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Intraoperative Factors Associated With Stranded Source Placement Accuracy In Low Dose Rate Prostate Brachytherapy

Muhammad F. Jamaluddin[1] , Sunita Ghosh[1], Michael P. Waine[2], Mahdi Tavakoli[2], John Amanie[1], Albert D. Murtha[1], Don Yee[1], Nawaid Usmani[1]*

[1]Department of Oncology, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, AB, Canada

[2]Department of Electrical and Computer Engineering, Faculty of Engineering, University of Alberta, Edmonton, AB, Canada

Purpose

The quality of a low dose rate prostate brachytherapy implant depends on the accurate placement of sources in their planned locations. This study investigates intraoperative factors that potentially contribute to stranded source placement inaccuracy in prostate brachytherapy.

Materials and Methods

Intraoperative video images of the brachytherapist's hand motions and needle insertions during the implant procedure were acquired for analysis. Using video analysis software, maximum and average needle insertion velocities were determined. The number of needle insertion attempts and the use of the brachytherapist's other hand to manipulate the needle direction were also recorded. Sources misplacements were analyzed using an ultrasound-based method described elsewhere.

Results

15 patients agreed to undergo this study. 1619 iodine-125 seeds were inserted using 357 needles. 1197 seeds were confidently identified using ultrasound images and included in the analysis. The mean overall misplacement was 0.49 cm (0 to 2 cm, 95% CI= 0.47-0.51). 614 seeds were delivered with a single pass and 583 seeds with >1 passes (range 2 to 6). The mean maximum needle velocity was 12.34 $cm{\cdot}s^{-1}$ (range 4 to 28 $cm{\cdot}s^{-1}$) and mean average velocity was 4.76$cm{\cdot}s^{-1}$ (range 0.4 to 17.4$cm{\cdot}s^{-1}$). 747 seeds were delivered with manipulation of the needle. The generalized linear model (GLM) test was used to analyze factors contributing to seed misplacement and it was found that a maximum speed <12$cm{\cdot}s^{-1}$ was associated with a decrease in seed misplacement by 0.049cm vs. a maximum speed > 12 $cm{\cdot}s^{-1}$, p=0.0121). Other evaluated factors were found to have no statistically significant correlation with seed misplacement: average speed (p=0.4947), manual manipulation of needle (p=0.9264) and number of needle passes (p=0.8907).

Conclusions

This study identified that needles inserted with lower maximum velocity were associated with less seed misplacement. Manual manipulation of the needle, number of passes and average speed did not show statistically significant correlation with seed misplacement.

*Corresponding author: Nawaid Usmani, MD, FRCPC, Department of Oncology, University of Alberta, Cross Cancer Institute, 11560 University Avenue, Edmonton, Alberta, Canada, T6G 1Z2
Email address: Nawaid.usmani@albertahealthservices.ca

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Introduction

Accuracy and good quality implant

Accuracy of radioactive source placement is important for optimal dose delivery to the prostate gland, while sparing organs at risk [1]. In contemporary transperineal low dose rate (LDR) prostate brachytherapy procedures, the grid holes in a template allow the operator to insert needles at specified coordinates based on transrectal ultrasound (TRUS) pre- or intraoperative plans. Sources do not always end up in the intended locations due to factors such as needle deflection, prostate movement during insertion, intraoperative edema, prostate deformation by the ultrasound probe and the effect of drag on sources upon withdrawal of the needle [2]. Only limited actions can be taken by the operator to steer a needle to its desired location including manual manipulation of the needle shaft, rotating the beveled tip and varying the speed of insertion.

Many researchers have studied needle insertion parameters in phantom and laboratory settings and developed robotic systems to assist in needle steering and source delivery. However there are some limitations in performing phantom studies and in laboratory settings. Phantom models (agarose, gelatin, polyvinylchloride (PVC), various animal tissues) have all been used to study needle steering and deflection. However, except for animal tissues, phantoms are mostly homogenous and differ from real clinical cases where a needle must penetrate through several layers of different types of tissue (skin, muscle, fascia, prostate capsule and prostate gland), each with different tissue densities and mechanical properties [3]. Studying needle steering from *in-vitro* experiments to create a model of needle steering for real cases can be challenging.

