Needle-like instruments for steering through solid organs
A review of the scientific and patent literature

Scali, Marta; Pusch, T.P.; Breedveld, Paul; Dodou, Dimitra

DOI
10.1177/0954411916672149

Publication date
2017

Document Version
Accepted author manuscript

Published in
Institution of Mechanical Engineers. Proceedings. Part H: Journal of Engineering in Medicine

Needle-like instruments for steering through solid organs: A review of the scientific and patent literature

Marta Scali, Tim P Pusch, Paul Breedveld and Dimitra Dodou

Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials Engineering, Delft University of Technology, Delft, The Netherlands

Correspondence concerning this article should be addressed to Marta Scali, Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials Engineering, Delft University of Technology, Mekelweg 2, 2628 CD Delft, The Netherlands. Email: m.scali@tudelft.nl

Abstract

High accuracy and precision in reaching target locations inside the human body is necessary for the success of percutaneous procedures, such as tissue sample removal (biopsy), brachytherapy, and localized drug delivery. Flexible steerable needles may allow the surgeon to reach targets deep inside solid organs while avoiding sensitive structures (e.g. blood vessels). This article provides a systematic classification of possible mechanical solutions for three-dimensional steering through solid organs. A scientific and patent literature search of steerable instrument designs was conducted using Scopus and Web of Science Derwent Innovations Index patent database, respectively. First, we distinguished between mechanisms in which deflection is induced by the pre-defined shape of the instrument versus mechanisms in which an actuator changes the deflection angle of the instrument on demand. Second, we distinguished between mechanisms deflecting in one versus two planes. The combination of deflection method and number of deflection planes led to eight logically derived mechanical solutions for three-dimensional steering, of which one was dismissed because it was considered meaningless. Next, we classified the instrument designs retrieved from the scientific and patent literature into the identified solutions. We found papers and patents describing instrument designs for six of the seven solutions. We did not find papers or patents describing instruments that steer in one-plane on-demand via an actuator and in a perpendicular plane with a pre-defined deflection angle via a bevel tip or a pre-curved configuration.

Keywords

Deflection, mechanical design, medical needles, steerable needles, solid organs

M. Scali, T. P Pusch, P. Breedveld and D. Dodou (in press). Needle-like instrument for steering through solid organs: A review of the scientific and patent literature. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine.* http://dx.doi.org/10.1177/0954411916672149

Introduction

Medical needles are common devices used in percutaneous procedures, such as tissue sample removal (biopsy),[1] internal radiotherapy (brachytherapy),[2] and localized drug delivery.[3] The success of these procedures depends on the accuracy and precision with which the target site is reached. During biopsy procedures, for example, malpositioning of the medical needle can lead to false diagnosis and healthy tissue damage.[4,5] Similarly, accurate positioning of radioactive seeds is necessary for brachytherapy,[6] and wrong positioning of the needle during peripheral or central anesthesia could cause neurological complications.[7]

When the target is reachable via a straight trajectory, rigid needles are typically used. The physician carefully chooses the puncturing angle and pushes the needle for- ward in order to reach the target. Once the needle is inside the tissue, only small adjustments of the trajectory are possible. Misestimating the puncturing angle requires withdrawing and reinserting the needle, which elongates procedure times and increases patient discomfort.

Flexible steerable needles have the potential to allow the surgeon to reach targets located deep inside the body with higher accuracy and precision than rigid straight needles do. However, several parameters undermine the accurate placement of steerable needles, including needle deflection due to needle–tissue interaction, organ movement due to physiological processes (e.g. breathing), and human error.[8,9]

The navigation of a flexible steerable needle in the human anatomy can be controlled manually or automatically. In the latter case, a robot is used to align the needle with the target location in real time, thereby reducing human error during the pre-insertion phase.[10] Real-time correction of the needle path requires a detailed model of the interaction between the tissue and the needle. Defining the right model for the procedure is challenging due to a vast amount of variables that have to be taken into account, such as needle geometry and tissue properties (for a comprehensive review on this subject, see Gao et al.[11]). Therefore, mainly manually controlled steerable needles are used in percutaneous interventions. Manually controlled needles allow the physician to correct the trajectory of the needle toward the target by, for example, maneuvering the tip of the needle with a joystick, at the cost of inducing human error.[12]

The steerability of a flexible needle depends on the mechanical design of the needle and the control strategy used, with the latter having been more broadly investigated than the former[13] (for a review, see Abolhassani et al.[14]). So far, needle steerability in terms of mechanical design has been investigated in two reviews.[15,16] Cowan et al.[15] distinguished between three steering methods: (1) tip-based steering, relying on an asymmetric needle tip for deflection, (2) lateral manipulation, in which the base of the needle is moved perpendicularly to the needle insertion axis, and (3) steering by means of tissue manipulation, in which instead of steering the needle toward a stationary target, external forces are applied to the tissue to align the target with the needle trajectory. In the sec- ond review,[16] a distinction was made between active steering, referring to needles that are steered by means of actuation with no need of tissue interaction, and passive steering, relying on needle–tissue interaction forces that lead to deflection of the needle.

Both reviews follow a bottom-up approach in which existing needles and needle designs are clustered based on their steering strategy. Moreover, both reviews focus on scientific literature only and do not include patent literature. In this review article, we adopted a top-down approach, focusing on the fundamental differences between steering mechanisms of needle-like instruments and on logically derived design solutions, with the goal to create a framework of all mechanically possible solutions for three-dimensional (3D) steering through solid organs. Moreover, we expanded the search in the patent literature, and we applied a systematic search and review methodology, in order to provide a comprehensive overview of the state of the art.

Literature search methods

A search of the scientific literature and the patent literature for instruments that can be steered through solid organs was conducted using Scopus and the Web of Science Derwent Innovations Index (DII), respectively. In both databases, the search query was a Boolean combination of keywords regarding the following: (1) the instrument type, (2) the target

application, and (3) the function of interest, while excluding terms that led to a considerable amount of noise in the search results.

Scientific literature search

We conducted our scientific literature search in Scopus. Scopus offers several advantages compared to both Google Scholar and Web of Science. Google Scholar provides the broadest coverage out of all three search services,[17] but one of its limitations is that it does not allow for nested Boolean searches or for exclusively searching in the abstract of papers. Web of Science does allow for complex syntaxes and for searching within specific parts of papers, but it comprises fewer journals and conference proceedings than Scopus. Furthermore, in Web of Science, each paper is classified in only one discipline, meaning that even if a paper is related to both the disciplines of, for example, Engineering and Computer Sciences, it will still be classified in either Engineering or Computer Sciences, and not in both.[18]

In our Scopus search, we used the function ''LIMIT TO'' to limit the search to English language papers and within the subject areas ''Engineering'' and ''Medicine,'' which means that all the papers classified in Engineering and Medicine were included (i.e. even those that were not exclusively classified to these two disciplines but were cross-classified to third disciplines). The entire search query was *TITLE-ABS-KEY((needle OR probe OR cannula OR stylet) AND (tissue OR medic* OR surg*) AND (steer* OR deflect* OR articulat* OR maneuv* OR manoeuv* OR ''flexible needle'') AND NOT (sutur* OR syringe)) AND (LIMIT-TO (SUBJAREA, ''MEDI'') OR LIMIT-TO(SUBJAREA, ''ENGI'')) AND (LIMIT-TO(LANGUAGE, ''English'')).*

No limitation to the publication year was applied. Besides the search in Scopus, we checked the references of the papers included in this review for retrieving relevant works that were not captured by the Scopus search.

Patent literature search

We compared the Web of Science DII with Google Patents and Free Patents Online (FPO) and concluded that DII provides several advantages compared to the other two patent databases. Similar to Google Scholar, Google Patents does not support nested Boolean searches, and it only allows for full-text searches and searches in the title rather than exclusively searching in the patent abstract. Patent titles are often not informative, whereas a full-text search, albeit comprehensive, would lead to extensive noise in the form of irrelevant patents which happen to mention the search term(s) in an unrelated context. FPO does provide the option to limit a search exclusively to specific parts of a patent (e.g. abstract) as well as to use a nested Boolean search syntax. However, because patents typically use nonspecific formulations in their abstract, restricting a search to the patent abstract increases the risk of missing relevant patents. Patents in the DII database are complemented with an edited title and abstract that are manually prepared by a human abstractor based on the claims and novelty of the patent. The edited title and abstract also comprise information about the uses and advantages of the technology.[19] A search in the edited title and abstract can be performed using the DII ''Topic search'' (TS) field.

We restricted our search within the technological field with Derwent Class Code (DC) ''P3,'' which corresponds to the health section of the engineering area. Section P3 contains several subsections. We focused our search on the following subsections: ''P31,'' containing results from the group ''Diagnosis, surgery''; ''P33,'' representing ''Medical aids, oral administration''; and ''P34,'' representing ''Sterilizing, syringes, electrotherapy.'' We further

restricted the search region- ally using the first two letters of the patent number (PN). Specifically, we searched only for US (US*) and European (EP*) patents, as well as patent applications (WO*). The entire search query was *TS = ((needle OR probe OR cannula OR stylet) AND (tissue OR medic* OR surg*) AND (steer* OR deflect* OR articulat* OR maneuv* OR manoeuv* OR ‘‘flexible needle’’) NOT (sutur* OR syringe)) AND DC = (P31 OR P33 OR P34) AND PN = (US* OR WO* OR EP*)*. No limitation to the publication year was applied. Patents in which priority date and inventor names were identical were considered to be potential duplicates. After checking the edited title and abstract of such patents for false positives, duplicate patents were removed.

