Needle Steering Mechanics
and design cases

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Needle Steering Mechanics

and design cases

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Needle interventions play an important role both during the diagnosis and treatment of liver cancer. However, due to intermediate anatomical structures, such as the ribs and lungs, deep seated lesions are not always directly accessible. In addition, instrument-tissue interaction forces may cause needles to deflect during insertion. This leads to placement errors and possibly faulty diagnostic or therapeutic results. In literature, discussed methods to increase the reachability of deep seated lesions and decrease the chance on placement errors, include improvements of the medical imaging quality and of the initial needle-target alignment. In addition, the option to steer needles is actively being investigated.

Needle steering involves the planning and timely modifying of instrument-tissue interaction forces in order to control the deflections in tissue. Currently investigated steering methods employ needle base manipulations, bevel-tip needles, pre-curved stylets, active cannulas, programmable bevel-tip needles, and articulated-tip needles. The technique proposed in this work employs an actively articulated needle tip.

The aim of this research is to enhance our understanding of where needle-tissue interaction forces originate and how they can be effectively modified to steer needles. This is done by means of force measurements and device functionality evaluations during needle insertions in tissue simulants.

The influence of tip shape on the formation of bending forces during needle insertion was studied in a fundamental and macroscopic experiment (Chapter 3). It was found that articulated bevel-tip needles are more efficient in building up bending force than matched conical-tip needles. However, increasing the tip articulation angle has a larger positive effect on bending force. Furthermore, it was found that the resultant force orientation depends on the insertion force and that the size of this vector rotation varies per tip shape. In general, the radial (bending) force component increases faster than the axial (insertion) force component. The study of these relations is relevant for the accurate estimation of tip-loads in mechanics-based needle steering models.

To reach predefined targets, a teleoperation platform was developed (Chapter 4). The angle of an articulated, conical-tip needle was controlled in a closed-loop system. On-line feedback on the tip position was obtained through 3-D shape reconstructions, using fiber Bragg grating (FBG) based strain measurements. A simple PI-controller demonstrated the needle’s nimble maneuverability by continuously amending the tip angle and navigation path. An advantage of articulated-tip needles is that they do not require axial rotations to change the steering plane. Optimal paths may in the future be defined with respect to the clinical task, the limitation of tissue damage, and (when applicable) the abilities of a human operator.
Human operation of steerable needles is discussed by means of experimental results in manual and shared control steering tasks. In the implemented shared control setting (Chapter 5), a path planner determined a single-curved path to the target, in which the needle curvature and tissue straining conditions were minimized. The controller estimated the error between the actual and planned path and informed the human operator by means of low intensity force guidance. The ability of users to interact with the teleoperation platform and the acting kinematic needle steering constraints, was found to vary considerably. This stresses the need for studying the effective use of communication channels, e.g. by evaluating the weights users assign to the presented feedback. In the end, shared control may teach users how to cope with the acting needle steering constraints, and guide them in complicated steering tasks.

Manual needle steering tasks were performed by means of a novel, tip-articulated and hand-held instrument (Chapter 6). Targets in five principal steering directions were successfully reached under visual feedback. An average targeting accuracy of $0.5 \pm 1.1$ mm is reported for 100 mm insertions. This shows that active manual needle steering allows for an effective compensation of the variability among insertion paths.

This dissertation discusses important remaining challenges in the bridging of technical and clinical work fields and the realization of an operational steerable needle. The tip-tissue force measurements have provided insights in the ways current needle designs and mechanics-based navigation models can be improved. The tip-articulated needles show clear advantages for control systems, and allow for a manual approach in needle steering. Finally, the shared control of steerable needles was studied and may be of use to guide practitioners in case of a complex navigation task.
Samenvatting

Naaldinterventies spelen een belangrijke rol gedurende zowel de diagnose als de behandeling van leverkanker. Diepliggende laesies zijn echter niet altijd bereikbaar ten gevolge van de tussenliggende anatomie, zoals de ribben en longen. Ook kan het voorkomen dat de krachten die gepaard gaan met instrument-weefsel interacties ervoor zorgen dat de naald afbuigt tijdens het prikken. Dit leidt tot een foutieve naaldplaatsing en wellicht tot een foutieve diagnose of therapie. Beschreven methoden om de bereikbaarheid van diepliggende laesies te vergoten, en de kans op een foutieve plaatsing te verkleinen, gaan in op de kwalitatieve verbetering van beeldvormende medische technieken en op de verbetering van de naald-doel uitlijning voor het prikken. Verder wordt er actief onderzoek gedaan naar de mogelijkheid om naalden te sturen.

Naaldsturen omvat het plannen en tijdig aanpassen van instrument-weefsel interactiekraften met als doel de naald gecontroleerd te laten afbuigen in weefsel. De huidige stuurmethoden maken gebruik van naaldmanipulaties aan de hub, schuine-tip naalden, voorgekromde binnennaalden, actieve canules, programmeerbare schuine-tip naalden, en articulerende-tip naalden. De stuurmetode die is toegepast in dit werk maakt gebruik van een naald met een actief articulerende tip.

Het doel van dit onderzoek is het vergroten van ons inzicht in hoe naald-weefsel interactiekraften ontstaan en hoe ze effectief benut kunnen worden voor het sturen van naalden. Dit wordt bereikt door middel van krachtmetingen en functionele evaluaties tijdens het prikken in weefselsimulanten.

Aan de hand van een fundamentele en macroscopische studie (Hoofdstuk 3) werd de invloed van de tipvorm op het ontstaan van buigkrachten tijdens de naaldinsertie bestudeerd. Hieruit bleek dat een naald met een gearticuleerde schuine tip efficiënter buigkrachten genereerde dan een vergelijkbare naald met een conische tip. Het vergroten van de tiphoek had echter een sterker positief effect op de opbouw van buigkrachten. De oriëntatie van de kracht-resultante was afhankelijk van de insertiekraft en de grootte van deze vectorrotatie verschilde per tip. In het algemeen neemt de radiale (buig-) krachtcomponent sneller toe dan de axiale (insertie-) krachtcomponent. Het bestuderen van deze relaties is relevant voor een accurate implementatie van de tipkracht in mechanische stuurmodellen.

Een teleoperatie-platform werd ontwikkeld om vooraf gedefinieerde doelen te bereiken (Hoofdstuk 4). De hoek van een articulerende, conische naaldtip werd gecontroleerd in een gesloten regelsysteem en de tippositie werd online teruggekoppeld met behulp van een 3-D vormreconstructie van de naald. Deze reconstructie was gebaseerd op rekmetingen met fiber Bragg grating (FBG) sensoren. Een eenvoudige
PI-controller toont de wendbaarheid van de naald aan door continu de tiphoek en het
naaldpad te wijzigen. Een voordeel van articulerende-tip naalden is dat ze geen axiale
rotaties nodig hebben om de stuurrichting te veranderen. Een optimale planning kan
in de toekomst bepaald worden aan de hand van de klinische taak, het beperken van
weefselschade, en (indien van toepassing) de vaardigheden van de operator.

Door de mens aangedreven stuurbare naalden worden besproken aan de hand van
manuele en shared control stuurtaken. In de shared control methode (Hoofdstuk 5)
werd een gekromd pad naar een doel bepaald, met een minimale naaldkromming en
oprekking van het weefsel. De fout tussen het geplande en het werkelijke pad werd
teruggekoppeld aan de gebruiker met behulp van een lichte, begeleidende kracht. Het
vermogen van gebruikers om te interacteren met dit teleoperatie-platform, en met
de geldende kinematische stuurrestricties, bleek sterk te variëren. Dit benadrukt de
waarde van het bestuderen van effectieve communicatiemiddelen, bijvoorbeeld door te
onderzoeken hoeveel waarde de gebruiker toekent aan de beschikbare visuele en haptische
feedback methoden. Shared control kan gebruikt worden om te leren omgaan met de
geldende stuurrestricties en om de gebruiker te begeleiden tijdens complexe stuurtaken.

De manuele aansturing van een stuurbare naald met articulerende tip werd
onderzocht aan de hand van een nieuw, hanteerbaar instrument (Hoofdstuk 6).
Stuurdoelen in vijf principele richtingen werden succesvol bereikt met behulp van visuele
feedback. Een gemiddelde nauwkeurigheid van $0.5\pm1.1$ mm in de plaatsing van de tip is
gerapporteerd voor inserties van 100 mm. Dit toont aan dat een actieve besturing van een
naald effectief de variabiliteit tussen manuele inserties ongedaan kan maken.

Dit proefschrift bespreekt enkele belangrijke en openstaande uitdagingen in de
overbrugging van technische en klinische vakgebieden en in de realisatie van een
operationele stuurbare naald. De tip-weefsel krachtmetingen hebben nieuwe inzichten
opgeleverd met betrekking tot het verbeteren van de huidige stuurbare naalden en
de mechanische stuurdynamiek. De articulerende tip heeft sterke voordelen voor de
aansturing en maakt een manuele aanpak in het naaldsturen mogelijk. Shared control
technieken kunnen gebruikt worden om gebruikers te begeleiden tijdens de uitvoering
van complexe stuurtaken.
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1

Introduction

There are no such things as applied sciences, only applications of science.
— Louis Pasteur
One of the most common instruments used in the field of interventional therapy is the needle [1]. Percutaneous¹ needle interventions are used to create a mechanical duct to a target location deeper in the body. This way, needles can inject or extract fluids, extract tissue samples, and introduce catheters, ablation electrodes, radioactive seeds, and other instruments to the body. Although needles are by definition traumatic tools, the damage done is often limited in comparison to the surgical alternative. Needles are therefore classified as minimally invasive instruments.

1.1. Hepatocellular carcinoma

Liver cancer or hepatocellular carcinoma (HCC) is the fifth most common type of cancer, and the third leading cause of cancer-related deaths worldwide [2]. Early stage diagnosis of HCC is difficult for several reasons, including the organ’s deep location underneath the lower ribs, making it difficult to access and feel the liver. In addition, the organ has a considerable functional reserve, concealing direct indications of hepatic dysfunction. Finally, the sensitivity and specificity of HCC diagnosis in (cirrhotic) livers are limited with the currently available imaging modalities [2].

Needles play an important role both during the diagnosis and treatment of HCC. Percutaneous liver biopsy is a proposed option for confirming the diagnosis of HCC, both by the European (EASL) and the American (AASLD) associations for the study of liver diseases [3, 4]. Multiple treatment options, including radio frequency ablation (RFA), microwave ablation, and chemical ablation, make use of needles for the regional

Figure 1.1: Anatomical location of the liver and some of its surrounding structures. The percutaneous access to the liver can be restricted in parts by the ribcage and the lungs.

¹Oxford dictionary etymology (Latin): per cutem ‘through the skin’+-aneous.
administration of electric, kinetic, or chemical energy to denature the protein structures at the lesion site. Nevertheless, the use of needles in any of these interventions is limited by the anatomical location and percutaneous accessibility of the lesion.

As can be seen from Fig. 1.1, access to the liver can be partially obscured by the ribcage [5] and the lower parts of the lungs. In clinical textbooks, regions near the dome of the liver are regularly described as hard to reach [6–9]. The use of an angled gantry is proposed for these cases. Furthermore, lesions can be located near delicate structures, such as the portahepatis, the gastrointestinal system, or the gall bladder. Up to 30% of all small-sized tumors cannot be treated by means of RFA due to an unfavorable lesion location [2]. The investigation of reliable and accurate needle placement techniques may therefore have a large impact on both the HCC treatment plan and on the clinical outcome.

1.2. Needle types

The terminology used to classify and describe different types of needles is based on both geometry and functionality. For example, trocar needles describe a tip shape composed of three ground faces coming together at a central point. However, as a result of both clinical needs and conventions, the needle functionality and geometry are often closely related. Trocar needles are almost automatically related to the functionality of creating a portal through which other instruments can enter the body.

Alongside these descriptive terms, a large share of the needle jargon — mostly used to emphasize variations in the tip shape and outer needle diameter — accredits the respective designers. This includes among others the Quincke, Greene, Pitkin, Whitacre, Tuohy, Levy, and Sprotte needle. From a historical perspective, an overview of these needle types would help to understand the preferences or progressive insights leading to these shape revisions [10]. From a topological perspective, the discussion of tip shapes used in the clinic would be arbitrary and incomplete. For the purpose of this thesis, a more generic, conceptual discussion of needle shapes and sizes is desired.

The hollow needle, including the trocar needle shown in Fig. 1.2, is described by the outer diameter and length of its tubular section: the cannula. The space within the cannula is called the lumen. Depending on the needle type, the lumen can be filled with a stylet. The hub is the proximal end by which the needle is held or fixed. The tip is the distal end of the needle, which is used to puncture tissue. Most often, but not always, the tip ends in a sharp point belonging to the stylet, cannula, or both.

²Oxford dictionary etymology (French): *trocart, trois-quarts*, from trois ‘three’, and carre ‘side, face of an instrument’.
1. Introduction

Figure 1.2: A trocar needle is composed of a cannula and a stylet. The hub is used to hold or fix the needle and the tip, here part of the stylet, creates the initial cut and wedges open tissue so that the needle can enter.

1.2.1. Dimensions

Needles come in a wide variety of sizes. In terms of length, 3.3 mm needles are available for capillary blood collection (Omnican® Lance soft, B. Braun), and 655 mm needles for aspiration biopsy (EchoTip®, Cook Medical). According to the on-line Cook Medical product catalog, the length of needles available for the field of interventional radiology typically ranges from 100 to 200 mm.

The outer diameter of a needle is expressed in gauge (G). Needles are typically produced conform the ISO 9626 standard, with a size range of 10–33 G, or 3.4–0.2 mm in terms of the designated metric size. This standard also specifies the tube material, surface finish, some mechanical properties, and the wall thickness of normal and thin-walled tubes. In accordance to the selected length range, biopsy needles come in diameters between 12–25 G. This range can be divided in large (<20 G) and fine (≥20 G) needles [12]. Large needles are beneficial for harvesting more tissue, but also leave a larger wound. In addition, they have a higher flexural rigidity. To slowly introduce the field of needle steering, in which some flexibility of the shaft is needed to facilitate useful deflections

³The noun gauge stems from the French word 'jauge', meaning 'result of measurement' [11]. Although this suggests a standardization of size, the gauge is no true unit of length. Instead, the gauge is a metric that describes the 19th century limits for wire production (at this time, a universal unit of length was not at all existent). It quantifies the number of times iron wire had to be drawn in order to achieve a desired size. The available sizes, in turn, were based on the holes in a draw plate, which varied per manufacturing company. The resemblance among gauges is largely attributed to iron material properties. For each drawing step, the decrease in diameter was confined by the yield strength of iron (and a safety margin), and was approx. 11%.

With time, the demand for a universal standard to describe wire dimensions increased. This was both a result of improvements in measuring accuracy and of similar developments for other units, e.g. the foundation of the International System of Units. In practice, the facilitation of international trade must have played its part. In the UK, a new Weights and Measures Act was formulated to enforce this progression. In the period that followed, individuals and institutions tried to promote their own gauge. This resulted in a so called 'battle of the gauges' [11]. Finally, in 1883, an Order in Council was signed by Queen Victoria, establishing the British Standard Wire Gauge. This norm closely resembled the Birmingham Wire Gauge, and the gauge standard in use today.

⁴As this ISO standard involves a stainless steel base material (instead of iron), the gauge number has lost its practical agreement on meaning. It presents an arbitrary and irregular set of diameters. It does give the impression of a limited and defined number of size options, which may be convenient for stock control [11].
1.2. Needle types

In tissue, the relevant diameter range is narrowed down to 20–25 G. Note that in most fields of industry, the gauge is long replaced by metric units. As a result, the instruments produced for this thesis are not conform ISO 9626. Their diameters are expressed in mm. When relevant, comparisons with the clinically available sizes are made.

1.2.2. Tip geometry

Small alterations to the needle size and shape can have a large impact on the interaction with tissue. In terms of the tip shape, a lancet point or triple-ground bevel may reduce the initial peak insertion force by 40% compared to a regular bias, single-ground bevel [13]. In general, the knowledge on instrument-tissue force interactions for tip shape refinements on this detail level, is still very limited. As a result, this thesis does not cover complex shapes. Instead, it focuses on basic geometrical shapes. Figure 1.3 shows stylized versions of the more popular tip shapes currently on the market. These tip shape variations⁵ have appeared with the intent to simplify an intervention or to improve a clinical outcome. Envisaged improvements include a reduction of the [10]:

- fluid leakage,
- required tip penetration depth,
- occurrence of post-dural-puncture headaches (PDPH),
- required insertion force (using a cutting tip), and
- tissue trauma (using a non-cutting, e.g. tapered, tip).

Figure 1.3: A selection of tip shapes, based on van Gerwen et al. [16], showing (from left to right) a: blunt, beveled, conical, ogive (Sprotte), diamond (Franseen), and pre-bent beveled (Tuohy) tip.

⁵It should be noted that, from a geometrical perspective, the overview of needles used in the clinic is incomplete. Varying, for instance, the number of sharp edges (or ground faces) at the tip, would lead to the blunt tip (0), beveled tip (1), diamond tip (3), and conical tip (∞). Exploring the remainder of options according to this attribute would yield new tip shapes, e.g. a tip with opposing bevels (2). The ogive and pre-bent tips show that there are more attributes that can be varied, i.e. adding a second grinding direction leads to concave or convex surfaces, and adding a pre-bend in proximity to the tip leads to even more possible shape variations.
A clinical outcome that is of particular importance in this thesis, is the incidence of needle deflections during the insertion in tissue. It turns out that this factor is largely influenced by the tip shape. Sitzman et al. investigated the risk of spinal needle misplacement as a result of undesired deflections [14]. They report that needle deflections depend on the used tip shape and on the needle gauge. They also report increased risks for needles that are bend near the tip (they added these needles to simulate prior accidental needle-bone contact), and advise to discard needles in this condition. Okamura et al. found that needles with an asymmetrical beveled tip deflect more in silicone than those with a symmetric triangular or conical tip [15]. These observations took place during an analysis of insertion force components for various needle types. In accordance, the measured orthogonal force component for bevel-tip needles was larger.

1.3. Needle-tissue interaction forces

Forces acting on the needle can be classified as either contact forces, resulting from non-linear elastic tissue deformations, puncture forces and cutting forces, resulting from various tissue failure modes (i.e. non-elastic deformations), and friction forces. These forces can interact with one another, e.g. an increased (normal) contact force can increase the friction. In the case that a resultant non-axial (orthogonal) force component acts on the needle during insertion, a deflection may occur. The previous section showed that the tip shape plays a crucial role in the formation of these orthogonal forces.

The tip shape⁶ defines the interactions that will take place as the needle tip is pushed against tissue. As an asymmetric tip enters, a local inequality in compression arises, since a larger tissue volume is pushed to one side compared to the other. The tissue type,⁷ in turn, defines how the effective compression and tension levels translate to forces. As the needle proceeds, these forces are transferred to the cannula, and the tip interacts with a new bit of tissue. The cumulative effect of forces building up along the inserted length of the cannula determines the overall instrument shape.