None of the existing experimental models can accurately predict the parameters while the needle is inserted into prostate gland. Attempts to measure parameters involved *in-vivo* has been done but for limited numbers [4].

Using a novel approach, our study aims to establish the intraoperative parameters that may contribute to seed placement inaccuracy in permanent prostate brachytherapy implants done with stranded I-125 sources, using video analysis.

Materials and methods

Patient selection

This study was approved by the local institutional ethics committee. Patients with low-risk prostate cancer (Gleason score of 6 and less, prostate-specific antigen less than 10ng/ml and clinical staging T1a to T2b) and low-tier intermediate risk prostate cancer (defined as organ-confined disease and either Gleason score of 7 and PSA of 10 ng/mL or lower, or PSA of 10-20 ng/mL and Gleason score of 6 or lower) using brachytherapy as monotherapy (i.e. without androgen deprivation therapy or external beam radiotherapy) for their treatment were eligible for the study.

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Implant technique and image acquisition

Our technique has been described in detail before [5]. Briefly, 4 to 6 weeks prior to the prostate brachytherapy implant, a planning TRUS of the prostate was performed with the patient in the dorsal lithotomy position. Axial and sagittal images of the prostate were taken with a transrectal ultrasound probe operating at 6 MHz (8088 Biplane Transducer on BK Pro Focus UltraView 800, BK Ultrasound, MA, USA). The clinical target volume (CTV) was the prostate gland and with a 3 mm lateral and anterior margin and a 5 mm inferior margin was expanded to the planning target volume (PTV). A non-uniform distribution of sources in the prostate and periprostatic tissue was used to deliver a minimum peripheral dose of 145 Gy, while limiting the periurethral tissue to <150% of the prescription dose, and rectal D_{1cc} to $\leq$ the reference / prescription dose of 145Gy.

For the implantation, patients underwent general anesthesia in the dorsal lithotomy position. The planning setup was replicated by matching the intraoperative TRUS images with the planning TRUS. Stranded I-125 sources, model AgX100 in VariStrand sleeve material (Theragenics Corporation, Buford, GA, USA), of strength 0.400 mCi (0.508 U), loaded into 18g beveled tip 20cm long SeedLock3 needles (Theragenics Corporation, Buford, GA, USA) were inserted with a transperineal approach using a template for guidance. A single experienced brachytherapist (NU) inserted all of the needles analyzed for this study.

Video setup

A video camera was mounted on a tripod to the left of the operator, 2 meters away from the template, perpendicular to the direction of needle travel/trajectory. The camera was set up at the implant template height so that the operator's hands and the needle being inserted were clearly visualized. The video camera was set to capture video images at 1080p resolution, 30 frames per second and using .*avi* format. In each case, the operator displayed a 15 cm ruler parallel to the needle trajectory just prior to the first needle insertion for the purpose of calibration. The video recorded the entire procedure.

Analysis software

The video images were then analyzed using the motion analysis software Kinovea 0.8.15, available from: <http://www.kinovea.org>. Initial calibration involved measuring the length of the ruler displayed at the beginning of the procedure using the measurement tool in the software so that the number of pixels corresponded to a physical distance. The software's capability to track user-defined points allowed accurate determination of penetration distance, average velocity (V_{avg}) and maximum velocity (V_{max}) (Figure 1 A to E).

Parameters considered.

The parameters analyzed as factors associated with seed placement accuracy included the V_{max} of the needle at any particular point during insertion, the V_{avg} of the needle insertion, the number

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of insertion attempts made, any manipulation of the needle, and the distance traversed by the needle (penetration distance) during insertion.

Measuring source accuracy

At the end of each procedure, a series of axial images was taken at 5 mm intervals from the base cranially down to 5 mm below the apex of the prostate gland caudally and imported into the VariSeed 8.0.1 planning software (Varian Medical Systems, Inc., Palo Alto, CA, USA). Using the contouring tool, prostate gland and urethra structures were reconstructed. Using the preoperative VariSeed plan as a reference for intended needle coordinates, needle tracks and source locations that were clearly visible were identified on VariSeed and accordingly labeled with the corresponding coordinate at every axial image. For tracks that were not clearly identifiable on the axial images, the interpolation function on VariSeed was used. Sagittal and coronal image reconstruction also helped to identify less visible tracks on the axial images.