Eligibility criteria

Our review focuses on steerable needles. We defined a needle as an instrument that is able to puncture a solid tissue and move through it. Instruments that can move (only) through a body lumen, vitreous humor, or the vascular system were excluded. Furthermore, only those instruments that are capable of maneuvering along a curved path, that is, are able to steer, were considered as relevant. If a research group published multiple papers on the same needle design, only the most comprehensive paper, in terms of the description of the mechanical working principle, was included. Papers from different research groups reporting on steerable needles of similar designs were counted as independent designs. Works that focused on needle–tissue interaction, computational modeling, motion planning algorithms, or control of a steerable needle and not on the mechanical design of the needle were excluded. Also, works that only added a feature that does not relate to the steering performance of a needle presented in a different paper or patent were excluded.

Study selection

The title and abstract of the scientific papers were initially screened by the first author (M.S.) based on the above-mentioned eligibility criteria. The references of the two previous reviews[15,16] were also checked but did not reveal papers that were not already retrieved by our search. Next, the full text of the remaining papers was read. To test the clarity of our eligibility criteria, a sample of 50 scientific papers was chosen by M.S. and independently classified as relevant or not by the last author (D.D.). The blind test resulted in 92% (46 out of the 50 papers) agreement between the two authors.

The patents were also first screened based on the eligibility criteria by reading the title and edited abstract. Next, the selected patents were split between M.S. and T.P.P. and studied in depth by reading the full text. When in doubt (six patents), the two authors discussed the relevance of the work until consensus was reached about whether or not to include the work.

Literature search results

The searches yielded 1292 scientific papers and 1014 patents (last update 15 February 2016). A total of 78 patent duplicates were excluded, leaving 936 unique patents for further inspection. After checking the title and abstract of these papers and patents based on our eligibility criteria, 1102 papers and 857 patents were excluded, leaving 190 scientific papers and 79 patents for full-text inspection. After full-text inspection, 22 papers and 22 patents were identified fulfilling all criteria. After checking the references of these 44 works, two more relevant papers were found and added, leading to a total of 24 papers (Table 1)

and 22 patents (Table 2) included in this review.

Classification of possible mechanical solutions for 3D steering

To identify fundamentally distinct steering mechanisms, we first analyzed the instrument motions and geo- metrical features that are responsible for 3D steering. We assumed that every needle can be pushed forward (i.e. translated) and rotated about its longitudinal axis. Note, however, that when the needle interacts with the tissue, these motions can be compromised. Specifically, when a long and thin needle is pushed into the tissue, buckling can occur,[64] whereas rotation of a needle as it is advanced in the tissue can generate a torsional stress on the needle body which may result in angular lag between the orientation of the needle base and the needle tip, making the control of the needle trajectory difficult.[65] Moreover, to maneuver a needle in 3D, translation and rotation are not sufficient. To enable 3D steering, the needle (or its tip) should be also able to deflect. The first level of our classification concerns the way in which needle (or tip) deflection is induced. Specifically, we distinguish between needles with a *pre- defined deflection angle* and needles with an *on-demand deflection angle*. Needles with a pre-defined deflection angle have a pre-defined shape that determines the deflection angle of the needle. These needles can have a particular tip shape (e.g. bevel tip) or a particular body shape (e.g. pre-curved needles). Needles with an on-demand deflection angle have one or more means (e.g. wires, a magnetic head, etc.) able to change the deflection angle of the needle upon actuation.

The second level of our classification concerns the number of planes in which a needle can deflect. Needles with a pre-defined shape or an on-demand actuation can deflect in one plane, whereas deflection in a perpendicular plane is achieved by retracting the needle, rotating it about its longitudinal axis, and pushing it again forward. It follows that deflection in one plane (called henceforth *single deflection*) is sufficient for 3D steering. Some needles, however, allow for deflection in two perpendicular planes (called henceforth *double deflection*) without the need of rotation, which increases the number of possible 3D configurations of the needle, thereby improving steerability as compared to needles relying on single deflection.

The third level of our classification depicts eight distinct design solutions derived as combinations of the deflection method (first level of the classification) and the number of deflection planes (second level of the classification):

Table 1. Author(s), year of publication, key clinical application(s), affiliation of the first author of the relevant papers, and corresponding category in the classification of the relevant papers.

Author(s)	Publication year	Clinical application(s)[a]	Affiliation	Classification
Adebar et al.[20]	2016	Liver biopsy	Stanford University, Stanford, CA, USA	One on-demand deflection angle
Ayvali et al.[21]	2012	N/A	University of Maryland, College Park, MD, USA	One on-demand deflection angle
Burrows et al.[22]	2013	Neurosurgery	Imperial College, London, UK	Two on-demand deflection angles
Chen and Chen[23]	2009	N/A	University of Hong Kong, Hong Kong, China	Bevel tip
Drummond and Scott[24]	1980	Central anesthesia	University of Edinburgh, Edinburgh, UK	Bevel tip
Hamzavi et al.[25]	2008	Liver biopsy	University of Singapore, Singapore	Two on-demand deflection angles
Ko and Rodriguez y Baena[26]	2014	Neurosurgery	Imperial College, London, UK	One on-demand deflection angle
Konh et al.[27]	2015	N/A	Temple University, Philadelphia, PA, USA	One on-demand deflection angle
Kratchman et al.[28]	2011	Lung biopsy	Vanderbilt University, Nashville, TN, USA	One on-demand deflection angle
Losey et al.[29]	2013	N/A	Vanderbilt University, Nashville, TN, USA	Two on-demand deflection angles
Okazawa et al.[12]	2005	N/A	University of British Columbia, Vancouver, BC, Canada	One-plane pre-curved
Ryu et al.[30]	2015	Brachytherapy	Stanford University, Stanford, CA, USA	One on-demand deflection angle
Sears and Dupont[31]	2006	N/A	Boston University, Boston, MA, USA	Two-plane pre-curved
Swaney et al.[13]	2013	Neurosurgery	Vanderbilt University, Nashville, TN, USA	Bevel tip
Swaney et al.[32]	2015	Bronchoscopy	Vanderbilt University, Nashville, TN, USA	Two-plane pre-curved
Tang et al.[33]	2008	N/A	University of Hong Kong, Hong Kong, China	Two on-demand deflection angles
Terayama et al.[34]	2007	Liver biopsy, anesthesia	Osaka University, Suita, Japan	One-plane pre-curved
Torabi et al.[35]	2014	Brachytherapy	Harvard University, Cambridge, MA, USA	One-plane pre-curved
Van de Berg et al.[36]	2015	N/A	Delft University of Technology, Delft, The Netherlands	Two on-demand deflection angles
Wang et al.[37]	2010	N/A	Tianjin University of Technology, Tianjin, China	Bevel tip
Wang et al.[38]	2012	N/A	Tianjin University of Technology, Tianjin, China	One on-demand deflection angle
Webster et al.[39]	2006	N/A	Vanderbilt University, Nashville, TN, USA	Two-plane pre-curved
Yan et al.[40]	2007	N/A	Jefferson University, Philadelphia, PA, USA	One on-demand deflection angle
York et al.[41]	2015	Neurosurgery	Vanderbilt University, Nashville, TN, USA	One on-demand deflection angle

N/A is used when no specific application is mentioned.

[a]The clinical applications mentioned in the table do not represent the full scope of possible applications mentioned in the selected paper.

Table 2. Inventor(s), priority date, key clinical application(s), affiliation of the first author of the relevant patents, and corresponding category in the classification of the relevant patents.

Inventor(s)	Priority date	Clinical application(s)[a]	Affiliation	Classification
Arramon[42]	2003	Vertebroplasty	ArthroCare Corporation, Austin, TX, USA	One-plane pre-curved
Arvanaghi[43]	2006	Biopsies	Independent inventor	Bevel tip
Brockman and Harshman[44]	2012	Vertebroplasty	Stryker Corporation, Kalamazoo, MI, USA	One on-demand deflection angle/ Two on-demand deflection angles
Burger et al.[45]	2009	Vertebroplasty/ kyphoplasty	Osseon Therapeutics, Inc., Santa Rosa, CA, USA	One on-demand deflection angle
Desai and Ayvali[46]	2012	Biopsies (breast, prostate), brachytherapy	University of Maryland, College Park, MD, USA	One on-demand deflection angle/Two on-demand deflection angles
Eck[47]	2006	Drug delivery	Philips Intellectual Property & Standards GmbH and Koninklijke Philips Electronics N.V., Amsterdam, The Netherlands	Two on-demand deflection angles
Germain[48]	2001	Brachytherapy	DFINE, Inc., San Jose, CA, USA	One on-demand deflection angle
Kaplan[49]	2001	Brachytherapy	Microsperix LLC, Atlanta, GA, USA	One-plane pre-curved/
Kraft and Hole[50]	2002	Biopsies (bone marrow, fat, muscle tissue)	Independent inventor	One-plane pre-curved/One on-demand deflection angle/Two on-demand deflection angles
Krueger and Linderman[51]	2005	Vertebroplasty	Allegiance Corp. and CareFusion 2200 Inc.	One-plane pre-curved
Kuhle[52]	2002	Biopsies	Independent inventor	Bevel tip
Liu et al.[53]	2007	Vertebroplasty/ kyphoplasty	Osseon Therapeutics Inc., Santa Rosa, CA, USA	One-plane pre-curved/One on-demand deflection angle
Mathis et al.[54]	2004	Biopsies (lung)	PneumRx Inc., Mountain View, CA, USA	One on-demand deflection angle
Mehta et al.[55]	2010	Tissue repair to shoulder or other joint area	Independent inventor	One on-demand deflection angle
Melsheimer[56]	2009	Biopsies (bone, organs)	Cook Inc. and Cook Medical Technologies LLC, Bloomington, IN, USA	One-plane pre-curved/Bevel tip and one-plane pre-curved
Pellegrino et al.[57]	2010	Vertebroplasty/ kyphoplasty	Relievant Medsystems Inc., Redwood City, CA, USA	One-plane pre-curved
Rodriguez y Baena and Frasson[58]	2009	Brain or liver surgery	Imperial College, London, UK	Two on-demand deflection angles
Ryan and Winslow[59]	1991	Discectomy	Surgical Dynamics, Inc., Concord, CA, USA	One on-demand deflection angle/Two on-demand deflection angles
Salcudean et al.[60]	2002	N/A	University of British Columbia, Vancouver, BC, Canada	One-plane pre-curved
Smits et al.[61]	2002	N/A	Medtronic, Minneapolis, MN, USA	One on-demand deflection angle/Two on-demand deflection angles
Swaney and Webster[62]	2013	Biopsies, brachytherapy, drug delivery	Vanderbilt University, Nashville, TN, USA	Bevel tip
Webster et al.[63]	2005	Bio-sensing	Johns Hopkins University, Baltimore, MD, USA	Two-plane pre-curved

N/A is used when no specific application is mentioned.