1.4. Needle steering

The insight in relations between needle types, instrument-tissue force interactions, and resulting instrument deflections in tissue, have led to the conception that needle paths can ultimately be controlled. This equates to the possibility to steer needles through tissue. A steerable needle is deemed beneficial to reduce the occurrence of lesion targeting errors, while following planned straight or curved paths. In addition, steerable needles

⁶The contact surface and symmetry, the location and sharpness of the point and cutting edges, etc.
⁷The non-linear elastic properties, inhomogeneity, fracture resistance, etc.
1.5. Problem statement

may increase the applicability of minimally invasive approaches for lesions that would otherwise be considered hard to reach. For a needle to be steerable, the instrument-tissue interaction forces should be adaptable. This can be achieved by actively altering the tip shape, tip orientation, insertion angle, insertion speed, and so on. The following generic definition for needle steering is applied:

**Definition:** Needle steering involves the planning and timely modifying of instrument-tissue interaction forces in order to allow for controlled needle deflections during the insertion in (simulant) tissue.

To an extent, all needles are steerable. By actively altering the insertion line as the needle is embedded in tissue, the instrument deforms, becomes asymmetric, and can be steered. This technique is referred to as base manipulations. The effectiveness of this approach, however, reduces with insertion depth [17]. Actual design concepts for steerable needles appeared as early as the 1980s [18]. However, particularly during the 2000s, contributions to the field have been steadily growing. A review on needle steering methods is provided in Chapter 2.

1.5. Problem statement

A forthright method to design a steerable needle, that would work in all potential clinical settings, is non-existent. A major complicating factor is that needles are constantly embedded in and supported by soft tissue. These contact conditions, and the inter and intra-patient variability therein, causes the interaction forces — and the resulting needle deformations — to vary. The structural integrity of the needle under these varying conditions (preventing mechanical failure modes, such as buckling), requires the instrument to be stiff. As a result, needle steerability and procedural safety meet each other in a mechanical instrument stiffness trade-off. An optimal design would most likely vary per application or even per intervention.

The tissue in which the needle is embedded also introduces some nonintuitive navigational constraints, limiting the locations that can still be reached. Path corrections are not easily made and can be both velocity and environment dependent. To relieve the practitioner from these control considerations, robotic steering is an often suggested alternative. Therefore, a considerable amount of literature has been devoted to system modeling: delineating the factors that influence the needle steering kinematics, nonholonomic system constraints,⁸ and suitable path planning techniques [20].

⁸Definition adopted from [19]: “Nonholonomic systems are, roughly speaking, mechanical systems with constraints on their velocity that are not derivable from position constraints.”
1. Introduction

System models convey a fundamental understanding of (a limited part) of the world we live in. They can be either phenomenologically descriptive (top-down) or explanatory (bottom-up) in nature. By definition, a model is a representation of the real system, typically constrained by boundary conditions. A good model is generic and has limited constraints, so that it can function for a large set of possible system states. Although this is slowly changing, most kinematic needle steering models are descriptive in nature and follow a top-down approach. To an extent, this results from tissue dependent variables, deranging the possibility to formulate generic explanatory rules to describe needle paths. As a result, the validation of kinematic models is largely performed under idealized conditions, e.g. automating the insertion motion and puncturing in tissue simulants. In fact, over 50% of all publications in the field did not discuss any aspect of the intended clinical use [21]. Nonetheless, the real system is largely affected by relative motions and tissue-related 'uncertainties'. The inclusion of these factors potentially lifts some major constraints to the functionality of currently available navigation models.

For the progression from descriptive to explanatory models, both the effects of tissue and of instrument dependent (design) variables in the needle-tissue interaction mechanics need to be examined. Once a design is picked, its variables are typically considered as constants in a navigation model. Hence, design variables have received comparatively little attention in needle steering [22]. However, the effect of tip design on the real system can be large, as was discussed in Section 1.2.2. The effect of tip design on the system model can, therefore, be equally large. Despite the various needles presented in literature, design parameters have been rarely used as independent variables for study. This introduces the following central theme, and aim of this thesis:

**Aim:** This work aims to increase the understanding of where needle-tissue interaction forces originate and how they can be effectively used to steer needles.

1.6. Approach and thesis outline

The instrument designs manufactured for this thesis are based on the mechanical properties of clinically available needles for the diagnosis or treatment of HCC.

The effect of varying the tip shape is discussed by means of phenomenological observations of both insertion forces and needle deformations. To this purpose, both passive (rigid) and active (tip-articulated) steerable needles have been produced. To limit the effect of tissue dependent interactions, experiments were conducted in tissue simulants. The relevance of including tissue related factors to future system models has been examined by conducting experiments in multiple tissue simulant types.
A second objective of this thesis was to examine the possibility to introduce the human operator in the needle steering process. The level of man-machine interactions was varied by conducting needle steering tasks in computer, shared, and manually controlled settings.

This thesis starts with a literature review of needle steering techniques in Chapter 2. The aim of this chapter is to create a database of strengths and weaknesses of already explored steering methods, and to relate these features to the mechanical instrument designs. Alternatively, as many needle steering studies do not discuss a specific application, this overview may help in matching the technical strengths to the clinical needs.

Chapter 3 compares the 6-DOF force/torque characteristics of multiple needle tip shapes during the insertion in artificial tissue. This study particularly focuses on the bending forces generated at the tip. The articulated, conical needle tip used in the remainder of this thesis is, here, discussed and compared to other tip designs applied in the needle steering research field.

In Chapter 4, a robotic setup for needle steering is introduced. The control scheme applied in this setup is kept simple to emphasize the characteristics of the mechanical design. A collaborating academic project partner proceeded by developing more elaborate control schemes to steer this particular needle [23].

In a slightly different control approach, the human controller and computer controller have to co-operate. This shared control implementation is discussed in Chapter 5. In the implemented case, the human operator had the authority, but received low intensity force guidance from a haptic interface during the navigation task. The force levels were based on the error vector with respect to the planned optimal path.

A manually controlled steerable needle is presented in Chapter 6. The accuracy and repeatability of steering with this device in four principal steering directions is presented and discussed.

Finally, Chapter 7, summarizes the research findings of this thesis and discusses their relevance in light of the overall progress in this research field. The various examined instrument designs and steering methods are compared, and suggestions are made for the future heading of needle steering research.
Design choices in needle steering — a review

Abstract Alignment errors can arise during needle tip placement in deep-seated tissue structures. This can lead to diagnostic errors and undesired therapeutic outcomes. Path corrections by means of needle steering have been investigated in scientific studies for the past decades. In this chapter, several approaches are compared, each of them with their own strengths and weaknesses. The applicability of various needle steering techniques is discussed in terms of mechanical design choices in order to assess and guide on-going work in this research area. Included steering techniques apply needle base manipulations, bevel-tip needles, pre-curved stylets, active cannulas, programmable bevel-tip needles, and articulated-tip needles. These techniques are classified as either passive or active, based on how steering is achieved. Mechanical properties of developed needles vary largely. Flexural rigidity, for instance, was found to vary with a factor $10^6$. Mechanical interactions, such as torsion and buckling, are described per steering technique. Different research objectives have led to different needle designs. Design criteria are typically based on these objectives, and not necessarily on clinical needs. However, the effectiveness of steering techniques depends heavily on this design, on the navigation medium, and on the intended task. In the proposed classification scheme, this dependence is quantified by the flexural rigidity.
2. Design choices in needle steering — a review

2.1. Introduction

To reduce the damage to healthy tissue, there is both the desire to use fine needles, and to expand their use for deeper and more difficult to reach targets. The combination of these factors poses some interesting practical challenges. After all, there must be a limit to the controlled use of thin and flexible instruments, when interacting strongly with complex and poorly known environments. Cannula bending and buckling, for example, may result from a sudden increase in reaction forces at the tip, when puncturing a membrane. The magnitude of such a response relies on the mechanical characteristics of both the tissue and the needle.

The performance of an insertion may be assessed by the final tip placement accuracy. In a typical intervention, the target lies in line with the needle and is reached without complications. However, unforeseen mechanical instrument-tissue interactions can lead to alignment errors. These errors can result from human factors, imaging limitations, instrument deformations, and unpredictable tissue reactions, such as sudden deformations and sliding of multi-layered structures [20]. Furthermore, target movements caused by physiological processes, such as breathing [24] and heartbeat, can introduce placement difficulties. Consequences of tip misplacement can be additional damage due to re-puncturing [25], false negative diagnostic results, poor dosimetry, and tumor seeding [26].

2.1.1. Background

Needle steering describes a research field in which dynamic needle-tissue interactions are used to correct for existing needle-target alignment errors in the insertion process. Simple translations and rotations of the needle base with respect to the insertion point presumably describe the first needle steering attempts in clinical practice. These base manipulation techniques are still in use today, as complete reinsertions of the needle are said to increase the risk of complications [25]. Meanwhile, other needle steering techniques are being developed, which is the topic of discussion in this review.

In particular, the modeling and control community picked up needle steering as a practical case to implement a number of fundamental kinematics and mechanics-based navigation models. A discussion on how to deal with the existing needle movement restrictions and elastic constraints plays a central role in this field. Several review studies have summarized these topics [20, 27–30]. In general, it has been acknowledged that little attention has been paid to needle design parameters [22]. A large part of the work on needle steering has focused on bevel-tip needles. Therefore, this review will focus on steering mechanisms and mechanical design aspects of developed needles. This is done irrespective of the initial research motivations, whether they aim to evaluate a
mechanical system or an underlying navigation model. Although the functionality of a mechanical design may be largely influenced by the employed navigation model, the reverse is also true. The correctness of a navigation model and the relevance of selected parameters are directly related to the design. In fact, design choices may not only affect navigation models quantitatively, but also the framework for which they hold in terms of disturbance rejection and control robustness. The needle deflection sensitivity to tissue density variations is, for instance, influenced by the tip type [15]. Alternatively, buckling phenomena are typically not a part of the navigational plan, yet they are often reported in validation experiments [29, 31].

2.1.2. Aim

Path corrections by means of needle steering have been investigated in scientific studies for several decades. Different research objectives in these studies have led to different needle designs. Design criteria are typically based on the set objectives, and not necessarily on clinical needs. As a result, current designs all have their pragmatic limitations.

Aim: This study describes the various needle steering techniques, and discusses their applicability, based on mechanical functionality and design choices.

2.1.3. Survey method

A literature search was performed in PubMed and Web of Science (last updated on 24–08–2014), with search queries containing combinations of the words needl*, steer*, robotic*, biop*, interact*, and forc*. Search results were divided in fundamental research (n=49), pre-puncture alignment techniques (n=60), and steering techniques (n=87).

Needle placement approaches can be divided in initial alignment and subsequent correction (e.g. steering) techniques. Pre-puncture alignments can be robot-assisted. Insertions are either performed manually [32] or automatically [24] under image guidance. An overview of several setups, typically comprising a robotic arm, has been provided by Cleary et al. [33]. The inverse approach, where the target is aligned with a straight needle path, typically makes use of blunt probes to manipulate tissue. Two examples of these systems are discussed by Reed et al. [29]. The scope of this review will, however, not extend to these alignment techniques.

Fundamental studies were read, contributing to our general understanding of the underlying mechanical interactions at the instrument-tissue interface. However, this review primarily extends to studies involving steering tasks and steerable needle designs.
2.2. Classification of steerable needles

It was found that 68% \((n=59)\) of the needle steering articles and proceedings appeared in robot, control, and automation journals, 23% \((n=20)\) appeared in (biomechanical) engineering journals, and 9% \((n=8)\) appeared in imaging journals. Furthermore, based on the introductory examples, programmed environments, or tissue models adopted, it was found that 59% \((n=51)\) of the articles did not sketch a clinical setting for needle steering, 14% \((n=12)\) focused on the prostate, 10% on the liver \((n=9)\), 8% on the brain \((n=7)\), 6% on the lungs \((n=5)\), and 1% on the breast, heart, and kidney \((n=1\) each). Of the validation studies, 39% \((n=34)\) was performed in a tissue simulant, 32% \((n=28)\) in a virtual environment, 16% \((n=14)\) to some extent in ex-vivo biological tissue, 10% \((n=9)\) in air, 1% \((n=1)\) in water, and 1% \((n=1)\) in in-vivo biological tissue. Of the biological tissue studies, three studies performed placement accuracy experiments and reported an average error: 2 mm \([34, 35]\), and 3 mm \([36]\). One study reported a single measurement for a path tracking error of 0.5 mm \([37]\).

2.2.1. Steering methods

Needle steering can be divided into passive and active techniques. In any case, the needle cannula bends during insertion. In passive steering, bending forces are a sole result of needle-tissue interactions. In active steering, either the tip or the cannula shape can be modified regardless of the tissue contact.

**Definition:** Active needle steering denotes the possibility to alter the needle-tissue interactions by actively modifying the needle shape.

This definition differs from the one used in vehicle dynamics, where active steering denotes a speed dependent adaptation of the ratio between steering wheel input and front wheel output. For needle steering, input-output relations with respect to control parameters, such as speed or environmental contact, are not that intuitive. By the current definition, active steering of a car would resemble the option to re-orient the front wheels. It would exclude the option to lift the car in its entirety to change its orientation. Similarly, the axial re-orientation of an asymmetric tip would be insufficient for active steering.

In this chapter, six steering techniques are distinguished, shown in Fig. 2.1. The techniques are, respectively, base manipulation, bevel-tip needle steering, pre-curved stylet steering, active cannula \((AC)\) steering, programmable bevel-tip steering, and articulated-tip steering. This figure also presents the degrees of freedom in needle control. Needle steering techniques will be discussed in this approximate chronological order, although time lines may overlap. The first two techniques are considered as passive, the latter four as active.
2.2. Classification of steerable needles

Figure 2.1: Illustration of steering techniques, including their degrees of freedom in actuation. Depicted are: (1) base manipulation, (2) bevel-tip (with and without pre-curve), (3) pre-curved stylet, (4) active cannula, (5) programmable bevel-tip, and (6) articulated-tip steering. The programmable bevel-tip needle is here presented with two segments, versions with four segments are available as well.

2.2.2. Modeling methods

For a better understanding of needle-steering techniques, a short introduction of the relevant mechanical interactions is in order. Axial forces acting on a needle during insertion are typically divided into puncture forces, cutting forces, and friction. Studies seem to suggest that cutting forces remain roughly constant, and that friction increases linearly with insertion depth. Axial force measurements by experiment have been summarized by van Gerwen et al. [16]. The orthogonal force components that result in bending of the needle are less well documented. A general understanding of how these forces are perceived to affect the insertion process is best conveyed by the progress in the formulation of navigation models, including the ones discussed in [20, 27–30].
Kinematic models are used to analyze and predict the range of motion of a given mechanism without relating this to the cause of motion. For needle steering, this allowed the adoption of several kinematic descriptive rules from the field of vehicle dynamics. Models adopted include the unicycle model [38], the bicycle model [39], the Dubins car model with binary left/right steering [40], and the underwater vehicle model with nonholonomic constraints [41]. Nonholonomic constraints are present in practically all needle steering models and describe the limitations of possible endpoints of the needle tip with respect to the previous path taken and the velocity-dependent constraints of the system. Typically, there is a zero velocity constraint implemented for lateral displacements in tissue and needle movements are described by a constant radius of curvature. To navigate under these conditions, several path optimization algorithms (e.g., Markov decision processes, artificial potential field and penalty-based methods, or rapidly exploring random trees) have been adopted and tested (for a review see [20]). Besides the idealized system parameters employed in these motion planners, it has been advised to take into account the practical uncertainties of the needle-tissue interactions and the imaging techniques. They can have a substantial impact on both the probability of finding a successful route and on the optimal path computation time [40].

Making these descriptive models robust for a large range of system conditions requires a substantial amount of fitting to experimental data. Alternatively, explanatory rules, between steering inputs and outputs, can be implemented. For example, relations can be derived between the ‘steering offset’ (a control input) and the curvature of a multi-segment, programmable bevel-tip needle [42]. Note that this is already similar to finding symbolic expressions that explain the underlying system mechanics.

Mechanics-based models for needle steering have included both numerical (e.g., finite element models) and symbolic approaches. Needle bending is often predicted by considering a cantilever beam loaded at the tip [43], and supported along its length by virtual springs [17], or a distributed load [44]. A generic representation of such a mechanics-based model, is shown in Fig. 2.2. These models typically presume quasi-

Figure 2.2: Simple mechanical representation of a needle, modeled as a cantilever beam, inserted in tissue. Tissue support is, here, expressed by a series of springs, and the load $F$ describes an orthogonal component of the asymmetric tip-tissue interaction.
2.2. Classification of steerable needles

static needle motions [17], and neglect friction along the shaft. Their advantage over kinematics-based models becomes apparent when departing from the conditions to which the model was fit. For example when the needle makes a double-curved path, instead of a single-curved path [44].

Steering techniques that consist of multiple interacting parts, may require additional models to deal with internal mechanics. In depth descriptions of the combined curvature of pre-curved concentric tubes by means of Euler-Bernoulli beam expressions have, for instance, been presented in parallel by two research teams [45, 46]. However, combining internal and external mechanical models is a challenging task in which the instrument pre-shapes can limit the achievable shapes within tissue [47]. Currently, concentric tubes are either described as catheter-like or minimally invasive instruments (simplifying the external mechanics) [47], or as designs for which the outer cannula is stiff compared to the inner pre-curved component (simplifying the internal mechanics) [36].

Last but not least, needle-tissue interaction models at a micro-structural level, e.g. at the needle point, can enhance our understanding of puncturing and cutting forces. In order to predict crack propagation, the integral of the energy release rate during cutting can be compared to the materials fracture toughness [48]. In this study, material deformations are predicted by a modified Kelvin model. Initial boundary displacements, and subsequent tip insertion, crack growth, and tissue wedging effects can lead to various levels of stored strain energy and crack propagation phenomena, called modes of interaction. These modes may also affect needle-tissue contact conditions and, thereby, the viability of modeling assumptions. The analysis of cutting speeds on (un-)stable crack propagation was, for instance, helpful in understanding insertion force levels [49].

2.2.3. Steerable needle geometry

Needle-tissue interactions, including contact and fracture mechanics, can lead to complex load distributions along the cannula. Needle steering, in essence, is described by the deformations that result from unevenly distributed loads acting on the needle. How much steering can be achieved within a given environment depends on the height of these loads and on the flexural rigidity of the needle. Therefore, a comparison of needle cross-sections and construction materials would be a relevant first step in a steerable needle design analysis.

Bending

The flexural rigidity of a needle describes its sensitivity in deflecting under influence of orthogonal loads. These orthogonal loads may result from the steerable needle shape (the control signal), or from tissue factors, such as inhomogeneities and relative motions
of structures (disturbance signals). How flexible a steerable needle needs to be depends on the planned path curvature, the tissue properties, and on the control signal-strength, i.e. the orthogonal load that can be produced by a specific needle shape. Needles that can produce a strong control signal, relative to any disturbances, are beneficial for robust control. These needles can be made more rigid and still achieve sufficient curvature. A low rigidity, on the other hand, reduces the tissue stresses needed to support a specific needle shape. The optimal flexural rigidity would therefore depend on the planned path complexity and on the estimated magnitude of disturbances. This last factor can sometimes be underestimated while studying needle-tissue interactions in artificial or virtual environments.