Once the tracks of individual coordinates were created, each iodine-125 source was identified within each track. Reference to the preplanning information was used to identify the source coordinates (axial X - Y plane), number of sources per strand and their location on each strand (Z plane). We have designed a classification for assessment of the sources specific for this study: For each track evaluation we classified the ultrasound appearance and characteristics into 4 categories: 1. definitely no source; 2.likely no source; 3. highly likely source; and 4.definitely source. Only echogenic areas on ultrasound with ‘highly likely’ or ‘definitely’ classifications were further assessed to determine source misplacement in the X, Y and Z dimensions. Using the X, Y and Z coordinates, the overall radial misplacement of sources was also calculated.

Statistical Analysis:

Descriptive statistics were used to describe the study population. Means and 95% confidence intervals were used to represent continuous variables. Frequencies and proportions were used to represent categorical variables. Generalized linear model (GLM) was used to determine factors associated with source misplacement. The independent factors were: post template needle manipulations (yes vs. no); V_{max} dichotomized by the median value ($\leq$12 cm·s^{-1} vs. >12 cm·s^{-1}); penetration distance dichotomized by the median value ($\leq$6.3cm vs. >6.3cm); and V_{avg} dichotomized by the median value ($\leq$4.28 cm·s^{-1} vs. >4.28 cm·s^{-1}) and number of passes. A p-value <0.05 was used to identify statistical significance. Two-tailed tests were used for all comparisons.

Results

Patient characteristics

Fifteen patients consented to participate in this study. The mean age of our cohort was 62 (range: 53 - 79) years. The mean prostate volume was 51 cc (range: 28-77 cc). Seven patients had low risk disease, while eight patients had intermediate risk disease. The characteristics of the study population are summarized in Table 1.

Source placement accuracy

357 strands with 1619 sources were used in total. Of the 1619 sources implanted, 1197 (73.87%) were confidently identified on the ultrasound images, with a detailed analysis of source placement accuracy previously described by our group [6]. The V_{max} of needle insertion was calculated for 88.5% of needles (n=316), V_{avg} of needle insertion for 90.1% of needles (n=322), and penetration distance for 90.1 %(n=323). Mean source misplacement and needle penetration distance were 0.49 cm (95%CI=0.47-0.51) and 6.46 cm (95%CI=6.24-6.68 cm) respectively. As well, the mean V_{max} of needle insertion was 12.34 $cm \cdot s^{-1}$ (95%CI=11.81-12.88 $cm \cdot s^{-1}$), while the mean V_{avg} was 4.76 $cm \cdot s^{-1}$ (95%CI=4.52-5.00 $cm \cdot s^{-1}$). 614 sources were implanted through a single pass during needle insertion via 190 needles, 345 sources through two passes via 98 needles, 178 sources through 3 passes via 47 needles and 60 sources through more than 3 passes through 20 needles. 735 (61.4%) of sources were implanted without manipulation of the needle, while 414 (34.6%) were inserted with the aid of needle manipulation. See Tables 2a & 2b for a detailed summary of the results.

Factors associated with source placement accuracy:

Of the five factors analyzed (See Table 3), a V_{max} of needle insertion of $\leq$12 $cm \cdot s^{-1}$ is associated with less misplacement (p=0.0121). As well, needle penetration distance trended towards significance (p value of 0.085), with a needle penetration distance $\leq$ 6.3cm associated with less source misplacement.

Discussion

One of the few *in-vivo* studies in the literature measuring needle intervention parameters in prostate brachytherapy was done by Podder *et al*. This group measured force and velocity of needle insertion using a hand held force sensor and a second device attached to the end of a brachytherapy needle to measure position and orientation for 25 patients (72 insertions in total). Their measured average maximum velocities were 14.2 $cm \cdot s^{-1}$ and 12 $cm \cdot s^{-1}$ for 17G and 18G needles, respectively, which were comparable to our average result of 12.34 $cm \cdot s^{-1}$ over 357 insertions [7]. Another *in-vivo* study of needle insertion accuracy by Cepek et al [8] utilized a 1.5 Tesla MRI scanner and MRI-compatible needles for laser ablation therapy of localized prostate cancer. This group evaluated 37 needle insertions and measured needle placement accuracy by comparing actual needle tip position with desired position at the target point, and found a median deflection error of 3.5 mm (range 2.1-5.4 mm).