[a]The clinical applications mentioned in the table do not represent the full scope of possible applications mentioned in the patent.

1. Bevel-tip needles

In this type of needles, the distribution of forces exerted by the tissue on the bevel tip is asymmetric, as a result of which the needle bends in the direction of the bevel.

2. One-plane pre-curved needles

These needles consist of an inner tube which has a pre- set curvature and is fed through an outer straight tube.

3. Double bevel-tip needles

These needles have a tip which is beveled on two sides perpendicular to each other.

4. Two-plane pre-curved needles

These needles consist of at least two segments with a pre-set curvature perpendicular to each other.

5. Bevel-tip and one-plane pre-curved needles

These needles are a combination of solutions (1) and (2).

6. Needles with one on-demand deflection angle

These needles contain at least one actuated part which causes deflection of the needle upon actuation.

7. Needles with two on-demand deflection angles

These needles have at least two parts that lead to deflection in perpendicular planes upon actuation.

8. Needles with one on-demand angle and one pre- defined deflection angle

These needles are a combination of solution (1) or (2) with solution (6).

We dismissed solution 3 (‘‘Double bevel-tip needle’’) as practically meaningless: a ‘‘double’’ bevel tip is in essence not distinct from the bevel tips in solution 1. Therefore, in the remainder of this review, we will con- sider only seven possible solutions as part of our classification (Figure 1).

Allocation of the retrieved steerable needle designs in the classification scheme

The needle designs retrieved from the literature were allocated into the seven possible mechanical solutions of our classification for 3D steering. Below, the working principle of each of these seven solutions is described, papers and patents which apply the respective solution are presented, and the main design variations are highlighted.

Bevel-tip needles

Upon advancement of a needle through a solid tissue, reaction forces are exerted by the tissue on the tip and along the needle surface. Due to the presence of the bevel, the distribution of these forces (so-called ‘‘tissue interaction forces’’) on the tip is asymmetric. The curvature of the trajectory can be controlled by rotating the needle while pushing it through the tissue. When the needle is pushed forward without rotation, it bends in the direction of the bevel. When the needle is rotated with a rate that is higher than the insertion rate, the needle follows an approximately straight trajectory (or, strictly speaking, a helical trajectory with small pitch). By altering between insertion with and without rotation of the needle, the surgeon can control the curvature and thus the final trajectory of the needle. This control strategy is often referred to as ‘‘duty cycling,’’ where the ‘‘duty cycle’’ is defined as the period in which the needle is inserted while being rotated divided by the period of insertion without rotation. A duty cycle of 100% yields a straight path, whereas the maximum needle deflection is achieved when the needle is not rotated at all (i.e. a duty cycle of 0%) (see previous studies[66–68] for examples of applications of this control strategy).

The bevel tip has been used in needles for percutaneous interventions already in the 1980s[24] and remains one of the most popular designs for steering during such procedures.[69] Several variations of the basic bevel- tip geometry have been presented in literature. The main purpose of these variations is to increase the maximum deflection angle of the needle either by geo- metric modifications of the shaft (or a segment of the shaft) that lower its bending stiffness[13,23,37,43,62] or by increasing the surface area that is in contact with the tissue.[52] Swaney et al.[13] and Swaney and Webster[62] presented a needle with a flexure joint incorporated in the bevel tip, which creates a so-called ‘‘flexure tip’’ (Figure 2). Upon insertion into the tissue, the flexure tip deflects more than the shaft due to the low bending stiffness of the flexure. The configuration of the flexed needle looks similar to a kinked bevel-tip needle and can bend more than a standard bevel-tip needle.[70] The curvature of the needle is adjusted using the ‘‘duty cycling’’ control strategy, where the needle is simultaneously rotated and advanced. When only rotation is applied to the needle body, the flexure at the tip disappears and the needle returns to a configuration similar to a standard bevel tip. The flexure joint can be replaced with a compliant mechanism, as shown in Chen and Chen,[23] in which the needle has a bevel tip and two compliant hinges, that is, flexible members that store energy when they are deformed (input) and transfer this energy to the environment (output). Another way to increase the deflection angle of a bevel-tip needle is presented by Wang et al.,[37] who developed an articulated bevel-tip needle made of multiple sections. The head of the needle bends due to asymmetric forces applied at the bevel tip, with the articulations that are distributed along the needle body increasing the deflection angle. Another approach for increasing the deflection angle relatively to a bevel tip is described by Kuhle,[52] who patented a needle having a bevel tip with a larger diameter than the diameter of the shaft. The underlying principle of this mechanism is that the larger diameter of the tip creates a larger contact area with the tissue, which leads to greater resistance from the tissue, thereby a larger deflection as compared to a needle with uniform diameter.

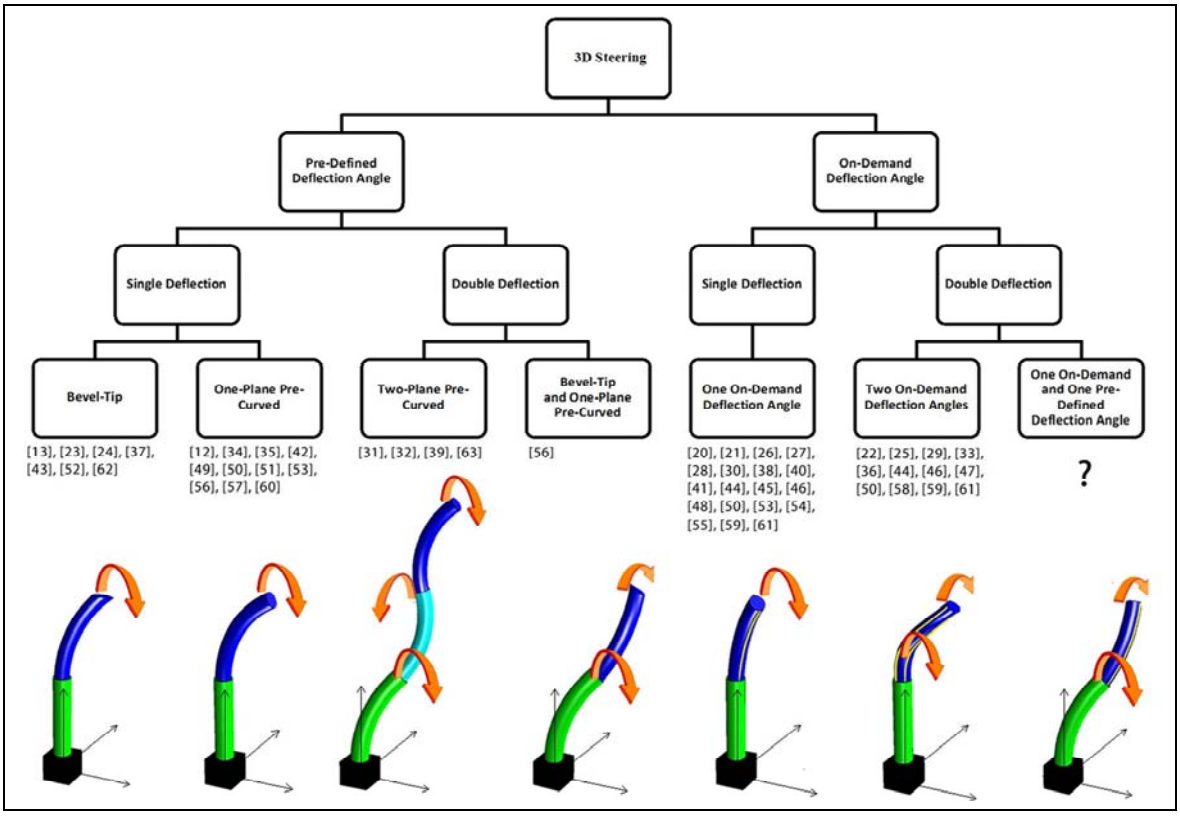

Figure 1. Classification of possible mechanical solutions for 3D steering through solid organs. Arrows indicate the planes in which the instrument can deflect. The question mark indicates that no examples of such instruments were found in the literature.

