End-point accuracy in manual control of a steerable needle
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None.

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Abstract

Purpose: The ability of a human operator to manually correct for errors in the needle insertion path, without partial withdrawal of the needle, is studied by means of an active, tip-articulated steerable needle.

Materials and methods: The needle is composed of a 1.32 mm outer diameter cannula, with a flexure joint near the tip, and a retractable stylet. The bending stiffness of the needle resembles that of a 20 G hypodermic needle. The needle functionality was evaluated in manual insertions by steering to predefined targets at a depth of 100 mm and a lateral displacement of 20 mm from the straight insertion line. Steering tasks were conducted in five directions and two tissue simulants, under image guidance from a camera. The repeatability in instrument actuations was assessed during automated insertions with a linear motor. Besides the tip position, the tip angles were tracked during the insertions.

Results: The targeting error (mean $|\text{error}| \pm \text{SD}$) during manual steering to five different targets in stiff tissue was $0.5 \pm 1.1$ mm. This variability in manual tip placement (1.1 mm) was smaller than the variability among automated insertions (1.4 mm) in the same tissue type. An increased tissue stiffness resulted in an increased lateral tip displacement. The tip angle was directly controlled by the user interface, and remained unaffected by the tissue stiffness.

Conclusion: This study demonstrates the ability to manually steer needles to predefined target locations under image guidance.
Introduction

During needle interventions such as percutaneous biopsy, fluid aspiration, and radiation or ablation therapy, an accurate tip placement is crucial for the success of the procedure. However, there are numerous needle-tissue interactions conceivable that disrupt the alignment with the target, including unforeseen movements and deformations of the needle or tissue.

The liver is subjected to quasi-periodic motions in the superior-inferior direction of 5-25 mm (1). Breath holding techniques are often used during percutaneous liver interventions to approach static conditions, but require a substantial amount of patient cooperation. In addition, lesion displacements may originate from the puncture event itself (2), as a result of the insertion forces acting on the complex set of interconnected and sliding tissue structures. In many cases, e.g. under CT-guidance, visual feedback is updated periodically. The physician’s situation awareness depends on both the quality and the frequency of information updates.

Incorrect needle positioning may be reduced by improving the preoperative needle-target alignment (3), and by using larger diameter needles that deflect less in tissue. Although these techniques help for pre-planning, they do not facilitate path corrections. To have a direct control over insertion paths, needle steering is studied. The envisioned use of steerable needles is either to correct for errors in the direction of the insertion path (the needle heading), by means of small curvatures and low tissue loads, or to increase the working range of the intervention by means of highly curved paths (4).

Manual needle steering demands for instruments that can be controlled in an intuitive manner. Instruments have been developed that use either tendon-actuated needle deformations (5, 6), or protruding pre-curved stylets (7, 8). Only one study presented data on manual insertion paths (6). The assessment of repeatability in manual steering has not yet been investigated.
This work presents a manually steered, tendon-actuated needle. The aim of this study is to determine whether a human operator can minimize the tip-positioning error when inserting a needle towards predefined targets. This task represents the intra-procedural correction of the needle heading. In addition, automated insertions have been conducted in a reference experiment with fixed tip angles to evaluate the needle steering functionality in terms of path reproducibility.

Materials and methods

The experimental runs consisted of both automated and manual insertions. The used set-up included a steerable needle, a tissue simulant, a camera, and a linear motor.

Needle specifications

Needle deflections in tissue result from asymmetric interaction forces, which often originate at the instrument tip (9). The needle used in this study has a conical (symmetrical) tip, see Fig. 1. It consists of a rapid prototyped handle with a thumb controller, a nitinol cannula with removable stylet, and a tendon actuated flexure joint near the tip. The cannula and stylet are fixed with a conventional Luer taper and have a combined bending stiffness that resembles a fine 20 G hypodermic needle (see Appendix E1). After needle placement, the handle and stylet are retractable, leaving the cannula on-site as an open working channel. The handle consists of a controller, a body, and a cover (see Appendix E2).