In the current study, the effect of needle velocity on source placement accuracy was assessed. The velocity profile in this study is expected to be different from robotic needle insertion in laboratory settings. In clinical cases, brachytherapy operators typically pause or slow down needle insertion as the tip nears the target to confirm the location of the needle with respect to the target, resulting in a non-uniform velocity. Our group used this rationale to evaluate two velocity measurements: maximum velocity V_{max} and average velocity V_{avg}. The effect of a slower

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insertion versus a faster insertion was compared. The median V_{max} value of 12 cm·s^{-1} was chosen to distinguish between slower and faster insertions. An insertion maximum velocity of more than 12 cm·s^{-1} was associated with more source misplacement (p=0.012). The finding in this study of the effect of velocity on misplacement was comparable to a few *in vitro* studies. Using PVC phantoms, Podder *et al* noted that a faster insertion velocity led to increased deflection at the target, due to axial force increasing with insertion velocity [9]. This finding is supported by another *in vitro* study by Khadem *et al* who investigated the effect of insertion velocity, force applied and axial rotational motion on bevel-tipped needles in tissue phantoms (gelatin, bovine tissue and plastisol). This group demonstrated that a higher insertion velocity led to a higher degree of needle deflection throughout all phantom models used [10]. In contrast, another phantom (PVC) study looking at the effect of speed of insertion and trocar stiffness of a brachytherapy needle by McGill *et al* suggested that a higher insertion velocity generated smaller needle deflection. This discrepancy may be related to the greater trocar stiffness in his study [11]. This also highlights the challenges faced when comparing *in vitro* needle steering studies done for different phantoms and under different experimental conditions.

The effect of small versus large penetration distance was also evaluated. When interpreting this result one needs to bear in mind that the penetration distance in this study was measured on the part of the needle shaft proximal to the brachytherapy template outside the patient, and the assumption was made that this same distance was traversed within tissue during needle insertion. The median penetration distance measured over the 357 insertions was 6.33 cm with range from 2.59 to 11.33 cm. A trend towards significance (p=0.085) for penetration distances of > 6.3 cm was associated with more source misplacement. This observation can be explained by the deflection experienced by bevel-tipped needles. The bevel causes an imbalance of forces at the needle tip during insertion, causing the needle to deflect towards the direction of the bevel, and as a result causing the needle shaft to follow a curved path inside tissue. Hence the larger the distance the needle travels into tissue, the larger the deflection, as shown in in vitro studies [10,12]

Our study also analyzed additional factors that we hypothesized might influence source placement accuracy. The number of needle insertions was thought to be associated with source placement accuracy, as repeated insertions were suspected to lead to poor source placement accuracy. Similarly, it was suspected that manipulating the needle with pressure placed on the needle shaft might lead to greater source placement inaccuracy. However, in this study, these factors were found not to be associated with source placement accuracy.

There are a number of factors contributing to the strength of this study. Firstly, to the authors' knowledge, this is the first intraoperative study to evaluate factors influencing the accuracy of I-125 source placement into the prostate gland, and among the few studies using *in-vivo* data to evaluate needle shape and insertion parameters [13]. Other *in-vivo* studies analyzed factors like velocity and force [4,7], but not other parameters like needle penetration distance and number of passes. The majority of studies of needle placement and accuracy have been done *in-vitro* using phantoms of varying compositions ranging from synthetic materials to animal tissues

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[10,14–17], which have limitations simulating real implants. The shapes of phantoms in experimental settings are different than the shape of the human pelvis and prostate gland. The density of a phantom is usually homogenous, while in a patient, the needle must penetrate through several layers of tissue of varying densities, mechanical properties and geometries: skin, muscle, fascia, prostate capsule and prostate gland. Although some studies have made use of different tissue densities to address this issue, they are still inadequate in mimicking real implants [3] as other factors such as prostate deformation, prostate rotation and prostate movement [17] during needle insertion have not been taken into account. As well, all of the cases in this study were performed by a single experienced brachytherapist, ensuring consistency of results by minimizing intra-operator variation. It would be interesting to replicate this study among different operators to validate if the parameters assessed would achieve similar results.