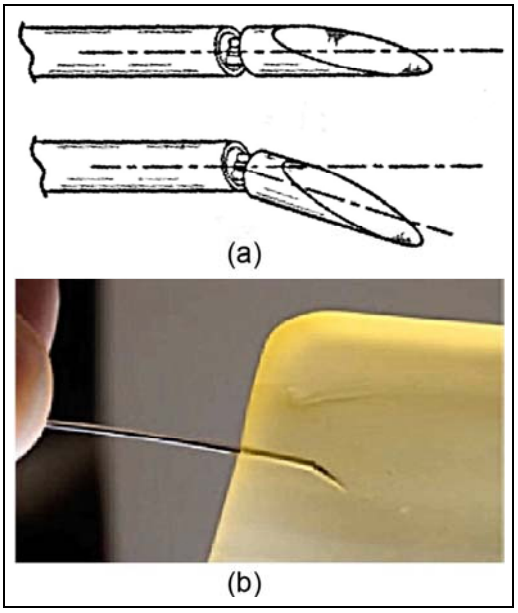

Figure 2. Example of a bevel-tip needle. The design presents a flexure joint at the tip, which deflects more than the shaft upon insertion in the tissue: (a) a schematic drawing (adapted from Swaney and Webster) and (b) a photo of the prototype (courtesy of PJ Swaney).

One-plane pre-curved needles

These needles consist of a straight tubular outer part (cannula) and a cylindrical inner part (stylet) with a pre-set curvature. The pre-curved stylet is fed through the cannula which forces the stylet to assume an approximately straight configuration. As the stylet is moved out of the distal end of the cannula, it returns to its initial bent shape, allowing the needle to follow a curved trajectory. Note that there exist nested cannula systems that cannot bend once into the tissue due to their high stiffness. These systems have been excluded from our review.

We found six needles that use this steering mechanism of a pre-curved stylet/straight cannula[12,34,35,51,53,57,60] and four needles with small variations of this mechanism.[42,49,50,56] Okazawa et al.[12] described a pre-curved stylet/straight cannula concept of a steerable needle (for the complete design description of the instrument, see also Salcudean et al.[60]) manually controlled with a joystick (Figure 3). Torabi et al.[35] used such a steerable needle in combination with a robotic system for placing seeds during brachytherapy. Another example of a straight cannula and pre-curved stylet is presented by Terayama et al.[34] in combination with ultrasound imaging that provided information about the position of the needle during the advancement through the tissue.

In one variation of the basic pre-curved stylet/ straight cannula design, the shaft has notches of various shapes and dimensions, which increase the flexibility of the instrument and hence achieve a greater deflection angle.[50] An increase in the deflection angle can be also achieved by having a cannula and a stylet that are both pre-curved in such a way that they enable (i.e. rein- force) deflection toward the same direction.[57] In a more substantial design variation, the instrument consists of a cannula with a pre-set curvature and a straight stylet. The instrument is in its straight configuration when the stylet supports the entire cannula length. Steering can be accomplished by retracting the straight stylet (fully or partially) to allow the pre-curved tip of the cannula to deflect.[42] Another variation is a hybrid instrument combining a pre-curved stylet with a bevel tip, both causing deflection in the same plane.[49,56] Among the pre-curved needles, the one presented by Liu et al.[53] is commercially available under the name of ‘‘Osseoflex SN,’’ used for the treatment of vertebral compression fractures.

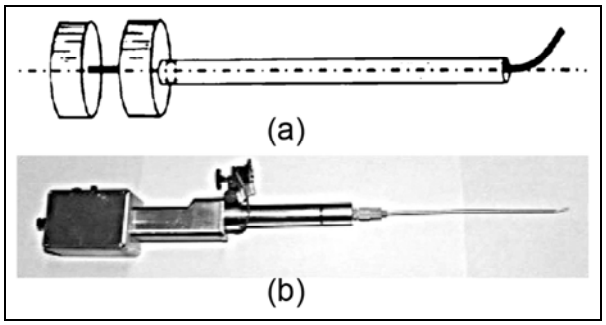

Figure 3. Example of a straight cannula and pre-curved stylet. The design shows the deflection of the stylet once it is pushed out of the cannula: (a) a schematic drawing (adapted from Salcudean et al.[60]) and (b) a photo of the prototype (from Okazawa et al.[12]).

Two-plane pre-curved needles

Two-plane pre-curved needles have at least two segments with a pre-set curvature perpendicular to each other. The working mechanism of these needles is the same as that of single pre-curved needles, with the difference that two-plane pre-curved needles can follow a 3D path through the tissue without having to rotate the entire needle. Two-plane pre-curved needles consist of multiple pre-curved concentric tubes arranged in a telescopic way. Each of the tubes can independently be extended and rotated axially with respect to one another. Each section of the shaft follows the trajectory of the tip, in what is called a ''follow-the-leader'' concept (see Sears and Dupont[31] for a detailed description of the concept). The overall shape of the needle is deter- mined by the position and orientation of each of the concentric tubes (Figure 4). Webster et al.[39] named this design ''active cannula'' (for the complete design description of the system, see also Webster et al.[63]). Recently, the concentric tube steering mechanism has been combined with the aforementioned flexure bevel- tip needle[13] to steer through lung tissue and reach peripheral lesions (design and application are described in Swaney et al.[32]).

Bevel-tip and one-plane pre-curved needles

In this type of needles, the working principles of the bevel-tip needles (solution 1) and the pre-curved needles (solution 2) are combined. A needle following this principle would have at least two segments: one segment with a bevel tip that causes the deflection in one plane, and another segment that is pre-curved and allows for deflection in a perpendicular plane. A common practice is to use the two segments where the bevel angle and the pre-curvature allow a deflection in the same plane. This design is used to increase the deflection angle as described in the category of one-plane pre-curved needles. However, in an embodiment of a patent by Melsheimer,[56] it is mentioned that the segment with the bevel angle can be used to generate needle deflection in the plane perpendicular to the plane of the pre-curved segment.

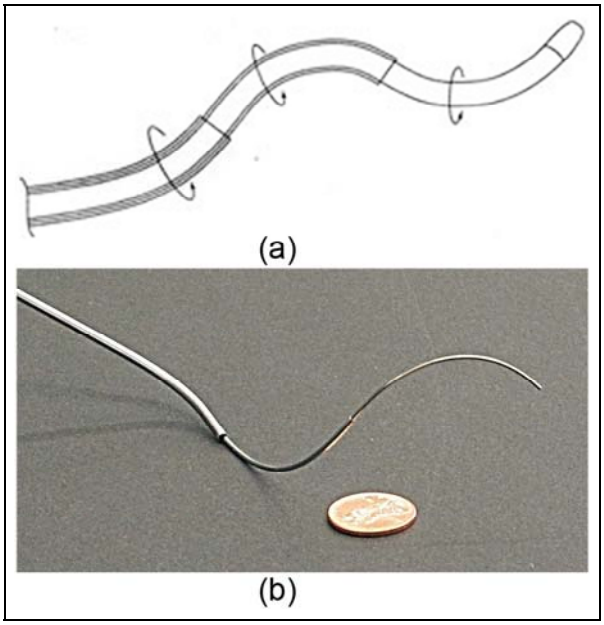

Figure 4. Example of a two-plane pre-curved needle. The design consists of multiple pre-curved concentric tubes arranged in a telescopic way: (a) a schematic drawing (adapted from Webster et al.[63]) and (b) a photo of the prototype (from Webster et al.[39]).

Needles with one on-demand deflection angle

Needles with one on-demand deflection angle have at least one actuated part which causes deflection of the needle on demand. The deflection angle of the needle can be locally and actively controlled. Once deflected, the needle can be steered along a curved path. Even though needles of this type seem very diverse due to the wealth of possible actuation means (e.g. mechanical, thermal, and magnetic actuation), they all follow the same working principle of 3D steering.

Tendon-driven needles are examples of mechanically actuated steerable needles in which control wires or rods are used to make the needle deflect.[20,28,41,44,45,48,50,53-55,59,61] Two tendons (wires) run along the length of the needle body, whereas a handle at the needle base is used to pull one of the tendons, increasing the tendon tension. Since the wires are eccentrically attached to the needle tip, the tension in one of the tendons makes the tip deflect. The deflection angle of the tip depends on the force applied on the tendon, with a larger pulling force corresponding to a larger deflection angle. In two examples, Burger et al.[45] and Liu et al.,[53] the shaft of the instrument has segments with lower bending stiffness than the bulk of the shaft. Because of the lower bending stiffness, these segments deflect upon actuation more than the rest of the shaft. A series of asymmetric cuts at the needle tip is presented in York et al.,[41] creating a compliant region, which bends in one direction by pulling a single wire.

In another design of a tendon-driven needle, a flexural conical tip (inspired by the flexure tip in Swaney et al.[13]) is used to create an articulated tip.[20] The tip is actuated by a nitinol pull wire that runs along the needle shaft, in combination with a miniaturized cable pulley. Among the needles that are tendon-driven, the one presented by Mathis et al.[54] is commercially avail- able under the name of ‘‘Seeker Steerable Biopsy Needle™’’ (PneumRX, Mountain View, CA, USA). The needle has a cannula and a stylet. Its trajectory is controlled by a joystick which allows the physician to make fine adjustments intra-operatively. This needle is mainly used for transthoracic lung biopsy.[28]

Actuation for 3D steering can be achieved using shape-memory or pseudoelastic materials, which can change their shape in response to a stimulus (e.g. heat). When embedded in the shaft of a needle, these so-called smart materials enable active and local control of the needle deflection without the need of tissue interaction forces. Shape-memory alloy (SMA) wires, for example, are used to connect several deflectable segments in the shaft of the needle described by Ayvali et al.[21] and Desai and Ayvali[46]. The SMA wires are initially deformed with an annealing process to assume an arc shape. They are then straightened and placed between the segments of the needle. By increasing the temperature (e.g. induced electrically by Joule heating), the SMA wires return to their original arc shape (Figure 5). Similarly, Ryu et al.[30] presented a needle with a cannula and a stylet locally actuated by magnetic resonance imaging (MRI)-compatible SMA wires integrated at the end of the stylet. The MRI compatibility of this needle is achieved using laser heating instead of electrical current to actuate the SMA wires. Optical fibers run parallel to the body needle axis and conduce laser light over the tip, transmitting optical heating to the SMA wires.