Four tendons run through the needle lumen and connect the tip to the controller at the base. A flexure joint near the tip allows for active tip angulations (articulations) with two degrees of freedom (2-DOF), meaning that the tip can be articulated to any desired direction, see Fig. 1. These articulations facilitate the asymmetry needed for steering. The joint design is a product of
prior work on steerable needles, and of the classification of joint types by Jelínek et al (10). The four principal steering directions of the needle correspond to the four tendons, and are denoted respectively by B, F, L, and R (back, front, left, and right). In a clinical setting, back and front would represent the inferior and superior directions. A fifth, C (centered), direction was added to include straight paths. Steering to any direction can be achieved by simultaneously actuating multiple tendons, i.e. control actions are not limited to the four principal directions.

**Tissue simulants**

The stiffness of healthy and diseased liver tissue can vary considerably (11). To assess the steering sensitivity for this property, experiments were conducted in two simulants. Porcine gelatin (Gelatine, Dr. Oetker, DE) tissue simulants with concentrations of 4 and 8 wt.% were produced (see Appendix E3), similar to the extremes tested in (12). An increase in the mass fraction of gelatin resulted in a stiffer gel. The concentrations corresponded to elastic moduli between approx. 10-20 kPa. Tissue was stored in transparent containers of 125x85x120 mm (l,w,h). The containers were moved in-between measurements with 5 mm to prevent needle path-crossing.

**Experiments**

*Automated insertions*

Automated insertions of 100 mm at 10 mm/s were performed using a linear motor (EGSL-BS-55-250-12.7P, Festo, DE). The needle deflection was expressed as the final lateral displacement of the tip, as well as the radius of curvature of the traveled path. In addition, the needle heading and tip articulation angles were tracked, as described in the data analysis.
The steering direction and the tissue stiffness were varied. For the principal steering directions, fixed controller angles of 15° were used, corresponding to tip articulation angles of roughly 7°. This describes the proportionality in needle actuations, up to a tip angle limit of 10°.

The annotation of experimental conditions consists of a letter: C, B, F, L, or R, and a number 4 or 8, e.g. R-8 denotes steering to the right in 8 wt.% gelatin. Both variables were randomly assigned to the runs, and each combination was repeated ten times. In addition, a sequential series of ten runs (to the R-direction) was performed to check the accountability of the tendon-based transmission, e.g. friction, cable slack, hysteresis, on the variability in tip placement.

**Manual insertions**

During the manual runs, the tip angle could be adjusted in a continuous manner according to user preferences. The needle was controlled using the single-handed grip, shown in Fig. 2. All insertions were conducted by the first author of this paper. Prior user experience consisted of roughly 150 insertions during pilot studies. The steering task was image guided, using a direct video stream from the camera. Measured were the errors with respect to pre-defined targets, which consisted of physical lines engraved on a transparent acrylate plate in front of the sample container. The targets were located at fixed distances of 20 mm from the insertion line (for conditions B, F, L, and R) or on the insertion line (for condition C). Each target was reached ten times in a randomized order. All manual insertions were performed in 8 wt.% gelatin. To constrain the line of insertion of the needle (during both the manual and automated runs), a trocar was placed on top of the tissue simulant, as is shown in Fig. 3.
Image processing

The needle tip trajectories were recorded with a camera (FL3-U3-13E4C-C, Point Grey, CA, see Appendix E4). Frame filtering was done in Matlab (R2014b, The MatWorks, Inc., US). First, the image data was converted to 2-D grayscale colormaps, with values ranging between 0-1. The selected frames were reduced by the image data of the first frame. This method effectively segregated changes with respect to the first frame, such as the introduction of a needle. Lighting conditions and tissue motions also changed between frames, but generally at a much lower intensity. Therefore, the third step included a thresholding function to convert the grayscale intensities to binary data (threshold value: \( q = 0.9 \)). Finally, an area opening function was used to remove connected components with an area smaller than \( \lambda = 250 \). This parameter was chosen so that the needle itself was not removed in the first few frames.

For the automated runs, every 30\(^{th}\) video frame was processed, equating to an average tip travel distance of 5 mm. The travel distance served as its own length standard, as the integrated controller was well able to control its average speed (see Appendix E5). For the mean pixels-to-millimeter conversion, the linear motor accelerations and decelerations were effectively removed by considering only observed tip displacements within one standard deviation from the mean.