Figure 2.3: Cross-sectional views of the steerable needles evaluated in this review, including their material compositions. These cross sections have also been used to calculate the flexural rigidity values presented in Table 2.1. The second row at method 2 presents pre-curved bevel-tip needles. Hatching denotes the material was not specified. The figure (method 6) has been updated to include the needles presented in this thesis.
2.2. Classification of steerable needles

Table 2.1: Theoretical flexural rigidity \( [N \cdot m^2] \) of evaluated steerable needle designs. As a reference, clinically used fine (20–25 G) and large (14–19 G) needles are shown. Due to possible protruding tubes, the flexural rigidity of ACs is provided for both the instrument tip and base.

<table>
<thead>
<tr>
<th>Steering method</th>
<th>min.</th>
<th>max.</th>
<th>refs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fine needles</td>
<td>( 6 \cdot 10^{-4} )</td>
<td>( 7 \cdot 10^{-3} )</td>
<td>-</td>
</tr>
<tr>
<td>Large needles</td>
<td>( 7 \cdot 10^{-3} )</td>
<td>( 2 \cdot 10^{-1} )</td>
<td>-</td>
</tr>
<tr>
<td>1 Base manipulation</td>
<td>( 3 \cdot 10^{-3} )</td>
<td>( 7 \cdot 10^{-3} )</td>
<td>[26, 50]</td>
</tr>
<tr>
<td>2a Bevel tips</td>
<td>( 4 \cdot 10^{-5} )</td>
<td>( 1 \cdot 10^{-3} )</td>
<td>[51, 52]</td>
</tr>
<tr>
<td>2b Pre-curved bevel tips</td>
<td>( 1 \cdot 10^{-6} )</td>
<td>( 7 \cdot 10^{-4} )</td>
<td>[53, 54]</td>
</tr>
<tr>
<td>3 Pre-curved stylets</td>
<td>–</td>
<td>( 7 \cdot 10^{-3} )</td>
<td>[55]</td>
</tr>
<tr>
<td>4a AC (at the tip)</td>
<td>( 7 \cdot 10^{-4} )</td>
<td>( 2 \cdot 10^{-1} )</td>
<td>[36, 46]</td>
</tr>
<tr>
<td>4b AC (at the base)</td>
<td>( 7 \cdot 10^{-4} )</td>
<td>1</td>
<td>[36, 46]</td>
</tr>
<tr>
<td>5 Programmable bevel tips</td>
<td>n/a</td>
<td>n/a</td>
<td>[56]</td>
</tr>
<tr>
<td>6 Articulated tips</td>
<td>( 7 \cdot 10^{-3} )</td>
<td>( 8 \cdot 10^{-3} )</td>
<td>Chapter 4,6</td>
</tr>
</tbody>
</table>

Table 2.1 presents the flexural rigidity, \( E \cdot I \), of the considered steerable needle types in this review, with \( E \) being the material’s Young’s modulus, and \( I \) being the needle’s second moment of area. As this metric requires a linear elastic material, rubberlike programmable bevel-tip needles are excluded from this comparison. Flexural rigidity is determined based on the needle size, shape, and material, as visualized in Fig. 2.3. Whenever multiple tubes are present, the principle of superposition is used. For convenience, the following values are used: \( E_{ss} = 200 \) GPa (stainless steel), \( E_{nit} = 50 \) GPa (nitinol), and \( E_{PEEK} = 3.4 \) GPa (PEEK polymer). Exact values may differ, depending on heat treatments, crystal structures, etc. Clinically used needles are also shown as a reference. They are divided in fine 20–25 G needles and large 14–19 G needles [12].

Torsion

Besides flexural rigidity, torsional stiffness is of importance in the mechanical design of steerable needles. In particular for those needles that require axial rotations to steer. Initially, torsion was frequently neglected for the sake of presenting simpler and more intuitive interaction models. Torsion effects are, however, receiving more and more attention [57, 58]. This is underlined by the large share of acknowledged control issues that deal with out-of-plane motions [59–62]. Nevertheless, with the given information, torsional stiffness could not be summarized in a way similar to flexural rigidity for all needle designs. Where possible, torsion effects are discussed individually.
2.3. Passive steering techniques

In this section, passive needle steering techniques, such as classic base manipulation and bevel-tip needle steering, are discussed. The vast majority of needle steering research deals with passive steering, and of this group, most work is performed on bevel-tip needles. Besides nonholonomic constraints, passively steered needles are generally subjected to unilateral constraints, since these needles will only deflect when pushed in tissue [60]. While the needles are supported by tissue and remain in their linear elastic range during deformation, they will typically follow the same path during retraction.

2.3.1. Base manipulations

One of the first needle steering methods involved base manipulations [26]. Base manipulations are caused by rotating the needle at the hub, around the insertion point. This results in an alignment error between the needle insertion axis and the tip. Further insertion causes an asymmetric force-play along the embedded needle-length. In a robot controlled, open-loop setting, base manipulations were used to regulate the needle tip position and orientation with respect to the target location, as is shown in Fig. 2.4 [17]. A planar finite element model including potential fields with regions of repulsion and attraction was defined. Subsequent iterative path planning resulted from minimizing the total path potential. Validation studies were conducted in tissue simulants, but feasible needle paths were not always found due to the navigation constraints of the needle.

In order to reduce computational complexity, the finite element model was replaced by a planar beam model, subjected to friction and supported by virtual springs [17]. Minimizing the total spring energy during path planning would resemble finding a navigation solution with minimal lateral tissue pressure. This was used to optimize performance. In an inverse kinematic approach, this yielded a set of input base movements.

Figure 2.4: Obstacle avoidance by needle base manipulations (adapted from [17]). As a reference, the right-top corner shows a cross-sectional view of the needle, similar to what was shown in Fig. 2.3.
2.3. Passive steering techniques

A closed loop (using x-ray) test trial in ex-vivo tissue resulted in a tracking error of 0.5 mm for a 40 mm deep insertion [37]. Peak steering moments at the needle base of around 25 Nmm were reported. Under ultrasound guidance in artificial tissue, a 1 mm needle placement error was found after 35–40 mm deep insertions [50]. Interestingly, the latter study used an adaptable virtual spring model. Local tissue motions were assessed with speckle tracking ultrasound to subsequently update the tissue stiffness coefficients in the navigation model. Two tissue simulants with a different stiffness value were used and recognized.

Steering by means of base manipulation techniques is subject to depth dependencies. As the moment arm decreases and the tissue resistance increases with depth [29], accurate tip placement will be hampered [17], and the required steering moments around the base can be expected to increase. Therefore, base manipulation techniques generally focus on superficial targets.

In terms of the instrument design, base manipulation studies have used unmodified, fine (20–22 G), stainless steel needles with various tips, e.g., Franseen [26] or bevel [50]. Needle steering is assumed to result from the base manipulations, and the interacting effects with tip types and orientations have not yet been investigated or discussed.

2.3.2. Bevel-tip needles

During normal insertions in a silicone model, it was demonstrated that needles with a beveled tip bend more than those with a symmetric conical or triangular tip [63]. Several research groups have therefore focused on the steering possibilities using thin and flexible bevel-tip needles. As is demonstrated in Fig. 2.5, these needles are controlled by translating and rotating the needle along its longitudinal axis [52, 64]. It is often assumed that asymmetric interaction forces at the tip cause a bending effect with a constant curvature [39], but this assumption does not necessarily hold within compliant soft tissues [64].

Figure 2.5: Insertion and rotation of a bevel-tip needle. The imbalance in tip-tissue reaction forces will cause the shaft to bend (adapted from [28]).
The insight in bevel-tip needle steering in controlled environments reached advanced levels. Both phenomenological and mechanics-based models were introduced to control steering. Some studies have accounted for moving obstacles by means of 2-D intra-operative motion replanning (with a camera) [65]. Mechanically, interaction forces are related to the insertion speed [16, 52], and the tissue’s rupture toughness [67]. The curvature of inserted bevel-tip needles is not necessarily affected by insertion speed [52], but can be increased by:

- decreasing the needle diameter [66],
- decreasing the bevel angle [52],
- increasing the bevel surface [54],
- introducing a pre-curve near the tip,
- introducing a flexure joint near the tip [22, 68],

However, the effect size of these variables should be studied within the noisiness of biological tissue. In ex-vivo tissue, no significant effect in curvature was found by varying the bevel angle [66]. In-vivo, the path curvature has even been described as negligible [53].

Research was done to control not only steering direction, but also the magnitude (the radius of curvature). This was achieved by investigating duty cycled needle spinning [54], and actively variable bevels [42]. The duty cycle is defined as the ratio of the rotation period, $T_{rot}$, to the full cycle period, $T$. Here, $T = T_{rot} + T_{ins}$, with unrotated insertion periods, $T_{ins}$ [65]. Theoretically, a 100% duty cycle would produce a straight insertion line. Duty cycling can, however, cause helical marks in artificial tissue, which is a potential indication for iatrogenic tissue damage. With respect to the clinical use of rotating bevel-tip needles, it is noteworthy that some procedures require a specific bevel orientation during the insertion [70]. Furthermore, it has been suggested that bevel direction could make the difference between parting or cutting of fibrous structures [71]. To the author’s knowledge, conflicts between navigational and clinical demands for bevel orientation have not been investigated.

The kinematic constraints and control robustness of bevel-tip needle steering meet in a trade-off. Fine and flexible needles are less constrained in terms of bending potential. However, the path of a fine needle is easily affected by tissue irregularities [29]. The path of beveled needles was found more sensitive to tissue density fluctuations than that of triangular or diamond-tip needles [15]. These effects need to be considered in the placement plan [71]. Also, fine needles are more susceptible to buckling near the entry point [52], or within tissue [29]. A validation study in ex-vivo liver tissue with a 0.86 mm nitinol stylet — a large diameter for bevel-tip needle steering standards — showed that
several trials had to be terminated because the needle buckled before penetrating the encountered structures [31]. Another recent study reported similar findings [35].

During bevel-tip needle steering, torsional damping and friction can become substantial [58, 60, 72, 73]. Needle rotations of 180° (often used in 2-D control models to steer left or right) can lead to phase differences between the tip and base of up to 45°, after 100 mm insertions [59]. This potentially leads to large out of plane steering errors. Camera tracking of the needle was used as a dead-beat observer to estimate the actual bevel orientation in artificial tissue [60]. However, the quality of this estimate relies on the amount of sample points, i.e., the insertion depth. In addition, torsional dynamics can be implemented in control models [58]. Physical experiments in plastisol with time-varying torsion dynamics in a closed-loop setting showed improvements over purely kinematic control methods [57, 74]. Alternatively, it was found in artificial tissue that rotating or ‘wiggling’ the needle may release the built-up strain energy [72], a finding that may be coherent with the observation that post placement needle revolutions diminish target displacements [69].

Pre-bends and pre-curves have been introduced to enhance the steering behavior of bevel-tip needles [14, 54, 66, 75]. In terms of control, pre-curved needles show a velocity dependence in contrast to normal beveled needles [75]. The investigation of duty cycling of pre-curved needles showed that needle tips may not immediately follow the base movement due to tissue resistance. In addition, care should be taken to prevent sudden snapping motions to the unstrained needle state, which can lead to tip position discontinuities of up to 4 mm [76]. Besides snapping, corkscrew insertion motions should be carefully assessed. Replacing the pre-curve with a flexure near the tip potentially reduces tissue damage during these procedures [22].

Most often, bevel-tip needle steering experiments are performed with thin, solid, and superelastic nitinol stylets, ranging in diameter between 0.36 and 0.83 mm [51, 52]. This would resemble 21–28 G needles. Pre-curved needles may be thinner (down to 0.15 mm, <34 G) [54]. These stylets may be used as guidewires. Alternatively, these stylets can be replaced by cannulas, e.g. 0.86 mm nitinol tube [31], to be of use as an open working channels in clinical procedures.

2.4. Active needle steering

In this section, the main active needle steering concepts are discussed. During active needle steering, either the tip or the cannula shape can be actively modified. As a result, the needle-tissue interactions will change, and so will the planned path. Mechanically, the used needles are more complex than the earlier discussed passive needles. In terms of steering constraints, they are often expected to be more adaptive to variations in the
navigation medium. Most techniques make use of a combination of protruding stylets or cannulas, some of them being pre-curved. In case of multiple interacting tubes, the internal ratio in flexural rigidity values is of importance. This ratio is either in balance (close to 1) or dominated ($\gg 1$). In the latter case, the stiffer (typically outer) cannula determines the combined needle shape. As bending of actively steered needles is at least partly the result of internal mechanics, the need for bilateral path planning should be addressed. Similar to the internal mechanical interactions, the external interaction with tissue can be described as either balanced or dominated. The less needle steering relies on interactions with the environment, the higher the need for bilateral path planning.

### 2.4.1. Pre-curved stylets

Figure 2.6 shows a protruding, pre-curved stylet used as a guidewire to steer a cannula [55]. Mechanical interactions with the dominant cannula, as well as with the tissue, determine the overall shape of the guidewire. The degree of steering can be controlled by varying the exposed stylet length. An initial prototype for this technique was manufactured and tested in ex-vivo porcine tissue. A path planning algorithm was developed in a 2-D ultrasound guided system to determine the exposure length and cannula insertion depth required for steering. Once the cannula is positioned, the actuation mechanism and stylet can be retracted. From a control perspective, a reorientation of the steering direction can be achieved in the retracted stylet state, minimizing tissue interference and torsion effects.

For this technique, a modified 20 G bevel (Chiba) needle was used. The stylet was curved opposite to the bevel direction over a tip length of approximately 20 mm. In order to compensate for the bevel and travel along a straight line, the stylet was kept slightly exposed in its base configuration. Mechanically, a stiffness balance with tissue was sought. When completely retracted, the stylet curve should be straightened out by the cannula. However, tissue interaction forces should still be able to affect the cannula shape.

![Figure 2.6: As the pre-curved stylet and outer cannula are translated with respect to each other, the length of the exposed pre-curved tip is altered (adapted from [55]).](image-url)
2.4. Active needle steering

2.4.2. Active cannulas

An extensively studied active steering technique, shown in Fig. 2.7, uses multiple pre-curved concentric tubes, called active cannulas (ACs). Initial studies on balanced tube pairs were presented in parallel by two independent research teams [45, 46]. By means of rotating and extending the tubes with respect to one another, cannula curvature, tip position, and tip orientation can be adapted. Since the actuation forces are generated internally, these instruments do not need tissue contact to steer. In terms of trajectory control, balanced tube pairs are, in fact, not very tolerant to variable environments [31]. Therefore, these balanced ACs are often described as compliant, catheter-like mechanisms, useful for applications in open space or fluid-filled environments [46].

Piecewise circular shapes have been used to model balanced AC systems. This shape assumption holds when the overlap of curved sections is sufficiently short and the radius of curvature sufficiently small. The consideration of torsion effects in balanced AC systems has shown that, otherwise, non-circular shapes can result as well [47]. Internal interactions, but also the contact with tissue, may disturb the delicate mechanical balance present in these systems. When disregarded, torsional wind up can lead to both excessive placement errors and sudden snapping motions between (locally) stable cannula configurations [61, 62]. This risk is particularly large when balanced tube pairs are rotated to 180°, i.e., when straightening out a balanced tube pair. A bifurcation in the energy landscape will appear, and upon sufficient rotation, one of the cannulas will snap from a local to a global minimum in potential energy. A proper design of the stiffness pairs, or otherwise a limit to the allowed relative tube rotations, is required to prevent this [61].

The complexity of combining the internal mechanics with external instrument-tissue interaction models was discussed in Section 2.2.2. As a result, simplified AC designs were developed for use in tissue. The resulting tube configurations were, in fact, remarkably similar to the pre-curved stylet steering method. They consisted of one pre-curved inner tube and one straight, dominant outer tube. In the past, similar designs have been

Figure 2.7: Example of an AC consisting of three tubes (adapted from [61]).
presented and marketed [18, 78, 79]. To date, this is considered the only viable AC design for which the shaft can follow the tip during advancement in tissue [36]. Nevertheless, to the author’s knowledge, these needles were the first to be tested in combination with a therapeutic modality (ultrasonic ablation) in an ex-vivo tissue setting [77]. Placement accuracy measurements yielded tip errors on randomly picked targets in liver tissue of 3.3±2.7 mm (mean ± SD), under 2-D ultrasound tracking [36]. Information on the needle path or target depth was not presented.

As the description of ACs is generic, the presented needles vary considerably in complexity and size. Nitinol pre-curved tubes with straight stylets were used, with diameters down to 0.8 mm [61]. In contrast, a 4.2 mm needle was used to carry and guide an interventional tool [36].

### 2.4.3. Programmable bevel-tip needles

A quick developing needle steering technique, based on biomimetic concepts, uses a programmable bevel-tip [42]. The latest version of this instrument consists of four interlocked segments that can slide along one another, shown in Fig. 2.8. Each segment is actuated by a linear motor at the base and allows for a geometrical change of the respective tip section. Therefore, these instruments are actively controlled. Similar to normal bevel-tips, cannula bending results from interactions at the tip-tissue interface.

Tip control and steering occurs by setting the relative offsets of the interlocked segments. These settings relate the tip shape to a radius of curvature. This relation is tissue-dependent. Trocars have been used to prevent buckling. One of the lumens, leading to the instrument tip, contains an electromagnetic position sensor, which is used for closed-loop control of the insertion path.

The virtues of rapid prototyping have contributed to a quick evolution of this steering method, for which more or less every successive article presents an altered instrument

![Figure 2.8: Programmable bevel-tip consisting of four interlocked segments (adapted from [41]).](image)
2.4. Active needle steering

design. Considerable improvements include a decrease in needle diameter from 12 to 4 mm in a two-segment design, for 2-D navigation tasks [80], and down to 8 mm in a four-segment design for 3-D tasks [56]. A 6 mm four-segment design assessed target migration during ‘reciprocal motions’ (by actuating segments in turn), while navigating on straight paths [81]. This study showed insightful relations between the actuation approach and the insertion rate on tissue strain, displacement, and relaxation phenomena.

Steering tasks in tissue simulants aimed at the evaluation of device functionality for eight principal bending directions (every 45°). This was achieved by either single-segment actuation or by actuating two adjacent segments simultaneously. The found variation in steering response for different directions was attributed to different boundary conditions acting on the gelatin phantom [56]. Overall, the path curvatures ranged up to 0.017 mm$^{-1}$ for the single actuated segment configurations, and up to 0.010 mm$^{-1}$ for the double actuated segment configurations. This difference was attributed to the varying flexural rigidity of the two configuration types [56], illustrating the importance of this factor for both navigation constraints and modeling.

2.4.4. Articulated-tip needles

Articulated tip steering has been integrated in a variety of medical instruments, such as laparoscopic tools [82] and endovascular guidewires [83]. In needle steering, this technique has received comparatively little attention. During active tip articulations, the tip orientation can be actively modified. Actuations occur at the needle hub and the mechanical propagation of actuation signals can, for instance, be achieved by tendons. The needle tip is positioned on a flexible cannula. Between the cannula and articulated tip, any type of compliant structure or joint mechanism can be used. Cannula bending results from asymmetric external interactions with tissue structures, comparable to the operation of (pre-curved) bevel-tip needles.

Figure 2.9: A tendon actuated, articulated-tip needle, using FBG sensors for shape feedback.
Closed-loop navigation tasks were performed in tissue simulants, see also Chapter 4 (computer controlled) and Chapter 6 (manually controlled). In the computer-control setting, a PI-controller was implemented to steer the tip by means of needle shape reconstructions, using fiber Bragg grating (FBG) based strain measurements. The shape reconstruction process is described in [84]. Nine different target locations were defined, and an absolute error of $6.2\pm1.4\text{ mm}$ (mean ± SD) was found [85]. The precision, defined as the variability of locations reached (irrespective of the target location), was $2.6\pm1.1\text{ mm}$ over these nine steering conditions. The present systematic effects were attributed to behavioral characteristics of the mechanical system. This work describes the crucial factors that have to be controlled in order to achieve an equal steering response in each direction.