As mentioned in the section on bevel-tip needles, adding a flexure joint near the tip increases the deflection angle of the needle as compared to a needle with- out a flexure joint. Konh et al.[27] described a needle in which a flexure bevel tip is combined with SMA-wire actuation to control the needle deflection angle. The needle body is made of two hollow tubes connected by a nylon flexure joint and a nitinol wire which lies on the surface of the needle with one end crimped on the tip and the other end glued along the body of the needle. When the

needle bends upon actuation of the SMA wire, the presence of the joint allows for a larger deflection angle than in the case of a jointless needle.

Piezoelectric actuators are also used for controlling the needle deflection.[40] Applying an electric field on a piezoelectric element induces a mechanical effect (e.g. extension or contraction). The actuators are placed on different sides of the surface of the needle, such that their longitudinal strain results in needle deflection.

In the category ‘‘bevel-tip needles,’’ we described the design of an articulated bevel tip presented by Wang et al.,[37] where articulations are used to increase the deflection of the needle as compared to needles without articulations. The same authors proposed a variation of this needle composed of the same segments and a magnetic head.[38] An external magnetic field generates magnetic forces, which are used to manipulate the needle trajectory. By changing the direction and magnitude of the magnetic field, the needle can be steered in two perpendicular planes.

Another design of a needle with one on-demand deflection angle consists of two body parts aligned parallel to each other and each movable independently along the needle by means of two linear actuators.[26] The initial configuration of the needle has a conical shape with each of the segments having a bevel tip. Pushing the entire needle forward with the body parts aligned generates a straight path. In order to steer, an offset at the tip needs to be created, which is done by means of actuators that move the needle parts backward and forward. When the entire needle is pushed forward into the tissue, the offset creates an asymmetry that results in deflection in one plane. This design is an example of bevel-tip needle; however, the steering mechanism depends not only on the bevel tip but also on the actuation sequence. Therefore, we decided to include this design in the ‘‘one on-demand deflection angle’’ category.

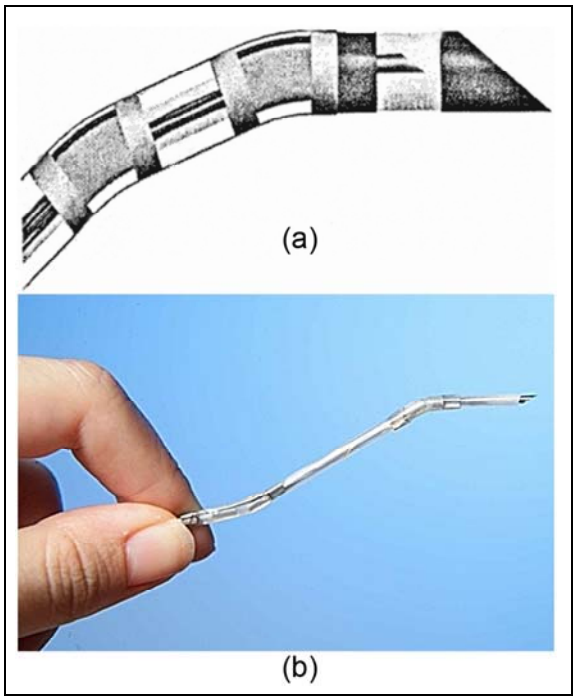

Figure 5. Example of a needle with one on-demand deflection angle. The design consists of several deflectable segments connected by shape-memory alloy (SMA) wires. The needle deflects upon actuation of the SMA wires: (a) a schematic drawing (adapted from Desai and Ayvali[46]) and (b) a photo of the prototype (from Ayvali et al.[21]).

Needles with two on-demand deflection angles

Needles with two on-demand deflection angles have at least two parts that lead to deflection in perpendicular planes upon actuation. Many of the mechanisms mentioned in solution 5 can be extended toward needles with two on-demand deflection angles. This is the case for the patents[44,46,50,59,61] which present alterations of the designs of one on-demand deflection needle to allow for deflection in two perpendicular planes.

For a needle with tendon actuation to deflect in two perpendicular planes, at least two wires placed at 90° radially to each other are needed. Pulling one of the wires will cause the needle to deflect in one plane, whereas pulling the other wire will lead to deflection of the needle in a plane perpendicular thereto. Van de Berg et al.[36] presented a tendon-actuated flexible cannula with a conical tip. This needle can deflect in two orthogonal planes by means of four actuation cables that run over a ball joint placed near the tip. Losey et al.[29] used two pairs of nitinol pull wires to actuate two flexure joints placed in series and rotated 90° with respect to one another. The so-called flexure-based ‘‘wrist’’ design is inspired from the flexure-tip needle described by Swaney et al.[13] (see solution 1). Wires were also used by Hamzavi et al.[25] to actuate three elements, each of them made of three sections and placed at the end of the needle.

In a similar way to the tendon actuation, the design of needles actuated by means of smart materials can be modified to allow for two on-demand deflection angles. Ayvali et al.[21] and Desai and Ayvali[46] proposed a modification of the needle design presented in the previous group by positioning the SMA elements in a configuration that allows deflection in two perpendicular planes. Another example of smart materials used as actuators in steerable instrument is magnetorheological (MR) fluids. In a patent by Eck,[47] the body of the needle is filled with an MR fluid that can switch between a fluid and a solid state by the selective activation of an external magnetic field. The transition from a fluid to a solid state increases the stiffness of the needle, thereby generating compression on the surrounding tissue. The needle is able to follow a desired path by means of solidifying the needle body, pushing it further, and then reducing the compression again by switching the state of the MR from solid to fluid.

Another method to introduce deflection in two perpendicular planes is shown in Tang et al.,[33] where the needle consists of a magnetized head and a body made of diamagnetic material. The two parts are separated by a compliant hinge, which increases the flexibility of the needle. When an external magnetic field is applied, the head of the needle bends, resulting in a change of the needle trajectory.

Another design of a needle with two on-demand deflection angles consists of at least three body sections aligned parallel to each other and each section being movable independently along the needle.[58,71] The body of this needle consists of four parts, each part having a curved outer surface and two inner surfaces that are interlocked to the surfaces of the adjacent body sections with a mechanism that enables a sliding motion (Figure 6). The frontal end of each of the body parts has a bevel tip, so that in the aligned configuration, the tip of the needle has a conical shape. When one body section moves forward, it will bend due to interaction forces between the tissue and the bevel tip. The rest of the needle will follow the bent part. The curvature of this multi-part needle can be controlled at any time during the insertion procedure by changing the offset between the body part which is moved forward and the rest of the needle. Burrows et al.[22] developed and tested a prototype with a diameter of 8 mm to demonstrate the 3D steerability of such a needle in an arbitrary 3D path with eight principal directions. This prototype is an improvement of the previous two-body-part prototype presented by Ko and Rodriguez y Baena[26] (solution 5). As explained earlier, because the steering mechanism depends not only on the bevel tip but also on the actuation sequence, we decided to include this design in the ‘‘two on-demand deflection angles’’ category.

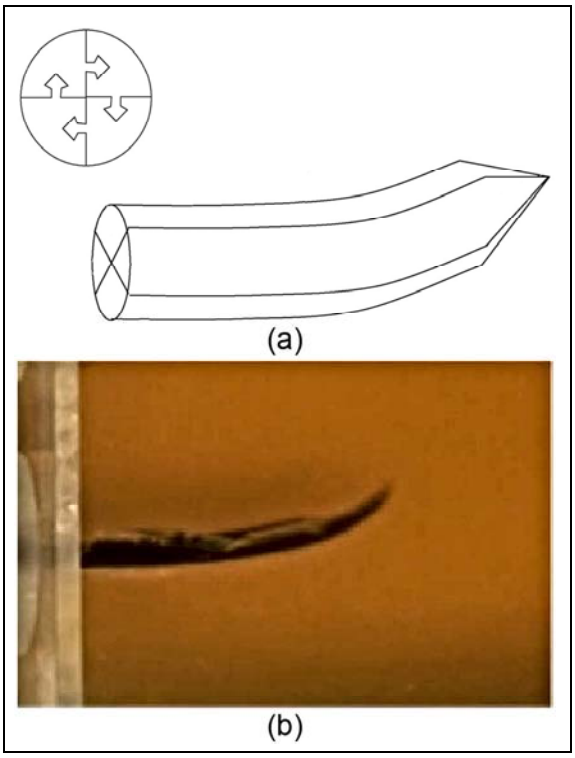

Figure 6. Example of a needle with two on-demand deflection angles. The design consists of four parts interlocked with a mechanism that enables a sliding motion: (a) a schematic drawing (adapted from Rodriguez y Baena and Frasson[58]) and (b) a photo of the prototype (from Burrows et al.[22]).

Needles with one on-demand angle and one pre-defined deflection angle

Needles in this category would have at least two segments: one segment bearing an on-demand mechanism of the aforementioned kind (e.g. steering wires, SMA) which causes deflection in one plane and a second segment with a bevel tip or a pre-set curvature for deflection in a perpendicular plane. No examples for needles using a combination of one on-demand deflection angle and one pre-defined deflection angle were found.

Discussion

In this article, we provided an overview of possible mechanical solutions for 3D steering of a medical needle. First, we distinguished between needles that deflect due to a pre-defined shape (pre-defined deflection angle) and needles that deflect due to a means of actuation that changes the deflection angle of the needle (on-demand deflection angle). Second, we differentiated between needles that deflect in one plane (single deflection) and needles that deflect in two perpendicular planes (double deflection). Finally, we defined seven mechanical solutions and classified the needle designs retrieved both from the scientific and patent literature into these solutions.