The method of analysis of manual insertions was largely similar. However, as the insertion speed was, at times, larger than 10 mm/s, more frames were selected for analysis (every 6\(^{th}\) frame). As the travel distance between frames was variable, the distance between the visible target lines was used as the length standard. In case the target was successfully reached, the tip could be partially obscured by the targets. Thus, for small placement errors (< 0.5 mm), the measurement accuracy was reduced. This effect was always conservative, in the sense that the
target lines were removed during image filtering. A stricter thresholding function in the experiment was used to partially resolve this (threshold value: $q = 0.97$).

Data analysis

The needle location was found by scanning for median pixel observation per row of the filtered video frames. All image analysis steps and statistical tests were performed in Matlab. The tip location was defined as the lowest observed point in each frame. The flexure joint was simplified as a hinge, allowing tip articulations to be expressed by the tip angles. The coordinates of the needle were used to construct two linear fits, at a distance of $0:d_{\text{joint}}$ and $d_{\text{joint}}:2d_{\text{joint}}$ from the tip, where $d_{\text{joint}}$ is approx. 15 mm, see Fig. 1. Using these two fits, the needle heading and tip angle were tracked. The angle between the second fit and the vertical insertion line defined the needle heading. The relative angle between the two lines defined the tip angle. A threshold path length of 30 mm ($2d_{\text{joint}}$) was used to ensure fit lines were based on sufficient data.

A linearly spaced interpolation was performed along the insertion line to evaluate the tip displacements and tip angles at fixed depths. This way, the mean and variability (standard deviation, SD) of these metrics were determined for each of the experimental conditions. The final tip position was defined at the end of the insertion. For the manual runs, the targeting error was defined as the average lateral distance from the target in the last five frames. It was therefore assumed the needle was held still after placement for at least 0.5 s.

The curvature in tip paths is presented for the 8 wt.% simulant, in each of the steering conditions. The curvature was found using a search function, during which the circle origin ($O$) moved over the gelatin surface. For each $O$, the variability (SD) in distance to the entries of the
tip path vector was determined. The circle radius \((r)\) and curvature \((\kappa = 1/r)\) were found at which the SD reached its minimum.

**Results**

**Sequential and automated insertions**

Tip position data of ten sequential runs in the R-direction are presented in Fig. 3. The left-hand figure shows a composite overlay of two video frames, at the end of two runs. Locations where the images have the same intensity are shown in gray. Differences are shown in two color bands: the orange needle is inserted in 4 wt.% gelatin, and the blue needle in 8 wt.% gelatin. The figure on the right shows the ten tip paths (orange and blue lines), the variability in data (light orange and blue patched surfaces), and the tip end-points (black circles). The average tip displacement and variability at the end of the insertions, were 13.1 ± 1.1 mm and 20.8 ± 0.5 mm, in 4 wt.% and 8 wt.% gelatin, respectively.

**Randomized and automated insertions**

Figures 4a-b present the precision in tip placement for the automated runs in the B-F and L-R steering planes. The C condition is split up to minimize data overlap. The light blue and orange patched surfaces show the variability in insertion paths in two standard deviations for visibility. The average tip position, variability, and the path curvature are shown in Table 1. This table also presents the marginal and grand means for the tip placement variability. When comparing this data to the sequential runs, it can be seen that the effect of constantly changing the steering direction is limited, both in terms of the location and variability in the final tip positions. A difference in variability is seen for the 8 wt.% gelatin, but not for the 4 wt.% gelatin.
Figures 5a-b present the mean and variability in tip angles during the automated insertions. The tip angles remained constant for all conditions, and the variability was small. The overlap in tip angles for the two tissue types showed that the tip can resist the imposed needle-tissue interaction forces, providing a constant actuation response.

**Randomized and manual insertions**

The resulting paths of the manual insertions, are shown in Fig. 4c-d. The targets are represented by black vertical lines. Compared to the automated runs, the variability among insertion paths increases rapidly at the start of the manual runs. However, as a result of active steering, the paths converge again as they approach the target. The mean and variability in placement errors are delineated per steering condition in Table 2. Some differences in tip placement variability are seen for the different steering directions.

The tip angles during the manual insertions, in Fig. 5c-d, illustrate the actuations by the user. Corrective actions could occur in the same, as well as in the opposite steering direction, dependent on how the first half of the insertion went. In Fig. 5d the average tip angle at the end of the insertion was oriented in the opposite direction, suggesting that, on average, tip trajectories followed a slight s-curve.