In a follow-up study, the control method was refined by a kinematics-based bicycle model, using on-line parameter estimation techniques to update the front frame offset (the 3-D ‘wheelbase’) in various artificial tissue layers [23]. A validation test in a 14.9 wt% gelatin resulted in an absolute targeting error of $2.0\pm0.78$ mm after 100 mm insertions.

Figure 2.9 presents an actively steered needle consisting of a conical steel tip on top of a PEEK cannula. In between, a ball joint mechanism is used. The needle stylet has grooves for glass fibers (with FBGs) and the cannula has grooves for steering tendons. The tendons are connected to the tip and controlled by four rotary servo motors. In size, the used needle is comparable to 14–15 G needles. Due to the material choice, the flexural rigidity, on the other hand, is comparable to a fine, 20 G needle.

2.4.5. Other techniques

A recent addition to the class of cannula deformation techniques, describes the use of a robotic controller for the actuation of a manually steered, tendon-driven, biopsy needle [25]. Limited information is provided on the instrument design. The device has a joystick handle to control the actuating tendons. As a result of tendon actuations, the needle shaft deforms with a constant curvature (instead of articulating the tip). In this study, the joystick was controlled by means of a couple of DC motors. The planar tip position in air was tracked with a camera. The number of iterative control steps, required to reach the target with sufficient accuracy ($<1$ mm), was reported. On average this was eight. This metric was considered to relate to the number of image captures required for accurate navigation in the lung environment.

Another recently developed, actively steered needle makes use of a shape memory alloy wire to generate a mechanical strain. This strain is employed to articulate the needle tip by means of a compliant structure [86]. The shape memory alloy wire is heated by means of laser light, delivered through optical fibers integrated in the needle. With this technique, a unidirectional active needle steering mechanism was realized within a 1.37 mm diameter nitinol structure. With this instrument, it was aimed to reach tip
articulation angles up to 10° and lateral deflections in tissue in the order of 20 mm. Future developments will initially focus on the reduction of power losses and waiting times, inherent to the used heating process, and will later focus on tissue simulant studies.

Simulations on compliant hinges in proximity to symmetric, magnetized needle tips were performed to investigate the feasibility of magnetic-tip articulations [87, 88]. Advantages of such a system would be the initial straight tip configuration, and the ability to steer to any direction by changing the location of the surrounding magnets. As the actuators can be kept at a distance, the instruments that have to be introduced into the human body can remain relatively simple. On the other hand, the interactions between a compliant mechanism and soft tissue will be crucial to investigate. Aside from modeling the risks on needle buckling phenomena and stressing the need for a proper hinge dimensioning [87], no test setups or instrument prototypes have, to the author’s knowledge, been presented.

Theoretically, cannula deformation can also be achieved by piezoelectric actuators, straining the needle surface on one end and compressing it on the other [89]. Some FEM simulations were performed to show the relations between actuator design and potential tip deflection. It was concluded that a set of thin (0.05 mm) and long (200 mm) actuators would be needed to produce planar tip deflections in the order of 0.15 mm, using a potential difference of 30 V. Suggestions to improve the tip deflection included the application of longer and slimmer actuators and the increase of the potential difference. However, the authors acknowledge that this may go at the cost of actuator robustness and procedural safety.

2.5. Discussion

Needle steering is investigated to allow for adjustments to the insertion path during the intervention. Needle steering methods include both passive and active solutions. During passive steering, cannula deformations result from interactions with surrounding tissue. During active steering, either the tip or cannula can, to some extent, be deformed without making tissue contact. The magnitude of the path adjustments relies on the steering method, the instrument shape, and the tissue environment, i.e., the mechanical instrument-tissue interactions. Needle steering, in practice, is complicated by the variability resulting from uncertainties in these interactions. This may even affect the insertion success rate [31, 35]. In addition, needle steering is constrained by both the navigation medium and the needle itself, including both design and operational factors, like the flexural rigidity and the insertion velocity. All in all, the manual control of flexible needles is said to be difficult and nonintuitive [90], and a lot of work in this field is devoted to the development of robotic steering approaches.
Although path planning techniques for needle steering have been studied extensively, it was noted that validation studies rarely use tissue or instrument design parameters as dependent variables. Typically, validation experiments assess the accuracy of navigation models under known (constant) system conditions, i.e., a fixed needle and a fixed artificial tissue type. As the selection of accurate tissue parameters is considered important for realistic needle insertion modeling [39], a valuable step of bringing the current models to practice would include the evaluation of the model sensitivity to these fixed parameters. Perhaps, a generic and robust navigation model may require the introduction of tissue (and instrument) dependent variables. A noteworthy contribution to this is found in a recent assessment of needle placement robustness in double-layered tissue simulants [65]. Steering constraints in both layers were determined a priori and used to adjust the navigation plan. Alternatively, tissue stiffness coefficients may be amended by means of ultrasound footage [50].

A classification of steering techniques is proposed by considering the mechanical functionality of developed needles. The effectiveness of needle steering depends heavily on the tissue environment and on the intended use. This dependence is described by the needle-tissue stiffness balance. Currently, it was found that over 50% of the analyzed needle steering studies refrained from discussing clinical applications. Steering with extremely flexible needles is often validated in well-known artificial tissues. Scaling of needle-tissue interaction mechanics and their uncertainties will be valuable, not only to ensure realistic movement constraints, but also to assess the procedural safety, steering robustness, and occurrence of buckling, snapping, and tissue slicing effects.

The effect of insertion velocity during needle steering depends on the navigation medium. Findings in artificial tissue seem to agree that axial force (regularly related to target movement [91]), and in particular friction, increases with increasing velocity [16]. Findings in biological tissue, on the other hand, suggest that puncture force remains either constant or decreases with increasing velocity [16, 92]. Note that, for steering tasks, the velocity should not just depend on optimizations in terms of forces or target movements, but on many factors, including the control approach, the limitations of human motor control (when applicable), the reliability of available feedback, the desired path curvature, and the nearby presence of delicate structures. Axial rotations can potentially reduce friction and total axial force [16], even when the rotations are performed after tip placement [69]. However, the risk on tissue damage should be carefully addressed.

Although this review assessed steerable needle designs, it should be noted that some of the discussed steering concepts were not developed with the purpose of validating a particular design. Instead, they were used to validate a mathematical model. There is a fundamental difference between the two, as one optimizes to a single robust working solution, whereas the other optimizes to a generic underlying control method. Any confinement to such a method with respect to applicability is undesired. Although different research goals have led to different setups, eventually a combination of these goals — a needle and a control model — is desired. As many well-written reviews on control aspects exist [20, 27–30], the critical analysis of needle designs and their practical
2.5. Discussion

Table 2.2: Frequently used test conditions and objectives in needle steering studies. The steering methods include: 1 base manipulation, 2a beveled tip, 2b pre-curved beveled tips, 3 pre-curved stylets, 4a balanced ACs, 4b dominated ACs, 5 programmable beveled tips, and 6 articulated tips.

<table>
<thead>
<tr>
<th>Meth.</th>
<th>S/C¹</th>
<th>Tip type</th>
<th>Materials²</th>
<th>Target³</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>S/C</td>
<td>Various</td>
<td>SS</td>
<td>Shallow</td>
<td>Min. curvature/tissue load [17]</td>
</tr>
<tr>
<td>2a</td>
<td>S</td>
<td>Bevel</td>
<td>Niti</td>
<td>Deep</td>
<td>Study parametric relations [52]</td>
</tr>
<tr>
<td>2b</td>
<td>S</td>
<td>Bevel</td>
<td>Niti</td>
<td>Deep</td>
<td>Max. curvature/steering range [54]</td>
</tr>
<tr>
<td>3</td>
<td>S/C</td>
<td>Bevel</td>
<td>SS</td>
<td>Deep</td>
<td>Miniaturize design [55]</td>
</tr>
<tr>
<td>4a</td>
<td>C</td>
<td>Pr. bevel⁵</td>
<td>Niti</td>
<td>Open</td>
<td>Max. planning accuracy [47]</td>
</tr>
<tr>
<td>4b</td>
<td>S/C</td>
<td>Pr. bevel⁵</td>
<td>SS/Niti</td>
<td>Deep</td>
<td>Max. planning accuracy [36]</td>
</tr>
<tr>
<td>5</td>
<td>C</td>
<td>Deep</td>
<td>R</td>
<td>Deep</td>
<td>Min. trajectory error [93]</td>
</tr>
<tr>
<td>6</td>
<td>S/C</td>
<td>Conical</td>
<td>P/SS</td>
<td>Deep</td>
<td>Study systematic behavior [85]</td>
</tr>
</tbody>
</table>

¹ Instrument includes a stylet (S) and/or cannula (C).
³ Aimed target location: shallow, deep, or accessible through open space.
⁴ The tip can be part of an internal tool.
⁵ Programmable beveled tip.

As a result of differences in experimental designs, test conditions, and performance metrics, the direct comparison of needle steering techniques is difficult. Steering potential in air or tissue will differ largely. Steering potential also differs among organs [53]. In terms of task performance, some studies aim to reach superficial targets with a minimized needle curvature, whereas other studies focus on steering extremes for deep targets. Radii of curvature and placement accuracies for several combinations of steering techniques, control approaches, and test environments are summarized in [93]. Such experimental results may in absolute sense be indicative, but should always be regarded in their full context (in terms of test conditions and experimental objectives). Table 2.2 presents some of these factors. The discussion that should be provoked by addressing these differences is why we actually need steering. It is often suggested and assumed that needle steering provides new minimally invasive approaches and allows targets to be reached that were formerly inaccessible. Another objective may be to perform existing interventions more effectively, accurately and with less complications.

Finally, the importance of a human operator to guide, interpret, and safeguard the intervention should not be underestimated. Reed et al. stated that the control of insertion speed and the selection of a needle path should be human operated for a needle placement
robot to be clinically viable [29]. It was said that the physician relies on visual feedback from imaging techniques and kinesthetic feedback from the instrument in combination with a mental image of the anatomical structures [17]. Other sensory information, such as tactile feedback from intra-procedural force measurements [20] or needle shape reconstruction by local strain measurements [84] may also aid in task performance. These additional feedback methods are interesting research topics to investigate, both to increase our understanding of needle-tissue interactions and to enhance the operator’s awareness of ongoing events.

2.6. Conclusion

Some remarks can be made regarding the clinical use of the evaluated steering techniques and instrument designs. Base manipulations may be used to reach shallow targets, as the effectiveness of this approach reduces with target depth. Breast biopsy or local anesthesia can be viable clinical applications. Nevertheless, alternative methods, such as tissue fixation, needle-target alignment, and preloading [94], should also be considered. Other passively steered needles, such as bevel-tip needles, require a certain path length for effective steering. In terms of optimal use, these needles deal with an inherent design conflict. Maximal steering is achieved with high tip-tissue interaction forces within dense tissue. Fluctuations in density are, however, undesired in terms of steering robustness, since the used fine needles are typically very flexible. The functionality of pre-curved bevel-tip needles in the brain is being investigated [34]. Pre-curved styllets and simple AC designs can perhaps be used in liver biopsy or brachytherapy. AC designs with balanced tube pairs require limited tissue contact conditions. They may be considered for catheter interventions or minimally invasive therapies. For programmable bevel-tip needles, this same division is thinkable. Scaling down of current designs is an ongoing challenge. Possibly, thinner needles will require harder construction materials, e.g. metals, which may decrease current friction issues. On the other hand, an increased friction (or added fixations) may be investigated for open air steering. This can lead to multichannel designs suitable for a minimally invasive setting. The articulated-tip needle aims for deep therapies such as liver biopsy, but further experiments in a biological tissue setting are in order to validate their functionality.

This review stresses the value of studying mechanical characteristics of the tissue and needle, e.g., flexural rigidity and torsion stiffness, irrespective of the research objectives. The variance of these factors in current needle designs is illustrated in this chapter. Currently, this variance is primarily attributed to technical and/or control design challenges. Eventually, these factors should be determined according to clinical needs.
The influence of tip shape on bending force during needle insertion

This chapter has been submitted for publication

Abstract Only few studies exist in which bending forces are compared for multiple needle steering techniques. In this work, the effect of the tip shape on the tip-tissue force interactions was studied using 10 mm diameter needle tips. Six different tips were selected, including beveled and conical tips, with or without pre-bend or pre-curve. A six-degree-of-freedom force/torque sensor measured the loads after insertion steps in artificial tissue. Results show that the relation between bending (radial) force and insertion (axial) force is not always proportional. This suggests that the tip load does not have a constant orientation, which is often assumed in mechanics-based steering models. For all tip types, the resultant force assumed a more radial orientation with increased axial load. This effect was larger for straight tips than for pre-bent and pre-curved tips. Furthermore, the increase of the axial and radial forces with insertion depth (the $F_a$ and $F_r$ slopes) were determined. The slopes of the beveled tips were consistently higher than those of the matched conical tips. However, the effect of tip angle was larger than the effect of tip type. This shows that the use of bent or curved tips is of value for increasing the bending force, as well as for producing a more constant orientation of the tip load.
3. The influence of tip shape on bending force during needle insertion

3.1. Introduction

The occurrence of needle deflections in clinical practice is typically attributed to unbalanced force interactions at the tip. This imbalance occurs during the insertion phase and results from the needle itself, which may be asymmetric in shape, or from uneven properties or boundary conditions in tissue. However, our understanding of the contributing factors in either of these categories, such as the tip type or the tissue stiffness, is limited. In this study, the insertion (axial) force and bending (radial) force components were measured for various tip shapes. This enabled the quantification of the radial-to-axial force ratio and the comparison of resultant tip loads for different steering techniques.

3.1.1. Background

The practical use of bending forces for steering of needles has been explored at lengths over the past decades [27], despite the limited theoretical knowledge on the formation of needle-tissue contact loads. Often, needle shape estimates rely on mechanical models that describe the movement constraints of a deflecting rod, suspended and propagating within a soft, elastic material [17]. For top-down — descriptive — models that summarize the needle kinematics, tip-tissue interactions do not have to be understood in detail. One can directly relate an input variable, e.g. the duty cycle of a rotating bevel-tip needle, to an output metric, e.g. the radius of curvature of the resulting needle path [95]. For bottom-up — explanatory — models, the underlying causes of observed loading conditions are relevant. For example, one can estimate the tip force by means of a force orientation prediction, e.g. orthogonal to a bevel surface, an axial insertion force measurement, and a friction estimate obtained from test sets [96]. These models distinguish the general asymmetric forces at play, but currently do not yet provide insight into their constitution. It is not yet known how the insertion method, the tissue environment, and the tip geometry affect the mechanics, and neither is it known how this type of information should be processed in mechanics-based models.

3.1.2. Related work

A study of deflections of various (bend) needle tips was provided by Sitzman and Uncles [14]. However, to arrive at parametric relations of the asymmetric tip-tissue interactions, supportive force data are needed.

Okamura et al. measured insertion forces in silicone at the base of bevel, conical, and triangular tipped needles [15]. By means of a radial-to-axial force ratio, they showed that
bevel-tip needles bend more than conical or triangular-tip needles. In addition, they noted that axial force may decrease with the number of sharp edges at the tip.

Podder et al. measured the six-degree-of-freedom (6-DOF) force-torque response during in-vivo prostate brachytherapy interventions, using diamond-tip needles [97]. The average maximum insertion force was approx. 15 N, compared to a bending force of approx. 1 N for these symmetric tips.

Wedlick et al. studied curvature for various arc lengths of pre-curved needles in plastisol [75]. They showed that the radius of curvature of the tip path was inversely proportional to the arc length and also that steering of pre-curved needles was dependent on insertion velocity.

By means of a novel macroscopic approach, Misra et al. revealed that the transverse forces at the needle tip decreased with increasing bevel angle [51]. Needles, 15 mm in diameter, with bevel angles between 10–60° were inserted in plastisol. Transverse forces up to 4.4 N were measured, but corresponding insertion forces were not reported. The presented parametric tip force and tip moment relations were considered to be independent of the input force.

Majewicz et al. studied not force, but curvature after needle insertions in ex-vivo goat liver [66]. They compared multiple bevel angles, but could not conclude that there was a difference in curvature. They suggested this was a result of the increased tissue inhomogeneity and viscoelasticity of biological tissue, compared to artificial tissue. An increase in needle curvature with pre-bent angle was found. In a continuation of this work, insertion forces were measured during puncturing of canine prostate, kidney, and liver tissue using conical, beveled, and pre-bent beveled tips. Tip type did not have a clear effect on the required insertion force, but forces did differ among the tested organs [53].

3.1.3. Aim

The above work shows that the descriptive modeling of bending mechanics in real tissue can be complex. For the development of explanatory models, it is useful not only to study the system as a whole, but also to focus on isolated parts of the system. This includes fracture mechanics at the tip [48], and friction along the shaft [98]. Another factor, which is expected to be crucial in the constitution of an asymmetric tip load and a needle deflection, is the tip-tissue contact force. With the exception of beveled needles, this factor has only been discussed implicitly, as a part of the complete-system, during actual insertions in (simulant) tissue.

**Aim:** This study aims to provide a quantitative comparison of tip-tissue contact forces for various asymmetric needles, having either a beveled or conical tip.
3. The influence of tip shape on bending force during needle insertion

The present work studied the tip-tissue forces in relation to tip geometry by minimizing obscuring factors, such as non-linear tissue elasticity, friction, and fracture forces. This required the use of homogeneous tissue simulants. This work is relevant for the formulation of explanatory, mechanics-based system models, the optimization of tip designs, and for the proper actuation of shape-adaptable needles, such as concentric tubes [46], compliant needles [22], and articulated-tip needle [85, 99, 100].

3.1.4. Approach

The relations between needle tip geometry and tip-tissue interaction forces were studied for beveled, pre-bent beveled, pre-curved beveled, pre-bent conical, and pre-curved conical needle tips. Tip insertions were controlled by means of a micro-positioning stage and mechanical loads were measured with a 6-DOF force-torque \( (F/T) \) sensor. The influence of the choice of tissue simulant was investigated by performing experiments in both silicone-based and agar-agar-based simulants.

Figure 3.1: Experimental setup showing the a) manual stages, b) force sensor with global coordinate system, c) needle tip, and d) tissue simulant. On the right, a schematic mechanical representation of the measurement is shown, including the axial and radial forces, \( R_a \) and \( R_r \), and the resultant moment \( M \), at the tip.
3.2. Materials and methods

Since fracture phenomena are difficult to control, we excluded them from this study by applying only small tip displacements. The force-displacement response is conceivably linear in this range (see Section 3.3), even though the overall curve is not. This allows for a comparison of slopes in the force-displacement curve, termed the effective stiffness. Since current mechanics-based deflection models often split-up the axial and radial force components, the same was done for the effective stiffness.