Comparative study

Our review includes a patent search which was not considered in the two previous reviews focusing on the mechanical design of steerable needles.[15,16] The number of included papers is relatively small (24 design papers) with respect to the total number of papers published on this subject.

The reason is that if a research group published multiple papers on the same needle design, only the most comprehensive paper, in terms of the description of the mechanical working principle, was included. Our analysis of the literature indicated that single- deflection needle designs are more popular than double-deflection ones, with only eight papers and nine patents describing double-deflection needles, while 16 papers and 19 patents describe single-deflection needle. This may be due to the fact that single deflection is
sufficient for 3D steering and it requires simpler mechanical designs than double deflection. However, double-deflection mechanisms allow steering in two different planes without the need of rotation of the needle body, reducing problems with the control of the trajectory of the needle. The interest in on-demand deflection angle needles seems to be quite recent and diverse (employing SMA, piezoelectric, magnetic field, cables, etc.). Double deflection is more prevalent in combination with an on-demand deflection angle (five papers and seven patents compared to three papers and two patents on pre-defined deflection angle needles).

Tissue interaction

When we advance a needle in the tissue, forces arise on the tip and the body of the needle, the so-called needle– tissue interaction forces. Depending on the design of the needle, these forces may influence the trajectory of the needle (for an overview of experimental needle– tissue interaction forces data, see Van Gerwen et al.[72]).

Needles with a bevel tip require tissue interaction forces in order to be steered. The distribution of these forces on the tip is asymmetric due to the presence of the bevel. As a result, the needle bends in the direction of the bevel. The deflection of the needle due to the bevel is a function of several parameters, including needle diameter, bevel angle, insertion velocity, and gel elasticity.[73] Macroscopic and microscopic observations of needle–gel insertion[74] showed that increasing the velocity and the needle diameter results in smaller needle deflections, while increasing the gel elasticity results in larger needle deflections. Increasing the bevel angle shows a non-monotonic variation in the needle deflection. Needles with three different bevel angles (30°, 60°, and 75°) were inserted in a gel with known stiffness. A bevel angle of 30° and 75° resulted in larger needle deflection compared to the bevel angle of 60°. This behavior is explained by the coupling between the rupture and the compression of gel at the tip in microscopic observations. Specifically, during the insertion of the needle with bevel angle of 30°, a long and narrow gel rupture and low compression of the gel were observed, while using the needle with bevel angle of 75° resulted in a wide and short gel rupture and high compression of the gel. These two combinations (30° and 75°) generated higher needle deflection compared to a needle with bevel angle of 60°. In general, increasing the gel elasticity results in larger needle deflections.

Thanks to their pre-set curvature; pre-curved needles, on the other hand, do not require tissue interaction forces in order to be steered. However, when the needle is inserted in the tissue, needle–tissue interaction forces may affect the needle deflection, with a greater degree of the pre-set curvature leading to a larger needle deflection.[70] Furthermore, increasing the gel elasticity will result in larger needle deflection as observed for the bevel-tip needle.

The on-demand deflection instruments may or may not rely on tissue interaction for steering, depending on their working principle. Specifically, the wire- and SMA-actuated needles[75] can be steered without the need of interaction forces. Designs in which the bevel tip is used to steer and the actuation means is used to change the bevel tip continuously (e.g. the multiple needle part presented by Rodriguez Y Baena and Frasson[58]) can only deflect when needle–tissue interaction forces are present.

Design choices related to the deflection angle of steerable needles

One of the requirements to take into consideration during the design of a steerable needle is the maximum curvature to be achieved. The curvature of a steerable needle depends on the geometrical characteristics of the needle, such as the tip shape and the shaft diameter, and the material properties of the environment, such as tissue stiffness. For example, in our survey, we showed that there are different ways to increase the curvature with respect to a standard bevel-tip needle. Swaney et al.[13]

showed how a flexure joint at the needle tip increases the deflection with respect to the standard bevel tip. In the same way, the use of compliant hinges at the tip increases the flexibility of the needle, which in turn results in larger deflection angles.[33] A needle with a pre-curved segment can achieve larger deflection angles than a needle with a bevel tip.[70] A combination of a pre-curved segment with bevel tip[49] or a combination of a pre-curved cannula with a pre-curved stylet[57] will reinforce the deflection in one direction.

The diameter of the shaft is another parameter that can be changed with respect to the tip of the instrument in order to achieve larger deflection angles. A smaller shaft diameter means higher shaft flexibility, leading to a larger deflection angle once the needle is inserted into the tissue. Kuhle[52] presented a needle in which the diameter of the bevel tip is larger than the diameter of the shaft. In this way, the contact area at the tip is increased, while the diameter of the shaft is kept small. The same design choice can be found in Engh et al.,[67] where a stainless steel tip of 16 gauge is attached to a nitinol shaft of 29 gauge. Adding notches of various shapes and dimensions at the tip increases the flexibility of the instrument and facilitates the deflection in one direction.[50] The same happens in the design of the ‘‘wrist needle’’[41] where asymmetric cuts at the end of the shaft create a compliant region that facilitates needle deflection.

Tissue properties also influence the deflection angle of the needle. For example, Majewicz et al.[76] found a significant difference in performance of the same pre- bent needle in ex vivo experiments versus in vivo experiments (minimum curvature radius achieved: 5.23 and 10.4 cm, respectively). The authors explained this difference as an effect of the increased stiffness and the inhomogeneity of the tissue due to perfused blood vessel in vivo.

Commercially available instruments

We found four commercially available steerable needles: the Osseoflex SN steerable needle (Osseon LLC,[77] Santa Rosa, CA, USA[54]), the Seeker Steerable Biopsy Needle (PneumRx), the Morrison Steerable Needle[78] (AprioMed AB, Uppsala, Sweden), and the Pakter curved needle set (Cook Medical Inc., Bloomington, IN, USA[79]). The patents corresponding to the needles by Osseon and PneumRx were retrieved from our systematic patent search, whereas the AprioMed and Cook needles were not in the list of the 952 retrieved patents. The Osseoflex SN is presented in Liu et al.[53] and categorized as an example of ‘‘one-plane pre-curved needle.’’ It is used mainly for the treatment of vertebral compression fracture (Figure 7). The Seeker Steerable Biopsy Needle is presented in Mathis et al.[54] described as an example of a tendon-driven needle in ‘‘needles with one on-demand deflection angle.’’ It is mainly used for transthoracic lung biopsy (Figure 8). The Morrison Steerable Needle was only found when searching for commercially available instruments in Google using the query ‘‘steerable needle.’’ The edited title and abstract of the corresponding patent in the DII database used the word ‘‘mandrel’’ to characterize the instrument, which was not included in our selected keywords for specifying instrument type. Adding the word ‘‘mandrel’’ to our patent search query yielded extra 25 patents. Within these works, only the patent from AprioMed was relevant for our study.[80] The AprioMed instrument fits in the ‘‘on-demand deflection angle - single deflection’’ solution of our classification and uses the control wire/rod principle to allow deflection. The needle com- prises a tubular stationary outer part with a semi- circumferential slot-like opening and a movable rod- like inner part that is attached to the stationary part only at the side of the opening that is close to the tip. As the movable part slides in and out of the stationary part, the distal section of the stationary part deflects. The Morrison Steerable Needle is mainly used for musculoskeletal percutaneous injection, aspiration procedure, and tissue sampling (Figure 9). The edited title and abstract of the patent of ‘‘Pakter curved needle set’’ do not include any of the words we used for describing the function of the needle, such as ‘‘steer’’ or ‘‘deflect.’’ This needle has a straight cannula in stainless steel (cannula) and a pre-curved stylet in nitinol; therefore, it could fall in the category of the ‘‘one-plane pre-curved needles.’’[81] Discography is a typical procedure where the Pakter curved needle set is used to inject contrast medium into the center of the disks (Figure 10).

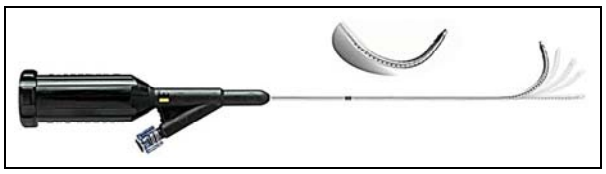

Figure 7. Osseoflex SN steerable needle (Osseon, Santa Rosa, CA, USA).[77]

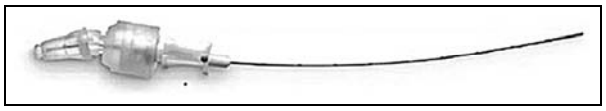

Figure 8. Seeker Steerable Biopsy Needle™ (PneumRx Inc., Mountain View, CA, USA).[54]

Limitations

This review focuses on the mechanical principles of steerable needles without taking into account additional technologies that can be used to help the physician during the percutaneous intervention (e.g. image guidance). We also did not consider control methods, computational modeling, and motion planning algorithms used in robotic-assisted needle steering.[64] Real-time data from image systems (computed tomography (CT) scan, MRI, fluoroscopy, and ultrasound) give information about the shape and position of the instrument during minimally invasive procedures.[82,83] Combining these data with computational models that predict needle deflection during insertion in the tissue would result in an accurate planning of the procedure.[84,85] Several models describing needle insertion into soft tissue are presented in the literature. Misra et al.[86] divided these models in linear elasticity-based models, nonlinear (hyperelastic) elasticity-based finite element (FE) models, and other models that are not based on FE methods or continuum mechanics (e.g. mass–spring–damper models).