**Discussion**

**Contribution and relevance**

Facilitating an accurate and repeatable tip placement is of value for reducing of the number of required insertions and the procedural invasiveness of percutaneous liver interventions (13). Cornelis *et al.* (14) reported the accuracy of 4.5 ± 1.2 mm for in-vivo, non-steered needle
insertions in swine livers under CT-guidance. The insertions continued until the physicians were satisfied. An option to correct for errors in the needle heading, without having to withdraw the needle, is provided by active needle steering.

Most research in the field of needle steering aims at developing automated or robotic systems, see (15) for a review. Robotic approaches are often suggested due to their accuracy and consistency compared to manual approaches (16). The majority of work within these robotic studies make use of beveled needles. The degrees of freedom in actuation of these needles (axial insertion and rotation) are considered unintuitive for the human operator (17), and lead to placement errors (18). The rotations can also lead to out-of-plane steering errors due to torsional friction (19). Tip-articulated needles do not require axial rotations for steering. They allow for both robotic (20, 21) and manual approaches (6).

The response of a closed-loop robotic system largely relies on the available system inputs, e.g. the imaging quality and the update frequency. Human operators are potentially more flexible in terms of intercepting relevant system inputs. The inherent safety of being able to withdraw the needle at any given time (7), is a valid argument to look into manual or human-in-the-loop control solutions. Furthermore, it is worth noting that the ease of implementation of a mechanical instrument is favorable compared to that of a robotic system. Manual and robotic systems can therefore be seen as complementary developments.

**Interpretation of results**

In four out of five steering conditions (in 8 wt.% gelatin) the variability in tip positions was smaller in manual runs than after automatic runs, whereas halfway the insertion depth the reverse was still true. Note that these experiments were not strictly equivalent, as one included active
steering and the other did not. However, this data shows that a human operator can correct for deviations in the insertion path. In general, corrections to a more curved needle state were difficult compared to corrections to the straight, relaxed state.

The tip angles stayed nearly constant throughout the automated runs. The lengths of tendons in an actuation pair, required to keep the tip angle constant, should change during deflection. In open space, a visible reduction in tip angle is seen as the needle is bent. In Fig. 5 this effect is not visible. Possibly, this results from the constant pressure acting on the tip during insertion. Tissue stiffness did, however, not influence this behavior, as can be seen from the overlap in tip angle data for the two tissue types. In case the tip angle would change with depth, so would the tip asymmetry. This is relevant for descriptive path modeling, as it could relate to the accuracy of presenting needle paths by circular arcs.

Although needle design parameters are generally seen as constants in navigation models, their contributions to the actual system are not minor. Even the smallest alteration to the tip shape can have a large impact on the interactions with tissue. A 40% reduction in the initial peak insertion force was achieved by using a bevel-tip ground under three angles, instead of one (22). Studying the effect of tip shapes (e.g. articulations) on needle steering is therefore of value to the field.

Limitations
This study addresses, in parts, the influence of steering in various media by tracking paths in two tissue simulants. In this proof of concept, the used translucent gels were a practical choice and allowed for high quality path recordings with a camera. However, the effect of tissue stiffness on the instrument deflections is visible from Fig. 4. The inclusion of real tissue characteristics (non-linearity, heterogeneity, etc.) in future studies is relevant for the evaluation of needle steering,
both in manual and robotic approaches. Furthermore, real tissue is needed to evaluate the risks on iatrogenic tissue damage and tissue laceration effects. These may directly result from the needle-tissue interaction forces. For simple path corrections, the tip angles, path curvatures, and needle strain conditions are expected to remain relatively small.

The approach of inserting a needle can vary from one operator to the next. Similarly, the data presented in this study was subject to the approach and skills of the operator. It was considered effective to first insert the needle, based on a feedforward estimate, and to assess the need for path corrections on behalf of available visual feedback, approximately halfway the insertion. As this approach may vary among operators, a more elaborate user-study should be conducted.

Finally, it should be noted that all needle placement errors were acquired in 2-D, using a single, fixed camera. In reality, errors can also occur out of the imaging plane.