3.2. Materials and methods

3.2.1. Measurement setup

The experimental setup consisted of a manual X Y Z-translation stage built up from three single axis micro-positioning stages with a 10 \( \mu \text{m} \) resolution (PT1/M, Thorlabs, US). A container of size 55x55x55 mm was glued onto a PMMA plate and fixed to the X Y-stage platform, as shown in Fig. 3.1. During the experiments, the container was filled with artificial tissue. The X Y-platform allowed for a maximization of the side-wall clearance for the various tip shapes. The Z-stage was used to insert the tips and thereby alter the magnitude of the tip-tissue loads. A detent ensured a constant alignment of the sensor and tip. As a result, \( F_y \) and \( T_x \) were expected to be the dominant force and torque components. Their relations to the loads at the base (\( F_{ax}, F_r, T \)) and tip (\( R_{ax}, R_r, M \)) are defined in Section 3.2.5. A 6-DOF F/T sensor (ATI nano17, ATI Industrial Automation, US), was used to collect the loads at the base of the needle tip. This sensor was connected to an amplifier (BPS4000, Calex Electronics Limited, GB), and a 16-bit DAQ system (NI USB-6210, National Instruments Corporation, US). Force data were sampled at 200 Hz.

3.2.2. Needle tips

Based on previous work on shape-adaptable needles [22, 85, 99, 100], six different tips were selected and compared. This included three bevel types and three conical types, each with a straight, pre-bent or pre-curved configuration, shown in Fig. 3.2. These tips were chosen in such a way that they formed complementary pairs in terms of their side-view surface projection. In this projection, each tip had an apex angle (\( \alpha \)) of 20°. Note that straight (symmetric) conical tips were not used. Instead, two versions of pre-bent conical tips, with tip angles (\( \theta \)) of respectively 10° and 20°, were used. The latter corresponds to the actuation limit of the articulated-tip needle described in [85]. In analogy, the pre-curved tips correspond to steerable needles with a compliant joint near the tip, where \( \theta = 30° \) [99]. The six tip types were denoted by a B or C for a beveled or conical tip, followed by a number that matched the tip angle. For the sake of similarity, the tip angle was defined by the line connecting the centerline at the base to the sharp end at the tip, shown by dotted lines in
Fig. 3.2. For tip B10 this meant that the tip angle equaled half the bevel angle.

The made needle tips were scaled-up models with an outer diameter \((d)\) of 10 mm, allowing a similar macroscopic approach as in [51]. This increased the tip-tissue contact surface, the general load magnitudes, and the signal-to-noise ratio, since needle diameter and insertion force are positively correlated [16].

### 3.2.3. Tissue simulants

In order to delineate the contact forces at the tip, the needles had to be embedded in tissue prior to testing. To achieve this, two tissue simulants were selected that respectively cured and congealed at room temperature: silicone rubber and agar-agar. After the tissue simulant preparation, one of the needle tips was fixed to the force sensor and lowered in the container. The tip was embedded in the simulant material with an initial depth of 45 mm. In total, for each simulant material, thirty containers were prepared using the protocols described below. The specimen hardness was estimated with artificial tissue test sets, using a Shore OO durometer (HT-6510-OO, Landtek, CN), with a 2.4 mm in diameter spherical indenter (18 mm in width).

Figure 3.2: Overview of the needle tips produced for this study. Shown on the left are the side-view projections, with or without pre-bend or pre-curve. On the right, photographs of the actual needle tips are shown with the original design as overlay for comparison. The tip types are denoted by a B or C, for beveled or conical tips, and a number corresponding to the tip angle, \(\theta\). The apex angle, \(\alpha=20^\circ\) (for all tips), the needle diameter \(d=10\) mm, and the radius of curvature \(r=40\) mm.
3.2. Materials and methods

Silicone preparation

The silicone material (Dragon Skin 10 Medium, Smooth-on, US) consisted of two components ($A$ and $B$) mixed at a 1:1 ratio. The specified hardness for this material was 10 Shore A. Based on a proposed tissue simulant for needle insertions by Wang et al. [101], the silicone was mixed with a 40 wt% paraffin-based oil (baby oil, Johnson & Johnson, US). This reduced the material stiffness and the friction between the tip and its environment [101]. For each container, 60 g oil was mixed with 45 g silicone component $A$. After stirring, 45 g silicone component $B$ was added. The mixture was again stirred and poured in the container. The silicone was left to cure with the appropriate needle tip in place for at least five hours. No vacuum chamber was used for the silicone preparation. After curing, the measured material hardness was approx. 34 Shore OO.

Agar-agar preparation

Since organic, gelatin-like phantoms are frequently used in needle insertion studies, a comparison study was conducted in a 2.5 wt% agar-agar in water solution (Agar Agar, Pit&Pit, BE). For this, 4 g of agar-agar powder was mixed with 156 g water and heated in a water bath under constant stirring, until the turbid suspension became a clear solution. This typically occurred at around $84^\circ$C. To reduce heat conduction to the force sensor, the assembly was delayed until the agar-agar solution cooled to $65^\circ$C. Further congealing occurred at room temperature, with the needle in place, over a time span of at least six hours. Due to a limited material elasticity, accurate hardness measurements could not be obtained. Shore hardness measurements started at approx. 50 Shore OO, but quickly dropped as the durometer probe plastically deformed the material. For a detailed evaluation of mechanical properties of agar-agar, the reader is referred to [102]. A low friction between tip and phantom was observed, which likely resulted from the high water content of agar-agar.

3.2.4. Experimental design and protocol

Tip shape (B10, B20, B30, C10, C20, C30) and specimen material (silicone, agar-agar) were selected as independent variables, and the force resultant measured at the base of the needle tip was the primary dependent variable. For practical reasons, a separate experiment was conducted for each specimen material. For both experiments, thirty specimens were prepared in a sequential order. The six tip shapes were assigned to these specimens in random order, with the restriction that each tip shape must occur five times.

During the experiments, the force sensor and manual stages were kept fixed to the frame and only the tips were replaced. A pin-in-hole tip-sensor connection with a set screw ensured a steady tip-stage alignment. The remaining variability in the axial tip orientation was measured by the force component out of the theoretical tip-symmetry plane.

A single specimen was subjected to $n$ load cycles ($n=5$ for silicon rubber, $n=1$ for agar-agar, due to a limited elastic material recovery in agar-agar). One load cycle consisted of
3. The influence of tip shape on bending force during needle insertion

Stepwise changes in the needle position from \( z_{ref} \) to \( z_{1N} \), \( z_{2N} \), and \( z_{3N} \) using the manual positioning stage. Here, \( z_{ref} \) was the initial position, which was constant for each run and corresponded to an unknown axial force. It was unknown in the sense that the pre-load was variable due to curing or congealing processes. The position \( z_{1N} \) corresponded to an increase in axial force of 1 N with respect to \( z_{ref} \), and so on. Once this force increase was reached, the insertion stopped and the measurement started. The force and torque histories corresponding to each step were recorded into separate files on a computer, and the translation required to reach the desired axial force (e.g. \( z_{1N} \)) was noted down.

3.2.5. Data processing

The measured \( F/T \) data were processed with a zero-phase moving average filter, using a kernel size of twenty. Figure 3.3 shows a typical example of filtered data in the force sensor coordinate system (the global \( XYZ \)-frame), for one of the measurements in agar-agar. The absolute \( F/T \) values are shown to allow for a straightforward comparison of magnitudes. The actual directions or signs are visible from Fig. 3.1. As similar effects were seen in both the force and torque response, the results section will focus primarily on the force data.

As the tips in this study have a symmetry plane, a force balance can ideally be solved in this plane (as in Fig. 3.1). Measured \( F_x \) values could have resulted from either nuisance or from variability in the axial orientation of the tip. To account for this, a radial force, \( F_r \), was defined by vector addition of \( F_y \) and \( F_x \). This equals rotating of the global frame, with an angle \( \phi \), to a local frame that is aligned with the tip’s symmetry plane. The local coordinate frame is denoted in 2-D by \( F_r \) and \( F_a \), where \( r \) stands for the radial, and \( a \) for the axial force component. In this transformation, \( F_a \) equals \( F_z \). Subsequently, it is

Figure 3.3: Filtered data from a typical measurement in agar-agar. Forces (left) and torques (right) increase during manual setting of the axial load (here to 3 N), and drop again once the insertion stroke is paused. The measurement interval is visualized by two black vertical lines.
assumed that the axial and radial contact forces at the tip, $R_a$ and $R_r$, can be approximated by the measured loads at the base, so that $R_r = F_r$ and $R_a = F_a$.

Figure 3.3 shows that $F/T$ magnitudes gradually decay with time after reaching a loading step. Measurement intervals were defined as the first 5 s upon reaching a new loading condition. This event was identified in the $F_z$ data by means of a peak search function in MATLAB. The radial-to-axial force ratio ($R_r/R_a$) was determined, in a similar approach to [15]. Note that this equates to finding the tangent of the resultant tip load vector angle, in the $a$-$r$ plane. It was found that the decay rates of force components were similar, and that this force ratio was nearly constant for most of the measurements. Expressed as a percentage of the initial value [mean, max], the force ratio decrease over the measurement interval was [2%, 11%] in agar-agar, and [2%, 15%] in silicone. To account for the few measurements that remained skewed, the median forces per interval were used as the data points.

Additionally, the force-displacement relation in silicone was analyzed by means of a linear regression. This study assumed a linear relation for small insertion depths. The slopes of the axial force ($F_a$-slope) and radial force ($F_r$-slope) with the axial tip displacement described the local effective stiffness. A coefficient of determination ($R^2$) showed how much of the measurement variability could be explained by this linear model.

### 3.3. Results

Figure 3.4 shows the orientation of the measured force resultant per load step, during the experiment in silicone. The figure does not contain information on force magnitudes. Vectors are color-sorted with respect to the applied axial load. The median resultant vector orientation, for each tip and loading condition, is highlighted by means of a slightly thicker and longer line. The order in which these median observations occurred was equal for all six tip types, suggesting that an increased insertion force caused a more radial orientation of the tip load.

![Figure 3.4: Summary of all resultant force vector orientations per tip shape and axial loading condition, in silicone. The slightly thicker and longer lines present the median observations per experimental condition.](image)
3. The influence of tip shape on bending force during needle insertion

### Experimental Conditions

<table>
<thead>
<tr>
<th>Tip Type</th>
<th>Radial-to-Axial Force Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agar-agar</td>
<td>B10 B20 B30 C10 C20 C30</td>
</tr>
<tr>
<td>Tissue simulant</td>
<td>B10 B20 B30 C10 C20 C30</td>
</tr>
</tbody>
</table>

Figure 3.5: Data summary of the bending force per 1 N of insertion force (radial-to-axial force ratio) for various beveled and conical tip types, measured in two phantom materials. The left figure shows box plots of the first loading cycle in silicone and agar-agar tissue simulants (n=15 per box). The right figure illustrates how this metric changes with subsequent loading cycles in silicone. During a loading cycle, tip loads were measured at subsequent cycles, denoted as $z_{ref}$, $z_{1N}$, $z_{2N}$, and $z_{3N}$, where $z_{ref}$ is the initial tip position, in which the tissue simulant had hardened.
3.3. Results

Figure 3.5 shows a summary plot of all the collected data, where the radial-to-axial force ratio is sorted by phantom tissue, tip type, and applied axial load. The left hand figure compares the force response during the first loading cycle in silicone and agar-agar phantoms. The largest differences in location of the force ratios were seen for tips B10 and C10. Noteworthy was the difference in measurement variance, which was consistently larger in agar-agar compared to silicone. The box plots for the silicone experiment showed an increased radial-to-axial force ratio with increased tip articulation angles.

On the right hand side of the figure, the data of the first loading cycle in silicone are compared to the data of subsequent cycles. A clear drop in the force ratio from the first to the second cycle was found for tips B10 and C10. For the other tips, the first cycle also showed a distinct response, but with a less clear effect.

Figure 3.6 (top) shows the axial force as a function of the axial translation. Data fits in this figure are based on a least squares estimator of a linear regression model. These fits are used to model the slope or effective stiffness of each of the studied tip shapes in silicone. The slopes are summarized in Table 3.1, along with the coefficients of determination of the linear fits. It can be seen that beveled tips had a larger slope than conical tips with a similar tip angle. The effective stiffness of tip B10 was 1.8 N/mm, compared to 1.0 N/mm for its paired conical tip version C10. However, the effect of tip angle in this study was larger than the effect of tip type (B/C). The effective stiffness values of pre-curved beveled and

![Figure 3.6: Axial force $|F_a|$ (top) and radial force $|F_r|$ (bottom) versus the axial insertion depth in silicone, using various needle tips. Linear least squares regression lines are also shown.](image)

| Axial force $|F_a|$ [N] | Radial force $|F_r|$ [N] |
|-------------------------|-------------------------|
| Axial tip translation [mm]| Axial tip translation [mm]|
3. The influence of tip shape on bending force during needle insertion

Table 3.1: Summary of the linear least squares fits that describe the axial and radial force increase with insertion depth in silicone. Presented are the slopes and the coefficients of determination ($R^2$).

<table>
<thead>
<tr>
<th>Tip</th>
<th>Slope $F_a$ [N/mm]</th>
<th>$R^2$</th>
<th>Slope $F_r$ [N/mm]</th>
<th>$R^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>B10</td>
<td>1.8</td>
<td>0.79</td>
<td>4.1</td>
<td>0.91</td>
</tr>
<tr>
<td>B20</td>
<td>2.8</td>
<td>0.92</td>
<td>9.5</td>
<td>0.95</td>
</tr>
<tr>
<td>B30</td>
<td>4.0</td>
<td>0.98</td>
<td>15.1</td>
<td>0.94</td>
</tr>
<tr>
<td>C10</td>
<td>1.0</td>
<td>0.84</td>
<td>2.6</td>
<td>0.98</td>
</tr>
<tr>
<td>C20</td>
<td>2.1</td>
<td>0.94</td>
<td>7.6</td>
<td>0.92</td>
</tr>
<tr>
<td>C30</td>
<td>3.3</td>
<td>0.97</td>
<td>11.6</td>
<td>0.97</td>
</tr>
</tbody>
</table>

Conical tips (B30 and C30) were 4.0 N/mm and 3.3 N/mm, respectively. The coefficients of determination of the linear models were all high, meaning that these models can largely explain the measurement variability. We also looked at the residuals, which seemed to be randomly distributed around zero.

In a similar way, the radial force versus insertion depth is shown in Fig. 3.6 (bottom). Overall, the $F_r$-slopes were higher than the $F_a$-slopes, as is also shown in Table 3.1. For pre-curved beveled and conical tips the effective stiffness values were respectively 15.1 N/mm and 11.6 N/mm. The difference between the graphs of Fig. 3.6 was presented in Fig. 3.5 by the $F_r/F_a$ ratio. For instance, the $F_r$-slopes for tips B10 and C10 were, on the whole, lower than their axial equivalents. This corresponded to the lower $F_r/F_a$ factors for these tip types. Overall, the beveled tips were more efficient than the conical tips for building up radial force per unit of insertion depth.

### 3.4. Discussion

This study investigates the impact of tip shape on the asymmetric tip-tissue reaction forces during insertions in silicone and agar-agar. The 6-DOF $F/T$ characteristics were measured for various types of beveled and conical needle tips.

#### 3.4.1. Tip types

The comparative research on tip loads, for various tip shapes or steering techniques, is sparse. At most, beveled tips with or without pre-curve have been compared to other symmetric tips. The present work discusses both the magnitude and orientation of the
force resultants, measured during the insertion of various asymmetric needle tips. Scaled tips with a 10 mm outer diameter were used. This helped to increase the force levels at the tip-tissue interface. A linear relation of tip force with the frontal contact surface, and therefore a quadratic relation with diameter, was assumed. Tip deformations were considered negligible.

Tip force is considered to be dependent on the tissue elasticity and rupture toughness [51]. As the tips did not deform during the indentations, the rotations of the resultant force-vectors can be attributed to an elastic material response. Assuming a constant tip-force orientation is required for a constant path curvature, this phenomena can explain why the path radii in some materials have been reported as constant, but not in others. For the path planning of bevel-tip needles, it is often assumed that the tip load is directed orthogonal to the bevel [96]. The accuracy of current navigation models can improve by reconsidering this assumption for different tip-tissue combinations.

It should be noted that the resultant force-vector origins in Fig. 3.4 were all drawn at the center of the tip-tissue contact surface. This eased the comparison of vector orientations. However, in reality, origin locations may deviate.

Differences between beveled and conical tips became prominent when the effective stiffness values — the slopes of the force-displacement curves — were compared. Both the slopes of the axial and radial force components were consistently larger for beveled tips than for the matched conical tips. Although an efficient formation of bending forces is a relevant design criterion for the development of steerable needles, there are more factors to consider. An example is the desired degrees of freedom in actuation. Conical-tip needles can be articulated to any direction to produce a geometrically similar shape, whereas bevel-tip needles have to rotate along their longitudinal axis to achieve the same.

An increased tip angle led to a quick increase of the effective stiffness. Most likely, the increased frontal surface area of these more pronounced asymmetric tips, contributed to this effect. This observation is in line with earlier studies that demonstrated increased path curvatures for pre-bent needle tips [53]. This stresses the potential benefit of tip articulations in needle steering. In addition, the dependence of the resultant force orientation on the insertion force was found to be small for articulated tips. A near-constant force orientation would suggest a proportionality that can be easily implemented into current mechanics-based navigation models. Extending these models to other needle steering methods, e.g. by means of a shape-related tip load expression, would increase their value for the needle steering research field.

### 3.4.2. Tissue simulants

Repeated loading cycles are typically used for material pre-conditioning. Pre-conditioning is a common treatment in tissue characterization studies to ensure a repeatable reference state in the specimen structure [103]. For tip characterization studies,
3. The influence of tip shape on bending force during needle insertion

A repeatable tissue reference state is also important. In this study, a drop in the radial-to-axial force ratio was seen between the first and subsequent loading cycles. This effect appeared to vary per tip type and was the highest for tips B10 and C10. As preconditioning will not take place in clinical practice, it may be argued that the first cycle is the most realistic. However, this would require the initial tip-tissue contact state in the phantom material to be sufficiently similar to that in tissue. In the current study, a difference in needle-tip lubrication conditions with subsequent runs, but also with the real system, may explain the observed difference in force response. Here, the subsequent loading cycles may actually present a more accurate force data representation.

Silicone offered a more consistent force response than agar-agar. It allowed for repeated loading cycles per specimen, whereas agar-agar did not. In addition, the variability in force data during the first loading cycle was considerably lower in silicone than in agar-agar. This may be the result of a difference in material elasticity. It was noted during the Shore hardness tests that agar-agar easily deformed plastically. This can affect the local material displacements, compressions and the force interactions at the tip. Besides the difference in variability, this may explain the difference in location between phantoms for tips B10 and C10 (see Fig. 3.5, left), since these tips required the largest axial displacements.

The difference in observed measurement variability between phantoms may be partially a result of the material preparation. For agar-agar, a thermal process is required, whereas the preparation of silicone takes place at room temperature. The uniformity of a heating process can be controlled by stirring. However, congealing is typically not uniform. This can lead to residual stresses throughout the specimen. This study assumed a local, linear force-displacement curve, but not a fully linear relation. A variable pre-stress at the reference position ($z_{ref}$) may have affected the domain in which loading tasks were executed. In case the effective stiffness differed for these domains, a higher measurement variability could indeed be expected.