Furthermore, buckling of the instrument was not considered in this review. Since buckling is an important failure mode of long slender instruments,[87] an overview of the instrument types in terms of their tendency to buckle would be a useful complement to this study.

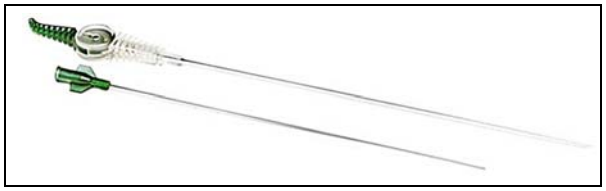

Figure 9. Morrison Steerable Needle™ (AprioMed AB, Uppsala, Sweden).[78]

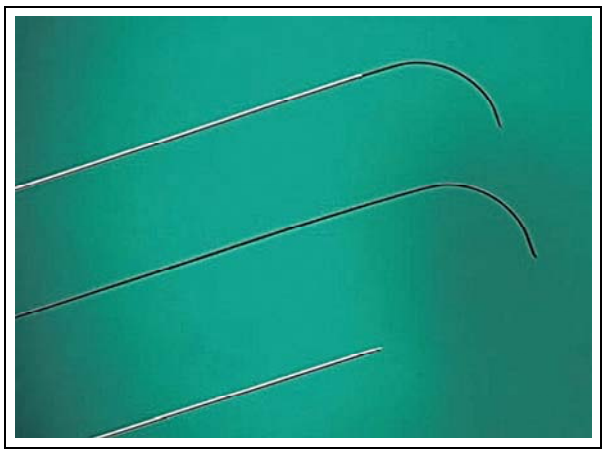

Figure 10. Pakter curved needle sets (Cook Medical Inc., Bloomington, IN, USA).[79]

Conclusion and future work

We proposed a systematic classification of possible mechanical solutions for 3D steering through solid organs, which was created with a top-down approach. First, we distinguished between mechanisms in which deflection is induced (needles with pre-defined deflection angle versus needles with on-demand deflection angle). Second, we distinguished between the number of deflection planes (one plane versus two planes). The combination of these two levels led to eight solutions, of which seven were considered meaningful. Accordingly, we allocated steerable needle designs retrieved from a systematic scientific and patent literature search into these seven solutions. This methodological approach allowed us to extend the solution space to all viable designs beyond these already materialized and present in literature. Indeed, we identified one solution (‘‘one on-demand angle and one pre-defined deflection angle’’) for which no existing steerable design mechanism was found. This ‘‘gap’’ may function as a source of inspiration for investigating new steerable needle mechanisms. The top-down approach used in this review can also be applied to other research questions and other fields of application. Future scientific and patent studies should also take into account computational modeling, motion planning algorithm, and control of steerable needles.

Acknowledgements

M.S. and T.P.P. contributed equally to this work.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: This research is sup- ported by the Dutch Technology Foundation STW, which is part of the Netherlands Organization for Scientific Research (NWO) and partly funded by the Ministry of Economic Affairs (project number 12712, STW Perspectief programme iMIT—Instruments for Minimally Invasive Techniques).

References

1. Phelan S, O'Doherty A, Hill A, et al. Epithelial displacement during breast needle core biopsy causes diagnostic difficulties in subsequent surgical excision specimens. *J Clin Pathol* 2006; 60(4): 373–376.
2. Nath R, Amols H, Coffey C, et al. Intravascular brachytherapy physics: report of the AAPM Radiation Therapy Committee Task Group no. 60. *Med Phys* 1999; 26(2): 119–152.
3. Horlocker TT and Wedel DJ. Neurologic complications of spinal and epidural anesthesia. *Reg Anesth Pain Med* 2000; 25(1): 83–98.
4. Youk JH, Kim EK, Kim MJ, et al. Analysis of false- negative results after US-guided 14-gauge core needle breast biopsy. *Eur Radiol* 2010; 20(4): 782–789.
5. Volpe A, Kachura JR, Geddie WR, et al. Techniques, safety and accuracy of sampling of renal tumors by fine needle aspiration and core biopsy. *J Urol* 2007; 178(2): 379–386.
6. Wan G, Wei Z, Gardi L, et al. Brachytherapy needle deflection evaluation and correction. *Med Phys* 2005; 32(4): 902–909.
7. Jeng CL, Torrillo TM and Rosenblatt MA. Complications of peripheral nerve blocks. *Br J Anaesth* 2010; 105(1): 97–107.
8. Kohn LT, Corrigan JM and Donaldson MS. *To err is human: building a safer health system*. Washington, DC: National Academies Press, 2000.
9. Carr JJ, Hemler PF, Halford PW, et al. Stereotactic localization of breast lesions: how it works and methods to improve accuracy. *Radiographics* 2001; 21(2): 463–473.
10. O'Leary M, Simone C, Washio T, et al. Robotic needle insertion: effects of friction and needle geometry. In: *Proceedings of the IEEE international conference robotics and automation*, Taipei, 14–19 September 2003, vol. 2, pp.1774–1780. New York: IEEE.
11. Gao D, Lei Y and Zheng H. Needle steering for robot- assisted insertion into soft tissue: a survey. *Chin J Mech Eng* 2012; 25(4): 629–638.
12. Okazawa S, Ebrahimi R, Chuang J, et al. Hand-held steerable needle device. *IEEE/ASME T Mech* 2005; 10(3): 285–296.
13. Swaney PJ, Burgner J, Gilbert HB, et al. A flexure-based steerable needle: high curvature with reduced tissue dam- age. *IEEE Trans Biomed Eng* 2013; 60(4): 906–909.
14. Abolhassani N, Patel R and Moallem M. Needle insertion into soft tissue: a survey. *Med Eng Phys* 2007; 29(4): 413–431.
15. Cowan NJ, Goldberg K, Chirikjian GS, et al. Robotic needle steering: design, modeling, planning, and image guidance. In: Rosen J, Hannaford B and Satava RM (eds) *Surgical robotics*, US, 2011, pp.557–582. New York, NY: Springer.
16. Van de Berg NJ, Van Gerwen DJ, Dankelman J, et al. Design choices in needle steering—A review. *IEEE/ ASME T Mech* 2014; 20(5): 2172–2183.
17. De Winter JCF, Zadpoor AA and Dodou D. The expansion of Google Scholar versus Web of Science: a longitudinal study. *Scientometrics* 2014; 98(2): 1547–1565.
18. De Winter JCF and Dodou D. A surge of *p*-values between 0.041 and 0.049 in recent decades (but negative results are increasing rapidly too). *Peer J* 2015; 3: e733.
19. The Thomson Corporation. *Derwent Innovation Index*^{SM}. 2007.
20. Adebar TK, Greer JD, Laeseke PF, et al. Methods for improving the curvature of steerable needles in biological tissue. *IEEE T Biomed Eng* 2016; 63(6): 1167–1177.
21. Ayvali E, Liang CP, Ho M, et al. Towards a discretely actuated steerable cannula for diagnostic and therapeutic procedures. *Int J Rob Res* 2012; 31(5): 588–603.
22. Burrows C, Secoli R and Rodriguez y Baena FM. Experimental characterisation of a biologically inspired 3D steering needle. In: *Proceedings of the 13th international conference on control, automation and systems*, Gwangju, Korea, 20–23 October 2013, pp.1252–1257. New York: IEEE.
23. Chen Z and Chen YH. Analysis of multi-hinge compliant needle insertion. In: *Proceedings of the IEEE international conference virtual environments, human-computer inter- faces and measurements systems*, Hong Kong, 11–13 May 2009, pp.314–318. New York: IEEE.
24. Drummond GB and Scott DH. Deflection of spinal needles by the bevel. *Anaesthesia* 1980; 35(9): 854–857.
25. Hamzavi N, Chui CK, Chui CC, et al. Flexible liver needle navigation using fish-like robotic elements. In: *Proceedings of the IEEE international conference on systems, man and cybernetics*, Singapore, 12–15 October 2008, pp.3491–3496. New York: IEEE.
26. Ko S and Rodriguez Y Baena FM. Toward a miniaturized needle steering system with path planning for obstacle avoidance. *IEEE Trans Biomed Eng* 2013; 6(4): 910– 917.
27. Konh B, Lee H, Lee HH, et al. Towards the design and development of an active needle for therapeutic procedures. In: *Proceedings of the IEEE annual northeast bio- medical engineering conference*, Troy, NY, 17–19 April 2015, pp.1–2. New York: IEEE.
28. Kratchman LB, Rahman MM, Saunders JR, et al. Toward robotic needle steering in lung biopsy: a tendon- actuated approach. *Proc SPIE* 2011; 7964.
29. Losey PD, York PA, Swaney PJ, et al. A flexure-based wrist for needle-sized surgical robots. *SPIE Med Imaging* 2013; 86711G.
30. Ryu CS, Quek ZF, Koh JS, et al. Design of an optically controlled MR-compatible active needle. *IEEE T Robot* 2015; 31: 1–11.
31. Sears P and Dupont P. A steerable needle technology using curved concentric tubes. In: *Proceedings of the 2006 IEEE/RSJ international conference on intelligent robots and systems (IROS)*, Beijing, China, 9–15 October 2006, pp.2850–2856. New York: IEEE.