**Conclusion**

This article assesses manual control of a tip-articulated steerable needle. The instrument consists of a 1.32 mm outer diameter nitinol cannula, with a tendon-driven flexure joint near the tip, and a retractable stylet. The flexural rigidity of the needle resembles that of a 20 G hypodermic needle. The variability in the final tip locations was found to be smaller after active steering by hand, than after automated insertions with a linear motor. It is concluded that a manual steering approach helps to reduce needle placement errors, and thereby the number of required needle insertions, as it allows for active corrections to the needle-target alignment.

**References**


**Online appendices**

**Appendix E1: Flexural rigidity of the needle**

The resistance to deflections (flexural rigidity) of the needle is designed to approach that of a fine 20 G hypodermic needle. The cannula and stylet are produced from superelastic nitinol tubing and wire, respectively. The cannula has a 1.32 mm outer diameter and a 0.18 mm wall thickness (EUROFLEX GmbH, DE). The stylet has a 0.5 mm diameter (Coretrade, NL). The space confined between the cannula and the stylet contains four tendons (1x19, Ø 0.2 mm stainless steel rope, Engelmann Vom Hofe Group, DE). After manufacturing, needle deflections were evaluated using an end-loaded beam deflection test. The Euler-Bernoulli beam equation resulted in an elastic modulus, $E$, of 64 GPa (the EUROFLEX GmbH specification was 41-75 GPa) and a flexural rigidity, $EI$, of $7.0 \times 10^{-3}$ Nm$^2$, which resembles that of a stainless steel 20 G hypodermic needle ($6.7 \times 10^{-3}$ Nm$^2$).

The cannula is largely responsible for the height of the combined flexural rigidity of the needle. This means that the removal of the stylet and the introduction of other instruments, with diameters comparable to the stylet, will have a limited effect on the instrument-tissue stiffness balance. The curvature of the needle should remain approximately constant. In addition, during movements, combined needle-tissue displacements are expected, suggesting the tip would remain at the same relative position to the target.
Appendix E2: Handle design and force transmission

The needle handle is 3D printed (EnvisionTEC Perfactory® 4, EnvisionTEC GmbH, DE), using a photo-reactive acrylate (EnvisionTEC 5 Gray, EnvisionTEC GmbH, DE). Rapid prototyping techniques are ideal for the exploration of ergonomic and intuitive handle designs, due to the favorable production time and the limited shape restrictions. The needle interface consists of a controller, a body, and a cover. The controller can rotate about point \( P \), see Fig. 1 of the paper. The body guides the tendons towards the needle hub. The cover is fixed to the body by means of a bayonet mount and seals the distal end of the handle. Without cover, direct access is given to the needle hub and to four miniature cable tensioners.

The tendons run through the lumen and exert a force parallel to the stylet. As a result, the moment arm for deflecting the tip is small; approx. equal to the inner radius of the cannula. During needle deflections, the shortening and lengthening of tendons is in theory symmetrical around the neutral bending line. In absence of cable slack, this relates to the required tendon translations at the base, and to the arm, \( d_p \), with respect to the center of rotation, \( P \) (see Fig. 1). Miniature cable tensioners are incorporated in the handle body to reduce the slack in the tendons. They are each composed of two shape-locked parts, connected with a bolted joint, and a pre-loaded compression spring. After removal of the cover, the cable tension can be amended by a small screwdriver. The springs ensure a centered preference orientation of the tip when the needle is unactuated.

Appendix E3: Tissue simulant preparation

The gelatin was produced the day before the experiment. Gelatin powder was solved in water, with the mentioned mass fractions, and cooled for at least six hours to increase the gelling rate.
At the end of the day, the samples were stored at room temperature to acclimate to lab temperatures. This was needed as temperature has an additional effect on the mechanical tissue properties, including the stiffness. For the automated insertion series, two sample containers were used per gelatin condition. They were filled from the same gelatin batch.

**Appendix E4: Camera set-up**

Needle insertions were tracked with a camera (FL3-U3-13E4C-C, Point Grey, CA), using the default framerate (60 fps) and resolution (1280 x 1024). The camera lens was positioned at a fixed distance of 0.4 m from the needle insertion line, shown in Fig 1. To increase the contrast between the translucent tissue simulant and the needle, two LED panels (DV-96V, FalconEyes, HK) were positioned behind the setup. An intermediate paper sheet served to create a diffuse, bright background, shown in Fig. 3. The needle was axially rotated with 90° to switch between the two steering planes (B-F and L-R), without having to alter the camera position.