It was shown that the mechanical characteristics of silicone-based specimens may be tailored with mineral oil to obtain stiffness and friction values with orders of magnitude comparable to tissue, whereas the effect on cutting force was found to be limited [101]. In terms of viscoelastic properties, hysteresis, and energy storage, silicone may exhibit a more elastic response than soft tissue [104]. The current study showed that a silicone phantom with a 40 wt% paraffin-based oil performed better than a 2.5 wt% agar-agar phantom in terms of repeatability for assessing tip loads.

3.4.3. Experimental design

The research objective was to study tip-tissue interaction forces as an isolated part of the whole system. The whole system is more complex and other variables can interact with the discussed relations. Fracture phenomena, for instance, can affect the magnitude of
the resultant tip force, including the bending force component. So can insertion velocity. For instance, velocity dependencies on the needle path were found for some tip types [75], and not for others [52]. Insertion velocity can, in turn, affect the fracture phenomena [48], complicating the set of acting relations. Whole-system mechanics may only be understood in a step-by-step approach. In the current work, fracture phenomena were not studied, and contact forces were measured at quasi-static states, i.e. after each tip translation. In a continuation of this work, these variables should be gradually introduced in order to converge to a whole-system representation of the tip-tissue mechanics.

Axial force was controlled and used to define loading cycles to which all tip types were subjected. If, instead of axial force, axial displacement would be kept constant in this study, larger differences in force response between conical and beveled tips may have resulted. This relation is illustrated by Fig. 3.6.

Finally, one parameter that was not controlled in this study was the timing between loading steps and cycles. Tissue relaxation effects were visible when returning from $z_{3N}$ to $z_{ref}$. Typically, a tip was kept 30–60 s at each loading step. The presence of force residuals can be seen from Fig. 3.6, as the axial forces are not exactly on 1 N, 2 N, and 3 N, respectively. The increase in axial force between steps was, however, kept constant. For future studies it is suggested to implement an automated insertion process, with a sufficiently long and constant pause between the subsequent loading steps.

3.5. Conclusion

To arrive at explanatory needle steering models, the relations between the resultant tip-tissue load vector and other system variables, such as tip type, tissue type and insertion velocity, should be studied in detail. The current work analyzed the tip-tissue interaction forces of six different asymmetric needle tips in two phantom materials. This gave insight in the effect and value of using pre-bent, pre-curved, or actively articulated needle tips for steering applications. The increase in axial ($F_a$-slope) and radial ($F_r$-slope) forces with insertion depth were consistently higher for articulated bevel-tips than for conical tips with a similar tip angle. However, a stronger positive effect on these slopes was found for increased tip angles, e.g. by adding a pre-bend or pre-curve to the tip. For small tip angles, a vector orientation dependence on the applied axial load was observed. An increase of the insertion force caused the tip vector to orient more radially. In case a pre-bend or pre-curve was added to the tip, this dependence was reduced, and a nearly constant vector orientation was found. These findings relate to the correctness of presenting tip loads by a single, constant vector, e.g. orthogonal to the bevel. The presented tip-load quantifications are relevant for the formation of mechanics-based system models, for the optimization of tip designs, and for the proper actuation of shape-adaptable steerable needles.
Design of an active tip articulated needle with FBG-based shape sensing

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Abstract  This work presents a new articulated-tip needle to facilitate active steering towards predefined target locations. It focuses on mechanical aspects and design choices in relation to the observed response in a tissue simulant. Tip steering with two rotational degrees of freedom was achieved by a tendon actuated ball joint mechanism. During insertion, the flexible cannula bends as a result of asymmetric tip-tissue interaction forces. The stylet was equipped with fiber Bragg gratings to measure the needle shape and tip position during use. A PI-controller was implemented to facilitate steering to predefined targets. During the validation study, nine targets were defined at a depth of 100 mm below the gelatin surface. One was located below the insertion point, the others at a radial offset of 30 mm in each of the eight principle steering directions. Per location, six repetitions were performed. The targeting accuracy was $6.2 \pm 1.4$ mm (mean $\pm$ SD). The steering precision was $2.6 \pm 1.1$ mm. The ability to steer with this new articulated-tip design is presented and the mechanical characteristics are discussed for this representative subset of steering directions.
4. Design of an active tip articulated needle with FBG-based shape sensing

4.1. Introduction

needles form a minimally invasive alternative to access deep seated locations within the human body for diagnosis and treatment of diseased tissue. In most of these treatments, e.g., taking a liver biopsy or thermally ablating malignant structures by means of radio frequency ablation, an accurate tip placement is of importance. The operator often works with visual feedback from computed tomography (CT) or ultrasound (US) devices. Nevertheless, the risk of needle misplacement tends to increase with target depth. Placement errors can arise from human errors, imaging limitations, and needle-tissue interactions [20]. While operating flexible needles, the compensation of discovered errors can be difficult and nonintuitive [90]. As placement errors become too large, needles are often completely retracted and inserted anew. Needle steering is being investigated as a solution to correct for errors in the target-alignment without having to retract the needle.

4.1.1. Related work

In the past decades, several needle steering techniques have been investigated, see Chapter 2. DiMaio and Salcudean [26] describe the base manipulation of unmodified clinical needles. Other passive needle steering techniques include beveled tips [64], occasionally with pre-curve [75], or flexure joint [22] near the tip. Active steering techniques include combinations of pre-curved concentric stylets and cannulas that can translate and rotate with respect to each other [45, 46, 55]. The use of multiple interlocked segments that can individually translate resulted in an actively variable bevel [42, 81]. In general, both the optimal control of passive needles and the optimal design of active needles are on-going research fields. In terms of mechanical design, passive needles are much simpler and cheaper. In terms of control robustness, active needles are potentially more adaptive to varying environmental conditions.

A key concern in needle steering has been the acquisition of kinematic knowledge on nonholonomic steering constraints. Recent research focus is shifting towards factors related to practical implementation, covering topics like the inclusion of planning uncertainties with respect to tissue variability [40], the consideration of torsional friction [58], and the reduction of model dependencies on a priori information [31].

4.1.2. Performance metrics

Many needle steering studies have focused on the evaluation of path planners [20]. Control actions for these methods are estimated in advance and can be updated intra-operatively [34, 76]. Planning paths requires (inverse) kinematic expressions for needle
4.1. Introduction

motion. To assess the error build-up of a steering task, some form of trajectory error [37] or end-point error [31, 105] is generally reported. For this, position information may be obtained from sensing technologies, such as cameras [52, 106], electromagnetic sensors [42], ultrasound probes [50], fluoroscopic X-ray [66], and fiber Bragg gratings (FBGs) [84, 107, 108].

Kinematic expressions to describe needle paths rely on shape assumptions, such as a piecewise constant radius of curvature [39]. Radius of curvature is an often used metric in kinematic models [51, 53, 60, 75]. However, the validity of constant radius path approximations has in the past been debated for certain needle-tissue combinations [47, 64].

For needles that require axial rotations to select a steering plane, torsion may affect the target reachability and should be addressed [57, 59]. In analogy, for needles that do not have this requirement, a representative subset of steering directions should be selected to investigate the symmetry in device response. Instrument-tissue interactions may differ due to imperfections in the designing, machining and assembling process. In a study of Burrows et al. [56], the eight principal steering directions (every 45°) of a programmable bevel-tip needle were evaluated. Differences per steering direction were attributed to variations of the needle's flexural rigidity for each protruding tip-segment configuration.

4.1.3. Aim

For objective validation and comparison of steerable needles, experimental repeatability is required with a stable support, a constant insertion speed [97], an equal environment, and an equal control approach. This may be obtained using computer or robot assistance. Currently, no standards are in place to assess the mechanical functionality of a steerable needle design. Typically, designs are presented in combination with a tailored control algorithm to optimize performance. This chapter presents a new steerable needle to facilitate active steering towards predefined target locations.

**Aim:** This study discusses the design characteristics of a tip-articulated steerable needle in relation to the observed response in tissue simulants.

4.1.4. Approach

For this analysis, a simple PI-controller was implemented that was naive to the effects of any needle, tissue, or insertion parameter. This allowed for an unbiased presentation of steering kinematics within a representative subset of steering directions.
4. Design of an active tip articulated needle with FBG-based shape sensing

Needle steering was achieved by means of a novel, tendon driven design. The used needle consists of a flexible cannula and a conical tip that can rotate with two orthogonal degrees of freedom. Needle deflections result from the asymmetric interaction forces at the needle-tissue interface. In order to track the needle shape and tip location, FBGs were integrated in the stylet. This stylet can be withdrawn after needle placement, leaving the cannula on-site as an open working channel. The characteristics of the shape-sensing stylet were analyzed for various needle configurations and deformations [84, 109]. As the insertion strokes were constant, targeting errors were measured in 2-D (top view) for the eight principal steering directions. To the author’s knowledge, this is the first study to combine an active needle steering technique with fiber Bragg grating based feedback on the cannula shape. The obtained shape information can ultimately provide an overlay on static or dynamic visual feedback from CT or ultrasound devices, in order to continuously update the tip position with respect to the target.

4.2. Materials and methods

The articulated-tip needle developed for this study is depicted in Fig. 4.1. It is composed of a flexible cannula, a retractable sensorized stylet, and a 5 mm long conical tip, with an apex angle of 20°, positioned on top of a miniature ball joint. Fig. 4.2, in turn, defines some of the relevant variables used to describe the needle design and functionality.

4.2.1. Mechanical instrument design

The 170 mm long needle consists of a stainless steel (SS) stylet with a radius \( r_1 \) of 0.5 mm, and three grooves for optical fibers (\( f \)). The polymer cannula (PEEK, IDEX Health & Science, US) has a radius \( r_2 \) of 0.9 mm and contains four grooves for tendons (\( t \)). Finally, a layer of heat-shrink tubing (PET, Vention Medical, US) covers the needle, keeps the grooves clean, and the tendons in place. The outer needle radius is approximately 1 mm. This resembles a 14–15 G needle, which is regularly used for liver biopsies [12].

The ball joint mechanism at the tip is tendon driven and actuated by four rotary servo motors (HS-5125 MG, Hitec, US), working in complementary pairs. By alteration of the servo positions, the needle tip can rotate with two orthogonal rotational degrees of freedom (2-DOF). The combined effect of servo motor actuations allows for tip articulations to any direction. This direction is described by the tip orientation angle, \( \phi \), presented in Fig. 4.2 as a possible (arbitrary) orientation of the neutral bending line. The needle is rigidly fixed to a linear stage (EGSL-BS-55-250-12.7P, Festo, DE), which realizes the insertion motion, in total providing a 3-DOF actuation system.
4.2. Materials and methods

Figure 4.1: Image of the steerable needle, showing: 1) the needle, 2) the actuation tendons, 3) the distal end of a linear stage used for the insertion motion, 4) the servo motors used to articulate the tip, and 5) an optical fiber running to the FBG interrogator.
Four tendons are fixed at the tip, run over a ball joint, along the cannula, and exit at the needle hub. Each tendon is fixed to a rack that connects to one of the servo motors. Before this connection was made, linear tension springs provided a pretension of approximately 1 N. After fixation, the springs serve to reduce gear play. The gear transmission was chosen in such a way that the linear translations of the racks allow a maximum tip rotation (tip articulation angle, $\theta$) of approximately 20°.

The degree of needle bending under influence of an articulated tip depends both on the force interactions at the tip and the flexural rigidity of the shaft. An approximation of the steerable needle’s ($SN$) flexural rigidity is obtained from the stylet ($styl$) and cannula ($can$) geometry:

$$[E \cdot I]_{SN} = E_{SS} \cdot I_{styl} + E_{PEEK} \cdot I_{can} \quad (4.1)$$

where $E$ is the Young’s modulus ($E_{SS}$=200 GPa, $E_{PEEK}$=3.4 GPa), and $I$ the second moment of area. For circular and annulus shaped cross-sections (this shape simplification is denoted by the subscript $SN'$), this approaches:

$$[E \cdot I]_{SN'} = \frac{1}{4} \cdot E_{SS} \cdot \pi \cdot r_1^4 + \frac{1}{4} \cdot E_{PEEK} \cdot \pi \cdot (r_2^4 - r_1^4) \quad (4.2)$$

An extended version of Eq. 4.2, taking into account the grooves in the needle stylet and cannula, would somewhat decrease the associative second moments of area, resulting in a flexural rigidity of $7.8 \cdot 10^{-3}$ N·m². By means of the steerable needle with a dummy stylet, an end-loaded beam deflection test, and the Euler-Bernoulli beam equation, a value of $8.2 \cdot 10^{-3}$ N·m² was found. This approaches a conventional, fine 20 G stainless steel needle ($6.7 \cdot 10^{-3}$ N·m²). The flexural rigidity may, in a constant radius approximation, relate the curvature ($\kappa$) to the applied bending moment ($M$):

Figure 4.2: The steerable needle consists of a stylet with radius $r_1$ and grooves for optical fibers ($f$), and a cannula with radius $r_2$ and grooves for the tendons ($t$). Tip articulations up to an angle ($\theta$) of 20° in any direction ($\phi$) can be achieved.
4.2. Materials and methods

\[ \kappa = \frac{M}{[E \cdot I]_{SN}} \]  \hspace{1cm} (4.3)

With regard to rotational symmetry of bending, the Huygens-Steiner theorem shows that the second moment of area remains unaffected by steering orientation if the summed effect of the grooves in the cannula and stylet is rotationally symmetric (independent of \( \phi \)). This effect is described by the squared distances between the grooves and the neutral line \( (r) \) and the cross-sectional areas of the grooves \( (A) \), according to:

\[ I_{SN}(\phi) = I_{SN'} - \sum (A \cdot r(\phi)^2) = C \]  \hspace{1cm} (4.4)

Here, \( I_{SN'} \) is the second moment of area of the grooveless needle. It can be shown that, both in case of a circle with three rotationally symmetric grooves, and in case of an annulus with four rotationally symmetric grooves, the second moment of area remains constant. Hence, the steering orientation should not affect bending of the individual parts, nor that of the needle in total.

4.2.2. Cannula shape reconstruction

The needle shape was reconstructed on the basis of strain measurements by three optical fibers. Each fiber contained four FBGs (HI-780 with acrylate recoating, Corning Incorporated, Corning, USA). They were located at \([20, 60, 100, 140]\) mm from the cannula hub. Wavelengths reflected by the FBGs were read by an interrogator (Deminsys, Technobis group, NL). The sensors were calibrated under constant curvature and the needle shape was extrapolated from the unfiltered fiber strain data. The approach, used methodology and sensing precision have been described by Henken \textit{et al.} [84]. The precision of the estimated tip location, extrapolated from this sequence of strain measurements, was approximately 1 mm. A more detailed analysis of errors due to variations in needle configuration and deformation can be found in [84] and [109].

4.2.3. Control of the needle tip

The linear stage had an integrated PID-controller and was set to operate at a constant speed of 5 mm/s to a depth of 100 mm. Tip steering was possible while the stage stroke lasted and was regulated by means of the servo motors. A digital PI-controller was implemented. The reference variable was the top-view \((x–y)\) tip position error with respect to a pre-set target. The controller output for the \( x \)-direction (similar to \( y \)) was:

\[ u_x(t) = K_p \cdot e_x(t) + K_i \int_0^t e_x(\tau)d\tau \]  \hspace{1cm} (4.5)
Here, $K_p (=0.1)$ was the proportional gain, $K_i (=0.05)$ the integral gain, and $e_x$ the error between the measured tip position and the target $(x-x_t)$. Each control iteration consisted of four steps: 1) the read-out of new FBG sensor data, 2) the shape reconstruction and visualization, 3) the tip error and controller output determination, and 4) the servo actuation. The median iteration time was approx. 0.1 s, which was considered sufficient for the set insertion speed. Tuning of the steering response was done in an iterative manner in test runs, based on the ability to approximate targets with a single smooth curve. In addition, FBG outputs were used to sense first tissue contact. To achieve this, a radial tip displacement threshold of 0.5 mm from the calibrated initial needle shape was used. Once the reconstructed tip position breached this threshold, the insertion was considered to be on-going. To ensure a near straight tip configuration during puncturing, the control gains were kept small, but nonzero, until the insertion phase initiated. After this, the PI gains were gradually build up within the first 50 iterations, or approx. 25 mm.

### 4.2.4. Tissue simulant

Experiments were performed in a 15 wt% porcine gelatin-water mixture (Dr. Oetker, The Netherlands). In terms of stiffness, this would be within the order of magnitude of 10 kPa, on the high end of what we consider clinically relevant for simulating liver structures. The mixture was prepared at 70°C, congealed and stored at 2°C, and retrieved just before the experiments. The same simulant was used to assess control parameters and to perform the experiments. To get rid of prior paths, a single reheat-cool cycle was used. Figure 4.3 shows the tissue simulant, the articulated-tip needle, and a supporting trocar.

### 4.2.5. Experimental design

Each puncture consisted of a constant speed (5 mm/s) stage stroke. The target depth was kept constant at 100 mm. In total, nine different targets with respect to the needle insertion point were defined. This includes the $[x, y]=[0, 0]$ coordinate, and the eight principal steering directions, with $\phi$ at every 45°, using a radial offset of 30 mm with respect to $[0, 0]$. Corrections by (partial) withdrawal of the needle were not allowed. By moving the tissue simulant in between measurements, needle insertion points were separated by at least 10 mm to avoid path crossing. For each of the targets, six repeated measurements were performed. The tip coordinates were tracked and stored.
4.2. Materials and methods

4.2.6. Data analysis

The tip position was determined at the end of the linear stage stroke. Position data were filtered with a 3rd order low-pass Butterworth filter, with a cut-off frequency of 0.5 Hz. The placement accuracy per target (mean ± SD) was taken as the in-plane error between the tip \((x,y)\) and target \((x_t,y_t)\). The placement precision, with respect to the average location reached \((\bar{x},\bar{y})\) was also determined. This indicates the puncturing repeatability, irrespective of systematic effects:

\[
accuracy = \frac{1}{n} \sum_{i=1}^{n} \left( (x - x_i)^2 + (y - y_i)^2 \right)^{\frac{1}{2}} \tag{4.6}
\]

\[
precision = \frac{1}{n} \sum_{i=1}^{n} \left( (x - \bar{x})^2 + (y - \bar{y})^2 \right)^{\frac{1}{2}} \tag{4.7}
\]

Figure 4.3: Image capture of needle steering in gelatin. The final tip position was \((x, y)\). A virtual target was located at \([x_t, y_t] = [-30, 0] \) mm. The target depth \((d)\) was 100 mm.
4.3. Results

The aim of this study was to analyze the mechanics of this steering technique and to understand its systematic behavior, irrespective of the exact type of controller that was used. A top view (x–y plane) of all needle tip trajectories is presented in Fig. 4.4. Visible effects in this graph can be attributed to both the applied mechanical design and the control design. Overall, a definite steering response in gelatin is observed. The targeting accuracy was $6.2 \pm 1.4$ mm and the precision was $2.6 \pm 1.1$ mm.

The initial tip heading was not always in line with the target, as control actions were deliberately kept small before the needle was inserted. However, once the gains increased, the implemented controller was able to correct for this. For some trajectories this resulted in...
4.4. Discussion

In slight s-curves in top view. Other steering conditions showed an early bifurcation in their trajectories. This happened for instance at \([x_t, y_t] = [0, 0]\) and \([x_t, y_t] = [0, -30]\). These effects had a large impact on both the mean and spread of the reported precision. For some tip orientations, the set gains were sufficient, whereas for others they were not, e.g. \([x_t, y_t] = [0, 30]\). This mainly affected the targeting accuracy.