32. Swaney PJ, Mahoney AW, Remirez AA, et al. Tendons, concentric tubes, and a bevel tip: three steerable robots in one transoral lung access system. *IEEE Int Conf Robot Autom* 2015; 2015: 5378–5383.
33. Tang L, Chen Y and He X. Magnetic force aided compliant needle navigation and needle performance analysis. In: *Proceedings of the IEEE international conference on robotics and biomimetics*, Sanya, China, 15–18 December 2007, pp.612–626. New York: IEEE.
34. Terayama M, Furusho J and Monden M. Curved multi- tube device for path-error correction in a needle-insertion system. *Int J Med Robot* 2007; 3(2): 125–134.
35. Torabi M, Gupta R and Walsh CJ. Compact robotically steerable image guided instrument for multi-adjacent- point (MAP) targeting. *IEEE T Robot* 2014; 30(4): 802– 815.
36. Van de Berg NJ, Dankelman J and Van den Dobbelsteen JJ. Design of an actively controlled steerable needle with tendon actuation and FBG-based shape sensing. *Med Eng Phys* 2015; 37(6): 617–622.
37. Wang YZ, Yin QL, Liu CL, et al. Towards an articulated needle. *Appl Mech Mater* 2012; 152: 946–951.
38. Wang YZ, Zhou ZG, Chen YH, et al. Towards a magnetic articulated needle. *Adv Materials Res* 2012; 393– 395(1–3): 1060–1063.
39. Webster RJ, Okamura AM and Cowan NJ. Toward active cannulas: miniature snake-like surgical robots. In: *Proceedings of the 2006 IEEE/RSJ international conference on intelligent robots and systems (IROS)*, Beijing, China, 9–15 October 2006, pp.2857–2863. New York: IEEE.
40. Yan K, Podder T, Ng WS, et al. Smart needle for percutaneous surgery: influential factor investigation. In: *Proceedings of the 2007 29th annual international conference of the IEEE engineering in medicine and biology society (EMBC)*, Lyon, France, 22–26 August 2007, pp.461–464. New York: IEEE.
41. York AP, Swaney PJ, Gilbert HB, et al. A wrist for needle-sized surgical robots. In: *Proceedings of the IEEE international conference robotics and automation*, Seattle, WA, 26–30 May 2015, pp.1776–1781. New York: IEEE.
42. Arramon YP. Bone access system. Patent 20060064101 A1, USA, 2006.
43. Arvanaghi B. Bendable needle assembly. Patent 20080097347 A1, USA, 2006.
44. Brockman CS and Harshman GJ. Systems and method for off-axis tissue manipulation. Patent 20130345765 A1, USA, 2013.
45. Burger K, Cheatwood J and Chen S. Steerable curvable vertebroplasty drill. Patent 20140316413, USA, 2014.
46. Desai JP and Ayvali E. Actuated steerable probe and sys- tem and methods of using same. Patent 20130296885, USA, 2013.
47. Eck K. Surgical needle and methods of guiding surgical needle. Patent 20090177151, USA, 2009.
48. Germain A. System for use in treatment of vertebral fractures. Patent 20100082033 A1, USA, 2010.
49. Kaplan EJ. Deflectable implantation device and method for use. Patent 20080091056, USA, 2008.
50. Kraft D and Hole J. Device and method for rapid aspiration and collection of body tissue from within enclosed body space. Patent 200701544460, USA, 2007.
51. Krueger JA and Linderman ED. Device system and method for delivering a curable material into bone. Pat- ent 200701118142 A1, USA, 2007.
52. Kuhle WG. Biopsy needle with flared tip. Patent 5938635 A, USA, 1999.
53. Liu YK, Lau JR, Threlkeld JE, et al. Closed vertebroplasty bone cement injection system. Patent 20090131945 A1, USA, 2009.
54. Mathis M, Thompson D, Addis B, et al. Steerable device for accessing a target site and methods. Patent 200601674416, USA, 2006.
55. Mehta VM, Lipford BL, Schneider E, et al. Arthroscopic tunnel guide for rotator cuff repair. Patent 20130345711 A1, USA, 2013.
56. Melsheimer JS. Deflectable biopsy device. Patent 20120220894 A1, USA, 2012.
57. Pellegrino R, Smith P and Harold C. System and methods for navigating an instrument through bone. Patent 2011085212 A2, USA, 2011.
58. Rodriguez y Baena FM and Frasson L. Steerable probes. Patent 20120279325 A1, USA, 2012.
59. Ryan TJ and Winslow CJ. Percutaneous discectomy sys- tem having a bendable discectomy probe and a steerable cannula. Patent 5285795, USA, 1994.
60. Salcudean SE, Rohling RN, Okazawa SH, et al. Steerable needle. Patent 20040133168, USA, 2004.
61. Smits KFAA, Rutten JJC and Adams PG. Method and apparatus for imparting curves in implantable elongated medical instruments. Patent 20030130712, USA, 2003.
62. Swaney PJ and Webster RJ III. Steerable surgical needle. Patent 20140276586 A1, USA, 2014.
63. Webster RJ, Okamura AM, Cowan NJ, et al. Active cannula for bio-sensing and surgical intervantion. Patent 20130018303 A1, USA, 2013.
64. Reed KB, Majewicz A, Kallem V, et al. Robot-assisted needle steering. *IEEE Robot Autom Mag* 2011; 18(4): 35–46.
65. Swensen JP, Lin M, Okamura AM, et al. Torsional dynamics of steerable needles: modeling and fluoroscopic guidance. *IEEE Trans Biomed Eng* 2014; 61(11): 2707– 2717.
66. Minhas DS, Engh JA, Fenske MM, et al. Modeling of needle steering via duty-cycled spinning. In: *Proceedings of the 2007 29th annual international conference of the IEEE engineering in medicine and biology society (EMBC)*, Lyon, France, 22–26 August 2007, pp.2756– 2759. New York: IEEE.
67. Engh JA, Podnar G, Kondziolka D, et al. Toward effective needle steering in brain tissue. In: *Proceedings of the 2006 28th annual international conference of the IEEE engineering in medicine and biology society (EMBC)*, New York, USA, 30 August–3 September 2006, pp.559–562. New York: IEEE.
68. Webster RJ, Kim JS, Cowan NJ, et al. Nonholonomic modeling of needle steering. *Int J Robot Res* 2006; 25(5– 6): 509–525.
69. Smuck M, Andrew JY, Tang CT, et al. Influence of needle type on the incidence of intravascular injection during transforaminal epidural injections: a comparison of short-bevel and long-bevel needles. *Spine J* 2010; 10(5): 367–371.

70. Wedlick TR and Okamura AM. Characterization of pre- curved needles for steering in tissue. In: *Proceedings of the 2007 31th annual international conference of the IEEE engineering in medicine and biology society (EMBC)*, Minneapolis, MN, USA, 3–6 September 2009, pp.1200– 1203. New York: IEEE.
71. Frasson L, Ferroni F, Ko SY, et al. Experimental evaluation of a novel steerable probe with a programmable bevel tip inspired by nature. *J Robot Surg* 2012; 6(3): 189–197.
72. Van Gerwen DJ, Dankelman J and Van den Dobbelsteen JJ. Needle–tissue interaction forces—a survey of experimental data. *Med Eng Phys* 2012; 34(6): 665–680.
73. Misra S, Reed KB, Andrew SD, et al. Needle-tissue inter- action forces for bevel-tip steerable needles. In: *Proceedings of the 2nd IEEE RAS & EMBS international conference on biomedical robotics and biomechatronics (BioRob)*, Scottsdale, AZ, USA, 19-22 October 2008, pp.224–231. New York: IEEE.
74. Van Veen YR, Jahya A and Misra S. Macroscopic and microscopic observations of needle insertion into gels. *Proc IMechE, Part H: J Engineering in Medicine* 2012; 226(6): 441–449.
75. Konh B, Honarvar M and Hutapea P. Design optimization study of a shape memory alloy active needle for bio- medical applications. *Med Eng Phys* 2015; 37(5): 469– 477.
76. Majewicz A, Marra SP, Van Vledder MG, et al. Behavior of tip-steerable needles in ex vivo and in vivo tissue. *IEEE Trans Biomed Eng* 2012; 59(10): 2705–2715.
77. Osseon, http://www.osseon.com/osseoflex-sn-steerable- needle/ (accessed 21 July 2016).
78. AprioMed, http://apriomed.com/products/morrison- steerable-needle/9292/ (accessed 21 July 2016).
79. Cook Medical, https://www.cookmedical.com/products/ ir_dchnsc_webds/ (accessed 21 July 2016).
80. Morrison WB and Akerfeldt D. Steerable medical puncture instrument. Patent 20120136381 A1, USA, 2012.
81. Pakter RL and Morris EJ. Hollow, curved, superlastic medical needle. Patent 6592559 B1, USA, 2003.
82. Glozman D and Shoham M. Image-guided robotic flexible needle steering. *IEEE T Robot* 2007; 23(3): 459–467.
83. Neubach Z and Shoham M. Ultrasound-guided robot for flexible needle steering. *IEEE T Biomed Eng* 2010; 57(4): 799–805.
84. Reed KB, Kallem V, Alterovitz R, et al. Integrated planning and image-guided control for planar needle steering. In: *Proceedings of the 2nd IEEE RAS & EMBS international conference on biomedical robotics and biomechatronics (BioRob)*, Scottsdale, AZ, USA, 19–22 October 2008, pp.819–824. New York: IEEE.
85. Alterovitz R, Goldberg K and Okamura A. Planning for steerable bevel-tip needle insertion through 2D soft tissue with obstacles. In: *Proceedings of the IEEE international conference on robotics and automation*, Barcelona, 18–22 April 2005, pp.1652–1657. New York: IEEE.
86. Misra S, Ramesh K and Okamura AM. Modeling of tool-tissue interactions for computer-based surgical simulation: a literature review. *Presence* 2008; 17(5): 463–491.
87. Sakes A, Dodou D and Breedveld P. Buckling prevention strategies in nature as inspiration for improving percutaneous instruments: a review. *Bioinspir Biomim* 2016; 11(12): 021001.