**Appendix E5: Needle tracking**

Besides the steerable needle, a dummy needle was used to analyze needle tracking. This needle consisted of a 2 mm diameter stainless steel stylet, and had a stiffness roughly twenty-two times higher than that of the steerable needle. It was assumed that needle deflections with this needle were negligible, so that the tracked tip paths would equal the linear stage strokes.

Table 3 shows the tracked tip translation during successive steps of the image analysis. The first column shows the direct (13 Hz) trace result of the Festo controller and encoder, averaged over ten runs (mean ± SD). The second column shows the tracked tip translation of the dummy needle in air, using the camera set-up. To calibrate the tracked paths, the needle moved directly
along graph paper. Composite image overlays, like the one in Fig. 3, were constructed and analyzed manually, using the first and last frame of each run. Results were averaged over ten insertions. This step illustrates the maximum meaningful number of decimals to present placement errors, with respect to the used imaging resolution. The final column presents the average of ten tracked paths in 8 wt.% gelatin, using the dummy needle. The paths were analyzed using the algorithms presented in the paper.

Table captions

Table 1: Data summary for the randomized and automated runs, showing the lateral tip displacement (mean ± SD) in [mm], measured at the end of the insertions, and the mean curvature [mm⁻¹] of the tip paths.

Table 2: Data summary for the randomized and manual runs, showing the mean absolute error (sign indicates direction) and variability (SD) in [mm], measured at the end of the insertions.

Table E1: Precision of the: Festo trace (in air), camera trace (in air), and tip search algorithm (in gelatin). As the average velocity was used to define the length standard in the tip search algorithm, its value was by definition 10 mm/s.

Figure captions

Figure 1. In the automated insertions, the steerable needle was connected to a linear motor and the controller was fixed (left image). A tissue simulant was placed underneath the needle, and the
tip trajectory was tracked by a camera. The right top image shows the cannula, stylet, and flexure joint. The controller fixation ensured a tip angle of approx. 7° (maximum is 10°), at a joint distance $d_{\text{joint}}$. The actuation line is shown in a cross-sectional side-view of the needle (right bottom image). This relates the controller angle, with a center of rotation $P$, to a tendon translation, with arm $d_p$, to a tip angle. During the manual insertions, the controller could be rotated freely to any desired direction, i.e. with two degrees of freedom (2-DOF).

Figure 2. Illustration of a single-handed and a double-handed method to hold and interact with the steerable needle.

Figure 3. Illustration of the needle, the tissue simulant container, and the trocar (left image). This image is a composite overlay of two frames obtained at the end of two insertions; one in 4 wt.% (orange) and one in 8 wt.% gelatin (blue). In addition, a summary of ten sequential and automated runs is shown for the two simulants in the right (R) steering direction (right image).

Figure 4: Summary of tip trajectories, in terms of both the axial and lateral tip displacement, during the automated (a, b) and manual (c, d) runs. The patched surfaces behind the paths show the variability, in 2 SD for visibility. The final tip positions are marked by black circles.

Figure 5: Summary of the tip angles with axial tip displacement, during the automated (a,b) and manual (c,d) runs. Per condition, the mean (black line) and variability (patched surface, in 2 SD) are shown.
Figure 1

- Linear motor
- Controller fixation
- Steerable needle
- Tissue sample platform
- Camera

- Flexure joint
- Cannula
- Stylet

- Needle heading & tip angle
- Tip angle
- Needle heading

- Actuation line & degrees of freedom (DOF)
  - Controller
  - Body
  - Cover
Figure 3

Sequential and automated

Axial tip disp. [mm]

Lateral tip disp. [mm]

4 wt.%

8 wt.%

Trocar

Container with gelatin

Needle
Figure 4

Randomized and automated

Randomized and manual

Conditions

Axial tip disp. [mm]
Lateral tip disp. [mm]

-90 -80 -70 -60 -50 -40 -30 -20 -10 0 0 10 20 30 40 50 60 70 80 90

4 wt.% 8 wt. %
Figure 5

Randomized and automated

Randomized and manual

FC-4 BRC-8 LFCBRL Conditions

Axial tip disp. [mm]

Tip angle [°]

4 wt.%

8 wt.%
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