated whether there is such lower threshold value, and it therefore must be concluded that any volume of intra-arterially placed soft tissue filler greater than zero is detrimental. Even the smallest amount of intra-arterial product placement can either occlude a capillary bed by itself or cause the formation of a blood clot that can cause a thrombo-embolic indirectly. The present calculations therefore were conducted to investigate whether the risk increases to inject any volume greater than zero into the blood stream.

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Based on the results obtained it can be concluded that the constant needle motion technique is not a safer procedure when administering facial soft tissue filler injections. The odds of encountering an artery within the covered soft tissue volume and the odds of injecting a volume into the arterial blood stream that is greater than zero increases with the number of performed injection passes.

5 | CONCLUSION

The results of this theoretical mathematical modeling study revealed that the constant needle motion technique covers a soft tissue area shaped like a cone and that this soft tissue volume increases with every performed injection pass. The number of performed injection passes increases the probability to encounter an artery within the subdermal soft tissue volume covered by the needle and that the probability of injecting any volume greater than zero increases with the number of performed injection passes. We therefore conclude that the constant needle motion technique does not increase safety but rather may increase the odds of causing intra-arterial product administration.

CONFLICT OF INTEREST STATEMENT

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

ETHICS STATEMENT

No ethics approval was required for this mathematical theoretical study.

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