The authors also acknowledge some limitations of the study. First, the use of TRUS for source identification has been criticized in some studies for its low sensitivity, typically between 51% and 83% [18]. US images provide relatively poor tissue contrast resolution and often contain shadows, reverberations and image artifacts that require proper interpretation to understand the image. The use of 3D views and image interpolation improved source identification in this study, with a source pickup rate of 73%. Secondly, due to the limitations of our set up, not all of the assessments were possible to do for some of the needles inserted. For example, in some cases the needles were partially or completely hidden either by the operator's hand or by the ultrasound probe on the stepper, especially for needles in the left lower quadrant of the implants. As a consequence, we were only able to measure 88.5% of V_{max} for analysis, 90.2% of V_{avg}, and 90.5% of the penetration distances (Table 2). From other studies looking at needle steering performed *in-vitro and in-vivo*, we have learned that other factors contribute to needle placement inaccuracy and deflection such as rotational motion of the needle, lateral force applied to the needle shaft, prostate motion and deformation, prostate edema, pressure of the ultrasound probe on the prostate gland and drag force on the source strand as the needle is withdrawn from the prostate gland [2,19,20]. This study was not able to analyze of all these potential factors which would require a more complicated setup and analysis.

Conclusions

In this study, a method for evaluating intraoperative parameters influencing source placement accuracy for LDR prostate brachytherapy using a video setup and motion tracking software is presented. The collected intraoperative data provided useful insights into the ranges of values for needle velocity, penetration distance and other factors encountered during actual brachytherapy procedures. Of the factors analyzed, a smaller needle insertion V_{max} of less than or equal to 12 $cm \cdot s^{-1}$ is associated with less source misplacement in prostate brachytherapy implants. This would suggest that clinicians or techniques utilizing robot-assisted insertions may wish to use a slower maximum needle insertion velocity when performing prostate brachytherapy implants.