On rare occasions, strain sensing inaccuracies were witnessed that were not present in reality. Since these inaccuracies had a cumulative effect during shape reconstruction, they showed up as discontinuities in the presented tip position. Within the rectangular box in Fig. 4.4, unfiltered tip position data are shown, including some of these effects. Typically, these reconstruction errors lasted a single iteration and occurred in the same insertion phase for different trials. Here, the cannula loading conditions were presumed comparable.

4.4. Discussion

This chapter presents a novel, articulated-tip needle and describes the working mechanics and instrument design. A miniature ball joint near a conical needle tip allows for rotations with two orthogonal degrees of freedom. The steerable needle is operated by means of four tendons, which are connected to the tip and operated in pairs. Rotations of the needle around its length axis are not needed for steering, reducing torsion effects on the needle. FBG-based shape sensing was integrated in the needle stylet and used to construct a closed loop PI control scheme for tip placement. After tip placement, the needle stylet can be retracted. Steering experiments were conducted in gelatin tissue simulants. The reported characteristics in tip placement provide a solid basis for future optimization of this needle steering approach.

Steerable needles can attain complex, multi-curved shapes. As navigation constraints depend on the previous path taken, needle steering is a complicated and nonintuitive task. Whether or not robot assistance or shared control of steerable needles will at some point be superior to manual use of straight needles in clinical practice, is left open. Likely, this will depend on the achievable degree of targeting robustness in highly variable and poorly known environments. The prospect of needle steering relies on the development of robust needle designs, suitable control methods, and high quality system feedback.

For feedback on the needle tip position, this study used FBGs, with a measurement precision at the tip of approx. 1 mm. The interpolation function used in this reconstruction is well able to capture intermediate strains, but its validity decreases with shape complexity. In this regard, the reported shape feedback artifacts will in the future be removed by burst mode data sampling. Another way to improve the shape feedback is by integrating more FBGs per optical fiber. However, this should depend on the clinical need for capturing complex shapes. For use in the liver, it is expected that most lesions can be reached by relatively simple, single-curved paths.
4. Design of an active tip articulated needle with FBG-based shape sensing

In terms of experimental results, some systematic characteristics in target reachability were described. Assuming the tissue simulant was sufficiently homogeneous, these differences may be explained by the internal device mechanics. They may, however, be diminished by refining both the mechanical design and the control approach.

4.4.1. Mechanical factors

Two known factors that have contributed to the systematic effects in the presented needle paths are the slight pre-curvature in the cannula and the position tolerance of the tendon fixations. The PEEK tubing curvature (radius of curvature estimated in the order of 10 m) may have led to slight base manipulation effects during the insertion. The second effect is, however, presumed more dominant. The fixations determine the transmission between the linear tendon displacement and the tip rotation. The steering response is very sensitive to inaccuracies at this location.

It was found that the tension levels in the tendons affect not just the relation between the tip orientation ($\phi$) and magnitude ($\theta$), but also the friction within the ball joint. Above a certain normal force threshold, stick-slip phenomena prevent joint rotations altogether, allowing for direct cannula deflections during tendon actuation. Depending on the envisioned clinical application, this balance may provide an adaptable stiffness mechanism, e.g. servo-controlled setting of the tension levels, which can be used to navigate under various environmental conditions, and possibly even in free space.

With a flexural rigidity of approximately $8 \cdot 10^{-3}$ N·m², this needle is comparable to conventional 20 G needles used in everyday practice. Needles with a similar stiffness have also been used for base manipulation needle steering [50]. Although multi-curved paths were possible, the presented needle is considerably stiffer than those used during bevel-tip needle steering. Bevel tip steering is typically done with 0.4–0.7 mm diameter wire, having flexural rigidity values that are one or two orders of magnitude smaller than a 20 G needle. The effect of this variable on the steering constraints and on robust control of our needle would be an interesting topic for follow-up research.

4.4.2. Control factors

This study used a generic PI-controller with equal gains for all directions. More complex controllers benefit the placement accuracy, but complicate the assessment of the mechanical device functionality. The controller included on-line $x$ and $y$ error estimates with respect to the set target, but was naive in the sense that it was not aware of remaining stroke length ($z$-direction). It did not plan an actual path, but merely observed values and tried to regulate them to zero. This task was not accomplished equally well for each
steering direction and these systematic effects were attributed to the mechanical needle
design. Follow-up studies with this needle are presented in [23, 110]. A more advanced,
kinematic model, similar to that of a bicycle, improved the steering performance and
resulted in a mean targeting error of 2.0 mm [23]. This value was further reduced by
combining the FBG-position data with ultrasound image data, yielding errors of 1.3 and
1.4 mm, in gelatin phantom and chicken breast, respectively.

An adaptable control strategy based on the navigation medium may be desired. Parametric
information on the steering mechanics should be updated during use. This
information may be obtained through pre-operative scans or on-site measurements. For
the articulated-tip needle, Roesthuis et al. explored a parameter estimation technique, by
means of the FBG-based shape feedback, to update the navigation model in an on-line
setting [23].

4.5. Conclusion

This work presents a new steerable needle to facilitate active steering towards predefined
target locations. It focuses on mechanical aspects and design choices in relation to
the observed response in gelatin. Steering with two rotational degrees of freedom was
achieved by four actuation tendons connected to a conical tip, placed on a ball joint. The
cannula was flexible and deformed as a result of asymmetric tip-tissue interaction forces.
The stylet was equipped with fiber Bragg gratings to measure the needle shape and tip
position during use. A most basic PI-controller was implemented to facilitate steering to
predefined targets. This allowed for the evaluation of steering kinematics and systematic
steering effects, which were attributed to the needle design. Overall, a targeting accuracy
of 6.2±1.4 mm, and a precision of 2.6±1.1 mm were presented. Fundamental studies
in needle-tissue interactions may help to improve the mechanical needle design, while
on-going work on adaptable control models, possibly with a human in-the-loop, will be
investigated to improve the needle tip placement accuracy.
Haptic shared control of a teleoperated steerable needle

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Abstract This study investigates the effect of intra-operative haptic shared control in needle steering. An on-line path planner was used to estimate the optimal tip angle for reaching predefined targets with an active, tip-articulated needle. Insertions were performed under visual guidance from a camera, showing the needle position and target location. The tip angle was directly controlled by the human operator through a haptic interface. Errors between the planned and actual angle were fed back to the user by means of low intensity force cues (up to 2 N). Targeting experiments were conducted in a tissue simulant. The targeting error with visuo-haptic feedback was 4.4±4.0 mm (mean ± SD), compared to 5.2±4.2 mm with visual feedback alone. Variations in user response to the supplied force stimuli were seen. These effects motivate further investigations into the perception and performance for modified levels of shared control authority and task complexity.
5. Haptic shared control of a teleoperated steerable needle

5.1. Introduction

During percutaneous interventions, variables related to the insertion method and soft-tissue properties may result in needle misplacement. Robotic support may help the physician to achieve a high accuracy and dexterity [111]. Further, robotic needle steering may decrease the occurrence of misplacement and enhance the performance of routine interventions by reducing the need for re-puncturing.

Although the robotic processing of information can be quick and adequate, the system functionality will always rely on the presented system inputs. The obtainment of proper inputs from optical, or other sensory systems still is a bottleneck in many clinical fields. Currently, robotic controllers rely heavily on static conditions and a priori estimates of tissue properties. While steering in (more) realistic environments, e.g. ex-vivo tissue, the ability to navigate along a planned path may be complicated [53]. Additionally, path planners may have to account for target and obstacle movements [112].

A human operator may be less consistent in information processing and may require practice to cope with the nonintuitive kinematic steering constraints [105]. Nevertheless, humans can be more flexible in terms of intercepting potentially relevant system inputs. A human-in-the-loop may improve the system robustness and safety. Ideally, the strengths of both a human and a robotic operator can be combined in a shared control system. Needle interventions may pose an interesting environment to test shared control operation [113].

Shared control requires the sharing of information. A standard method of communication between a human and a computer is a visual display. Alternatively, the sharing of haptic information can reduce surgical errors [114]. The use of kinesthetic haptic displays have been studied to communicate force and position data in surgical tasks.

5.1.1. Aim and approach

**Aim:** This study investigates the effectiveness of force guidance in needle steering for following a predefined (optimal) path.

In a 2-D virtual environment, the potential benefit of haptic guidance in the control of bevel-tip needles was already shown [113]. Another study assessed kinesthetic and vibratory stimuli on the optimal bevel position and orientation [115]. However, the used needles require duty cycling to change the path radius and steering direction. The cognitive mapping of system input and output motions for these needles posed a challenge for human operators [113]. This chapter investigates haptic shared control of a tip-articulated needle. This needle does not require axial rotations to set the steering plane,
and may therefore be more intuitive to control. A force field is implemented to help the human operator to find the optimal path. For a successful performance, the operator needs to control the path radius, not the tip position. Feedback is therefore coupled to the required tip angle, which defines the planned path radius.

5.2. Materials and methods

5.2.1. Teleoperation system

The needle has a 2 mm diameter and 170 mm long cannula, a sensorized stylet, and a tendon-driven conical tip on a miniature ball-joint. It has three degrees of freedom: two tip rotations, allowing tip angles of 0–20° to any direction, and an axial translation. A complete mechanical description of this system is presented in Chapter 4. As tissue simulant, a 10 wt% gelatin was used. An overview of connected components in this teleoperation system is shown in Fig. 5.1, and includes an articulated-tip needle, a

Figure 5.1: A needle steering teleoperation system, consisting of a tip-articulated needle, a camera to track tip positions and angles, and a haptic interface.
linear stage (EGSL-BS-55-250-12.7P, Festo, DE), a camera for needle tracking (FL3-U3-13E4C-C, Point Grey, CA), and a haptic interface (Omega.3, Force Dimension, CH).

The haptic interface was gravity-compensated. The Omega workspace center corresponded to zero needle motion. Deviations from the center induced a counteracting spring force. Forward Omega motion ($K = 40$ N/m) resulted in a rate controlled needle insertion ($z$-axis), where the maximum Omega displacement (60 mm) corresponded to a speed of 25 mm/s. Sideways ($x$-axis) and vertical ($y$-axis) Omega motions ($K = \text{diag}[20, 20]$ N/m) resulted in tip articulations. The reference position for vertical motions remained zero, as this related to steering out of the imaging plane. For sideways motions, the reference position, $d_{\text{plan}}$, was linearly coupled to the planned path radius of curvature. Force feedback was provided on the Omega position error: $e = d_{\text{plan}} - d_{\text{actual}}$. The model ran at roughly 9 Hz and feedback forces were saturated at 2 N.

For path planning, a conventional constant curvature approximation was adopted [28]. The maximum displacement of the haptic interface related to the steering limit: the minimum radius of curvature of the needle. This radius was experimentally estimated at 100 mm. A linear relation between the tip articulation angle and path curvature was implemented, as was demonstrated by Roesthuis et al. [23]. The path planner was updated for each model iteration by computing a renewed set of local target coordinates. The required path radius $r_{\text{tar}}$ to reach the target was derived from the circle equation:

$$r_{\text{tar}} = \begin{cases} \infty & \text{for } z_{\text{tip},0} \geq z_{\text{tar},0} \\ \frac{x_{\text{tar},1}^2 + z_{\text{tar},1}^2}{2|x_{\text{tar},1}|} & \text{for } z_{\text{tip},0} < z_{\text{tar},0} \end{cases}$$

(5.1)

Figure 5.2: The left image shows the coordinate frames, the region of interest (ROI), the angle of attack ($\gamma$), and the target (tar). The right top shows the unfiltered ROI. Below, the filtered ROI is shown, including the tip estimate (tip) and the tip angle, $\theta$. 

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5.3. Results

A first estimate of the puncture location was based on user input. A search box, termed the Region of Interest (ROI), was defined. The ROI was filtered and analyzed by a tip search algorithm in MATLAB/Simulink. Once the needle tip was found, a global coordinate system (subscript 0) was constructed, and a virtual target \([x_0, z_0]\) was defined. The needle insertion axis defined the positive \(z_0\)-direction, as is shown in Fig. 5.2. As the needle was inserted, a local coordinate frame (subscript 1) moved along, based on the tip position and angle of attack, \(\gamma\). The rotation of the local frame with respect to the world frame was parameterized in Euler angles, providing a 2-D rotation matrix, \(R\). This can be easily extended to 3-D by adding a second camera. Visual feedback consisted of the camera footage (using a grayscale colormap), the filtered ROI with tip location, and the target location. The planned path was not shown.

Filtering of the ROI was achieved by a spatial median filter \([6x6]\), followed by an image intensity adjustment that removed gray pixels belonging to the tissue simulant, and finally by a conversion to a binary image. The results are shown in Fig. 5.2. Based on the median pixel observation per row of the filtered ROI, center lines for respectively the needle cannula close to the tip, and the needle tip itself were defined. The first line provided the needle’s angle of attack, \(\gamma\). The second line provided the tip articulation angle, \(\theta\). The tip position was the lowest uninterrupted median observation in this search algorithm. It determined the location of the ROI for the next iteration.

5.2.2. Experimental protocol and data analysis

This study compared the effect of \(A\) visual feedback, and \(B\) visuo-haptic feedback, for five participants. This research was approved by the Human Research Ethics Committee (HREC) of the Delft University of Technology. The feedback conditions \(A\) and \(B\) were equally and randomly distributed over the targets \([x_{tar,0}, y_{tar,0}, z_{tar,0}]^T = [-30, 0, 121]^T \) and \([30, 0, 121]^T \) mm. A third order least-squares spline was fit to the tip position data. The end-point of each trial was considered at target depth: \(z_{tip,0} = z_{tar,0}\). A paired T-Test over the five subjects was performed to assess the effect of the implemented feedback on the targeting error. Here, the mean targeting error was estimated by measuring the remaining error of the tip in the \(x\)-direction:

\[
e_{tip} = \frac{1}{n} \sum_{1}^{n} (x_{tar,0} - x_{tip,0})
\] (5.2)

5.3. Results

Figure 5.3 shows the targeting error of each of the participants. It should be noted that the haptic feedback provided in this study was indicative, not forceful, and could easily
5. Haptic shared control of a teleoperated steerable needle

Figure 5.3: The bar graphs show the targeting error (mean ± SD) for steering tasks with A) visual and B) visuo-haptic feedback for five participants. The number of insertions per condition is also shown.

be overruled by the participant. Overall, with visual feedback, an error of 5.2±4.2 mm (mean ± SD) was found. With visuo-haptic feedback this was 4.4±4.0 mm. For both feedback conditions and for all participants it was found that the performance was highly variable. For three out of five participants, the mean error seemed to slightly improve by adding haptic feedback. The paired T-Tests did not show a significant effect.

5.4. Discussion

A teleoperation system was presented for needle steering, in which an active articulated-tip needle was coupled to a haptic interface. A continuous path planner was used to determine the optimal path, estimate the required tip angle, and present this to the user by means of low intensity force cues. In case the user would solely interfere with the insertion speed, the path planner would directly control the tip angle and steer the needle. In this study, the needle control was shared, leaving a high control authority to the user.

The implemented force guidance was based on straightforward, linear relations between the Omega probe position, the error between the estimated and optimal path radius (in a single-curve approach), and the feedback force, up to a saturation value of 2 N. There are numerous other path planners and force profiles thinkable to support the user in these steering tasks. Evaluating the effectiveness of these alternatives is considered valuable future work. Based on the current experiment, it is thought that force feedback in addition to visual feedback may support the needle endpoint accuracy in steering tasks. However, due to a large spread in data and a limited number of test subjects, no conclusive statements can be made at this point regarding the functionality of the implemented feedback conditions. It is noteworthy that there was a large variation in the ability of participants to deal with the needle steering kinematics. Possibly, velocity dependencies in the insertions play a role, as this factor visibly varied among participants. Velocity
dependencies were also attributed to rigid, pre-curved needles [75]. Furthermore, we found that people may react differently to the exposed types of feedback. It has been shown that the extent to which participants rely on various sources of information may depend on the task at hand [116]. In this regard, future experiments with different task complexities and different types of force feedback profiles, should be investigated.

5.5. Conclusion

We conclude that the general ability of operators to cope with the kinematic steering constraints of a teleoperated, tip-articulated, steerable needle varies considerably. The implementation of shared control in needle steering requires a careful assessment of effective communication channels, e.g. by evaluating the weights users assign to present feedback methods. Shared control may be used to teach users how to cope with the acting needle steering constraints, and to guide them in complicated steering tasks.
End-point accuracy in manual control of a steerable needle

Abstract The goal of this chapter is to study the ability of a human operator to manually correct for errors in the needle insertion path — without partial withdrawal of the needle — by means of an active, tip-articulated steerable instrument. The needle is composed of a 1.32 mm outer diameter cannula, with a flexure joint near the tip, and a retractable stylet. The flexural rigidity 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 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 100 mm deep, automated insertions with a linear stage. Besides the tip position, the tip angles were tracked during the insertions. The targeting error (mean $|error| \pm SD$) 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. This study demonstrates the ability to manually steer needles to predefined target locations under image guidance.
6.1. 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 [20], 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 [117]. 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 [69], as a result of the insertion forces acting on the complex set of interconnected and sliding tissue structures. A typical protocol for focal liver biopsy, under CT-guidance, describes the obtainment of a preliminary scan, and one for each successive needle adjustment [118]. In addition, ultrasound images may be used to guide these interventions. 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 [119], 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 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 needle insertion paths [21].

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 [25, 120], or protruding pre-curved stylets [55, 78]. Only one study presented data on manual insertion paths [120]. The assessment of repeatability in manual steering has not yet been investigated.

6.1.1. Aim and approach

**Aim:** This study investigates the ability of a human operator to minimize end-point errors in manual needle placement, using a tip-articulated steerable needle.

The steering task represents the intra-procedural correction of the needle heading, using a manually steered instrument. Besides manual insertion tasks, automated insertions with fixed tip angles were studied in a reference experiment to evaluate the needle functionality in terms of path reproducibility.
6.2. Materials and methods

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

6.2.1. Needle specifications

Needle deflections in tissue result from asymmetric interaction forces, which often originate at the instrument tip [39]. The needle presented in this chapter has a conical (symmetrical) tip, see Fig. 6.1. 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 flexural rigidity that resembles a fine 20 G hypodermic needle (see Appendix 6.6.1). 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 6.6.2).

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 articulations with two degrees of freedom (2-DOF), see Fig. 6.1. 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. [121]. 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. controller motions are not limited to the four principal directions.

6.2.2. Tissue simulants

The stiffness of healthy and diseased liver tissue can vary considerably [122]. To assess the steering sensitivity for this property, experiments were conducted in two simulants. Porcine gelatin tissue simulants (Gelatine, Dr. Oetker, DE) with concentrations of 4 and 8 wt% were produced (see Appendix 6.6.3), similar to the extremes tested in [98]. 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.

6.2.3. Experiments

Automated insertions

Automated insertions of 100 mm at 10 mm/s were performed using a linear stage (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. Also, 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
6.2. Materials and methods

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. 6.2. 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 predefined 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 visualized in Fig. 6.3.