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Figure

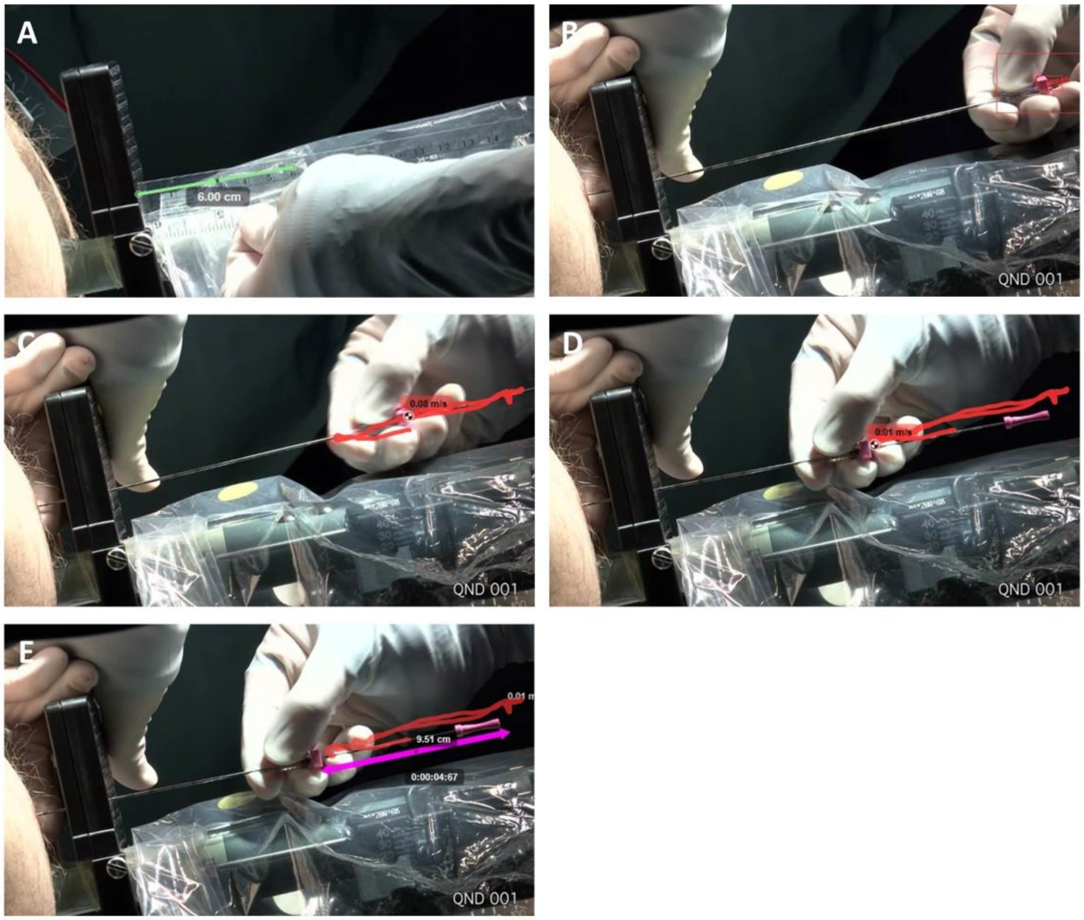

Figure 1 A. Calibration process. Calibration of captured images with software used for analysis. B. At the start of needle insertion, a landmark on the needle hub was identified, while the velocity, V=0 cm·s^{-1}. C. Approximately mid-way through each needle insertion, the needle reaches a maximum velocity, V_{max}, of 8 cm·s^{-1} in this example. D. Towards the end of the insertion process, V reaches 0 cm·s^{-1}. E. Needle penetration distance was determined by measuring the needle misplacement from the start of needle insertion to the end, 9.51 cm in this case and the time for this to occur was measured as 4.67seconds, giving an average velocity V_{avg} 2.04 cm·s^{-1} in this example.

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Tables

Table 1 ***Summary of patient and disease characteristics***

Age (Years)		
Mean (Range)	62	(53-79)
Prostate Volume (ml)		
Mean (Range)	51	(28 – 77)
PSA, (ng/ml)		
Mean (Range)	8.9	(3.0 – 15.5)
Clinical T Classification, n (%)		
T1c	6	(40)
T2a	7	(47)
T2b	2	(13)
Gleason Score, n (%)		
3+3	7	(47)
3+4	7	(47)
4+3	1	(6)
Risk Category, n (%)		
Low	7	(47)
Intermediate	8	(53)
Needles		
n	357	
Mean per patient (Range)	24	(17-29)
Sources		
n	1619	
Mean per patient (Range)	108	(77-140)

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Table 2a:	***Source misplacement and needle insertion continuous characteristics***			
	Magnitude of source misplacement (cm)	**Maximum velocity (V_{max}) of needle insertion ($cm \cdot s^{-1}$)**	**Average velocity (V_{avg}) of needle insertion ($cm \cdot s^{-1}$)**	**Needle penetration distance (cm)**
Number of observations	1197	316	322	323
Minimum	0	4	0.42	2.59
Mean	0.49	12.34	4.76	6.46
Median	0.52	12.00	4.28	6.33
Maximum	2.08	28.00	17.40	11.13
95% Confidence interval	0.47-0.51	11.81-12.88	4.52-5.00	6.24-6.68

Table 2b:	***Needle insertion discrete characteristics***
Number of passes	**n (%)**
1	190 (53.2)
2	98 (27.5)
3	47 (13.2)
≥4	20 (5.6)
Unknown	2 (0.1)
Needle manipulation	**n (%)**
Yes	224 (62.7)
No	120 (33.6)
Unknown	13 (3.6)

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Table 3 ***Factors associated with source placement accuracy***

Parameter assessed	***Estimate***	***Standard error***	***p-value***
Number of needle attempts	-0.00120	0.00876	0.8907
Needle manipulation (Ref=Yes)			
No	-0.00183	0.01977	0.9264
Maximum Velocity, V_{max} (Ref > 12 cm·s^{-1})			
$\leq$12 cm·s^{-1}	-0.04940	0.01966	0.0121*
Average Velocity, V_{avg} (Ref > 4.28 cm·s^{-1})			
$\leq$4.28 cm·s^{-1}	-0.01323	0.01938	0.4947
Needle penetration distance (Ref > 6.3 cm)			
$\leq$6.3 cm	-0.03337	0.01936	0.085

References are mentioned in parenthesis
*p<0.05