Image processing

The needle tip trajectories were recorded with a camera (FL3-U3-13E4C-C, Point Grey, CA, see Appendix 6.6.4). 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.

Figure 6.2: Illustration of a single-handed and a double-handed method to interact with the steerable needle.
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 removed 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. This final step was sometimes needed to remove small remaining areas, but in most cases (>99%), this step had no effect on the image and was redundant.

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 6.6.5). For the mean px-to-mm conversion, the linear stage 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 the median pixel observation per row of the filtered video frame. All image analysis steps and statistical tests were conducted 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 \( d_{\text{joint}} \), shown in Fig. 6.1, was approx. 15 mm. 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 (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 path curvature is presented for the 8 wt% simulant, in each of the steering directions. The curvature was found using a search function, during which a circle origin (O) moved over the gelatin surface. For each O, the variability (SD) in distance to the
6.3. Results

6.3.1. Sequential and automated insertions

Tip position data of ten sequential runs in the R-direction are presented in Fig. 6.3. 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, in 2 SD for visibility), and the tip end-points (black circles). The average tip displacements and variability at the end of the insertions, were $13.1\pm1.1$ mm and $20.8\pm0.5$ mm, in 4 wt% and 8 wt% gelatin, respectively.

Figure 6.3: 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).
6.3.2. Randomized and automated insertions

Figures 6.4a–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 average tip position, variability, and the path curvature are shown in Table 6.1. This table also presents the marginal and grand means for the tip placement variability. The instrument-tissue interaction forces were expected to be higher in the stiff tissue type, which corresponds to the larger lateral tip displacements that were found.

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 6.5a–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.

Table 6.1: 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, $\kappa$ [10$^{-3}$mm$^{-1}$], of the tip paths. The (4) and (8) indicate the gelatin concentration in [wt%].

<table>
<thead>
<tr>
<th>Direction</th>
<th>B</th>
<th>F</th>
<th>C</th>
<th>L</th>
<th>R</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\kappa$ (8)</td>
<td>3.0</td>
<td>3.0</td>
<td>-</td>
<td>3.2</td>
<td>3.5</td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>Displ. (4)</td>
<td>$-11.5\pm1.5$</td>
<td>$8.9\pm1.1$</td>
<td>$-1.0\pm0.7$</td>
<td>$-12.2\pm1.7$</td>
<td>13.3±1.3</td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>Displ. (8)</td>
<td>$-18.4\pm1.7$</td>
<td>$18.7\pm0.8$</td>
<td>$-1.6\pm0.8$</td>
<td>$-18.7\pm2.1$</td>
<td>21.2±1.3</td>
<td>1.4</td>
<td></td>
</tr>
<tr>
<td>Mean SD</td>
<td>1.6</td>
<td>1.0</td>
<td>0.8</td>
<td>1.9</td>
<td>1.3</td>
<td>1.3</td>
<td></td>
</tr>
</tbody>
</table>

6.3.3. Randomized and manual insertions

The resulting paths of the manual insertions, are shown in Fig. 6.4c–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 6.2. Some differences in tip placement variability are seen for the different steering directions.

The tip angles shown in Fig. 6.5c–d illustrate the actuations by the user. Corrective actions occurred in the same, as well as in the opposite steering direction, dependent on
Figure 6.4: 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.
how the first half of the insertion went. In Fig. 6.5d 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.

Table 6.2: 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>
<thead>
<tr>
<th>Direction</th>
<th>B</th>
<th>F</th>
<th>C</th>
<th>L</th>
<th>R</th>
<th>Mean</th>
<th>Error</th>
<th>&amp; SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Error</td>
<td>(8)</td>
<td>0.6 (+)</td>
<td>0.4 (-)</td>
<td>0.4 (+)</td>
<td>0.8 (-)</td>
<td>0.4 (-)</td>
<td>0.5</td>
</tr>
<tr>
<td>SD (8)</td>
<td>1.4</td>
<td>0.8</td>
<td>0.3</td>
<td>1.2</td>
<td>1.6</td>
<td>1.1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6.4. Discussion

6.4.1. 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 [123]. Cornelis et al. [124] 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, could be provided by active needle steering.
6.4. Discussion

Most research in the field of needle steering aims at developing automated or robotic systems, see [20] for a review. Robotic approaches are often suggested due to their accuracy and consistency compared to manual approaches [97]. 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 [113], and lead to placement errors [125]. The rotations can also lead to out-of-plane steering errors due to torsional friction [59]. Tip-articulated needles do not require axial rotations to steer. They allow for both robotic [23, 100] and manual approaches [120].

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 [55], is a valid argument to investigate 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.

6.4.2. Interpretation of results

In four out of five steering conditions (in 8 wt% gelatin) the variability in tip end-positions was smaller in manual runs than in 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. 6.5 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 [13]. Studying the effect of tip shapes (e.g. articulations) is therefore of value for both the development of steered and non-steered needles.
6.4.3. 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. 6.4. 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 outside of the imaging plane.

6.5. Conclusion

This study 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 stage. 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 of the needle-target alignment.

6.6. Appendices

6.6.1. Flexural rigidity of the 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, 0.2 mm diameter stainless steel rope, Engelmann Vom Hofe Group, DE). A cross-section of this needle is shown in Fig.2.3 (method 6). 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, \( E \cdot I \), of \( 7.0 \cdot 10^{-3} \, \text{Nm}^2 \), which resembles that of a stainless steel 20 G hypodermic needle (6.7 \( \cdot 10^{-3} \, \text{Nm}^2 \)).

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. Upon removal of the stylet, while the needle is embedded in tissue, the needle shape should remain approximately constant. In addition, combined needle-tissue displacements are expected, suggesting the tip would remain at the same relative position to the target.

### 6.6.2. Handle design and force transmission

The needle handle is 3-D 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. 6.1. 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.

Two conventional techniques for instrument actuation are thumb and wrist control. Although there is little consensus on the effects on performance, a strong user preference was found for thumb control of laparoscopic tools [126]. The presented needle also has a thumb interface and facilitates some conventional single-handed and double-handed grips, as shown in Fig. 6.2.

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. 6.1). 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.

### 6.6.3. Tissue simulant preparation

The gelatin was produced the day before the experiment. Gelatin powder was solved in water 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.

### 6.6.4. 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 (1280x1024). The camera lens was positioned at a fixed distance of 0.4 m from the needle insertion line, shown in Fig. 6.1. 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. 6.3. 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.

### 6.6.5. 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 flexural rigidity roughly twenty-two times larger 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 6.3 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 of the first and last frame per run, similar to the one shown in Fig. 6.3, were constructed and analyzed.
Table 6.3: 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.

<table>
<thead>
<tr>
<th></th>
<th>Festo trace (n=10)</th>
<th>Camera trace (n=10)</th>
<th>Tip search (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth [mm]</td>
<td>100.00±0.00</td>
<td>100.0±0.1</td>
<td>99.8±0.2</td>
</tr>
<tr>
<td>Speed (mean) [mm/s]</td>
<td>10.00±0.01</td>
<td>-</td>
<td>10.0</td>
</tr>
<tr>
<td>Speed (std) [mm/s]</td>
<td>0.27±0.01</td>
<td>-</td>
<td>0.3±0.1</td>
</tr>
</tbody>
</table>

manually to obtain the tip displacements. 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.
Discussion

A desk is a dangerous place from which to view the world.
— John le Carré
7. Discussion

7.1. The big picture

The aim of this thesis is to enhance our fundamental understanding of the origin of needle-tissue interaction forces, and to investigate how these forces can be actively modified for the purpose of needle steering. At the instrument tip level, mechanical needle-tissue interactions were studied in Chapter 3. This gave comparative insights into the steering potential of several needles discussed in review Chapter 2. The ability to alter needle-tissue interactions for the purpose of active steering was discussed by means of two proposed instrument designs in Chapters 4 and 6. Studied facets were:

- The influence of the tip shape by actively articulating a conical needle tip.
- The influence of the operator by performing needle steering tasks in a manual control, shared control, and computer control setting.

The work presented in this thesis is useful for future studies on active needle steering, defining needle design criteria, developing explanatory and mechanics-based navigation models, and considering human operation in (parts of) the needle steering task.

7.1.1. The development of a steerable needle

Past and current objectives

Needle steering started out with the search for pragmatic solutions to manipulate needles at the base, in order to reach deeper situated lesions while avoiding delicate structures, such as veins [26]. The used path planner minimized the path potential in a Finite Element Method (FEM) model of the needle-tissue environment. This approach did not allow for real-time updates, due to its computational complexity, and could not guarantee a feasible solution for each static potential field. Replacing the FEM model with a virtual springs model and planning the path by searching for the least curved needle shape, yielded a significant improvement to this steering approach, while adhering to the initial clinical objectives [17]. Numerous studies have, since then, focused on the development of alternative path planning techniques by means of system modeling and the optimization of path decision making processes.

System models were often based on kinematic rules adopted from other research fields, e.g. vehicle dynamics. They proved useful for the description of navigation constraints, were easily implemented, and could be updated at relatively high rates. Since the model parameters were not directly relatable to instrument or tissue characteristics, they heavily relied on fitting to experimental data. Clearly, models with more fitted parameters were better capable of describing the data, e.g. bicycle models were more accurate in describing needle paths than unicycle models [39].

Path planning options in needle steering have been studied in decision making processes, e.g. by means of Rapidly Exploring Random Trees [127–129]. Research in this
7.1. The big picture

Field mostly explored the reachable space (the kinematic motion extremes), while leaving the definition of path selection criteria to the clinician. As a result, modeled obstacles grew in size and paths increased in complexity. Navigation objectives, for instance, could aim to maximize the obstacle clearance [128], or minimize the chance on obstacle hits [130]. To the author's knowledge, paths with this much curvature have never been analyzed in mechanics-based system models. Such a step would be valuable to the field, since any induced needle curvature requires an acting force, which — if not generated by internal mechanics — will have to be supplied by supporting tissue.

Where this thesis fits in

Path planning of steerable needles will always require a careful assessment of the acting movement constraints. However, Chapter 4 demonstrates that the adopted steering technique strongly affects this requirement. Instead of computing the inverse kinematic relations to assess possible needle paths for reaching a target, a simple PI-controller, unaware of remaining path length, was implemented to do the job. The controller itself was not proposed as optional replacement for current systems. Instead, the take-home message of this chapter was that the articulated-tip needle provides a continuum of optional paths (within the maximum curvature constraints), enabling the use of this control approach. This resulted from the needle’s direct ability to amend the path radius by varying the tip articulation angle. More sophisticated planners were useful to reduce the targeting error, and will allow for other, functional path selection criteria.

The derivation of explanatory, instead of descriptive system models is a valuable next step in the implementation of robustly controlled steerable needles. On-going work in this field includes the replacement of model variables with ones that have a real-system significance [42], the formation of macroscopic [44] or microscopic [48] mechanics-based rules, and the inclusion of measurement uncertainties [40, 129] and tissue related variability, such as target motions [81, 131] and stiffness variations [23, 50, 65]. The tip shape study in this thesis contributes to these explanatory models. The objective of such a model would not be to mimic the real world system with the highest accuracy, but to assess and prioritize interacting variables, and ideally reduce the need for model fitting to every other system state.

Future heading

The final implementation of steerable needles will rely on a close collaboration with the clinical users. Crucial factors, at this stage, are the obtainment of needle-tissue force data in (or close to) the realistic setting, and the formulation of functional needle steering requirements. Direct inputs from clinicians may further help interpret relevant visual feedback cues, refine path selection criteria, and provide intuitive and meaningful feedback on the insertion progress. These inputs become particularly relevant when the clinician is actively involved with the steering task, e.g. during the proposed manual or shared control approaches.
7. Discussion

7.2. Tip shape

7.2.1. Fundamental contributions

To better understand the relations between tip shape and needle deflection, Chapter 3 characterized the force interactions of various scaled tip designs during the insertion in tissue simulants. The vector summation of the measured bending force and insertion force produced a resultant that could summarize this force play. In case bending force would increase at the same rate as insertion force, mechanics-based tip load modeling would simplify to finding a single shape-factor (proportionality) that expresses the ratio between the force components, i.e. the force resultant orientation. Unfortunately, it was found that this orientation could vary with axial load, and that the extent of this variability is dependent on tip shape. For articulated-tips, a near-constant orientation was found, meaning that a proportional relation would roughly hold. For other tip shapes, the relation between force components should be studied in more detail. Mechanics-based models for bevel-tip needles assume a constant tip load orthogonal to the bevel [43, 96]. The accuracy of existing models can be improved by reviewing and refining this assumption for different tip-tissue combinations.

7.2.2. Practical contributions

By analyzing the force-displacement relations, it was found that beveled tips are generally more efficient in building up bending force than conical tips. However, conical tips are more practical to use, since their inherent rotational symmetry allows for equal tip shapes in all articulation directions. To this purpose, beveled tips would have to rotate axially.

The steerable needles discussed in this thesis employ conical tips that can bend (ball joint) or curved (flexure joint) in a desired orientation. For single curved insertion paths, these needles behave in a predictable and controllable manner. Automated insertions with the manual needle, discussed in Chapter 6, showed that a fixed thumb control angle resulted in a constant tip articulation angle. A constant tip angle supports the assumption that tip paths may be effectively modeled by a single radius of curvature [23]. The path curvature was, on the other hand, found to be strongly affected by tissue stiffness (Chapter 6), and possibly by rupture toughness (Chapter 3). In addition, the curvature seemed affected by insertion velocity. It is assumed that this is particularly relevant for velocities below 10 mm/s. Velocity dependencies were in the past reported for pre-curved needles [75], but not for beveled needles [52]. Possibly, articulated tips introduce velocity dependencies to the system. These factors can, in a variable degree, affect the path of any type of inserted needle. However, tip-articulations allow for a direct control over the tip shape and over the acting tip-tissue interaction mechanics.
7.3. The human operator

A human operator may be less consistent in information processing than a computer. However, humans are expected to be more flexible in terms of intercepting potentially relevant system inputs. In addition, humans are self-learning, whereas robotic approaches currently still work with fixed control rules. The introduced variability in information processing is, therefore, not necessarily harmful for a robust and safe operation. This motivates the study of optional involvement of clinical experts or trained staff members during the steering task.

7.3.1. Execution, guidance, assistance, or supervision

Both the steering method and the planned path complexity contribute to the overall difficulty of the task at hand. These factors play a crucial role in the opportunities for human involvement in needle steering. The envisioned path complexity, presented in literature by the programmed virtual environments, varies considerably and the made choices are rarely supported by clinical data. In this thesis, the added value of simple path corrections — for example to stay on a straight insertion line — is assumed larger than the clinical need to steer to formerly inaccessible regions. This allowed for the evaluation of relatively simple steering tasks, executed by a human operator. More complicated tasks may benefit from active human guidance, assistance, or supervision during the insertion process. This equates to various levels of authority left to the human and computer controller, respectively.

7.3.2. Operation of bevel-tip needles

Planning of bevel-tip needle paths requires a computing power that is not easily left to a human operator. Path following requires either the control of duty cycle periods in axial needle rotations, or the sequential switching between steering conditions, e.g. by $\pi$ rad axial needle rotations to head to the left or right in a 2-D task. The solution space for the latter method is limited by the fixed path curvature, pressing the need for well-timed control actions. Other planning complexities include path curvature dependencies on tissue stiffness and out of plane steering errors due to torsional friction [58]. Nevertheless, by means of smart planners, human-in-the-loop operation is feasible [115]. It was found that the conversion from a joint space to a Cartesian space control interface was preferred by the user, and led to shorter targeting times and inserted needle path lengths in virtual steering tasks [113].
7. Discussion

<table>
<thead>
<tr>
<th>Human control</th>
<th>Shared control</th>
<th>Computer control</th>
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Figure 7.1: Control authority in needle steering on a continuous scale. This thesis discusses human control, shared control, and computer control of tip-articulated needles.

### 7.3.3. Operation of articulated-tip needles

In this thesis, steering of an articulated-tip needle is studied in human control, shared control, and computer control, as is depicted in Fig. 7.1. The extremes involve pure human and computer control, whereas any collaboration between controllers results in a shared control setting. Moving from left to right on this scale equates to shifting control authority from the human to the computer. The setting in Chapter 5 leaves a high control authority to the human operator.

The tip-articulated needle has highly favorable properties for manual or human-in-the-loop operation. The configuration space of the needle does not include axial rotations and the end-effector positions can be intuitively mapped to a Cartesian space controller. The planned path radius can be actively amended by varying the tip articulation angle. This input-output relation was found to be approximately linear for small tip angles [23]. In addition, the aligned (unarticulated) tip configuration allows for straight needle paths.

Nevertheless, also for tip-articulated needles, the path curvature remains dependent on tissue properties, and possibly insertion velocity. Torsion effects can play a role during curved needle configurations and out of plane tip loads. This may also result in out of plane steering errors, which are difficult to interpret from 2-D imaging data. This demands a high alertness during needle insertions.

The ability of a human operator to navigate along a simple curved path was demonstrated in Chapter 6, in tissue simulants and with proper visual feedback. This shows that variability among insertion paths, e.g. due to an unsteady hand or variable speed, can be actively compensated for by steering. Typically, users adhere to a particular, individual approach, allowing them to observe and learn from the system at hand. Between operators, differences in approach were seen and discussed in Chapter 5. Training programs are therefore considered to be valuable to familiarize users with the acting kinematic steering constraints. Shared control in needle steering allows for teleoperation with force guidance along complex trajectories and may also be used for training purposes.
7.4. Conclusions

- Variations in steerable needle design, e.g. in flexural rigidity, can be largely attributed to current challenges in mechanical and/or control design. In the end, the needle design should be based on clinical steering requirements. However, potential clinical applications of steerable needles are left undiscussed in approximately half the articles found in literature, stressing the need for more active collaborations with the clinical field.

- The progression from descriptive to explanatory needle steering models is of value for robust operation under variable system states. On-going developments in this field include the replacement of variables with ones that have a real-system significance, the formation of macroscopic or microscopic mechanics-based rules to express needle-tissue interactions, and the inclusion of sensor and tissue related system uncertainties.

- Mechanics-based models may be extended to multiple needle steering modalities by including a tip-shape related expression for the tip load.

- In a macroscopic analysis of the tip-tissue interactions, the tip load assumed a more radial orientation with increased axial load. The size of this effect varied with tip shape. The vector orientation was nearly constant for articulated-tip needles.

- Bevel-tip needles are more effective in building up bending force than articulated conical-tip needles with a similar tip angle.

- Articulated conical-tip needles can be effectively steered in simulant tissue and require no axial rotations to change the steering plane.

- Fiber Bragg grating (FBG) based shape sensing can be effectively used to estimate the cannula shape and tip location during needle insertion, without having to rely on medical imaging techniques.

- Tip articulations enable a continuum of possible needle paths, ranging from zero curvature to the maximum curvature constraint of that needle-tissue combination. This potentially allows for 1) the use of lighter path planning software, and 2) human operators in needle steering tasks.

- The implementation of shared control in needle steering requires a careful assessment of effective communication channels, e.g. by evaluating the weights users assign to present feedback methods. Shared control may be used to teach users how to cope with the acting needle steering constraints, and to guide them in complicated steering tasks.

- A human operator is capable of reaching off-axis targets in gelatin under visual feedback, by means of manual needle steering. It has been shown that variabilities in the path can be effectively compensated for by means of a tip-articulated needle.
References


7. Discussion


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