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Needle Insertion Force Estimation Model using Procedure-specific and Patient-specific Criteria

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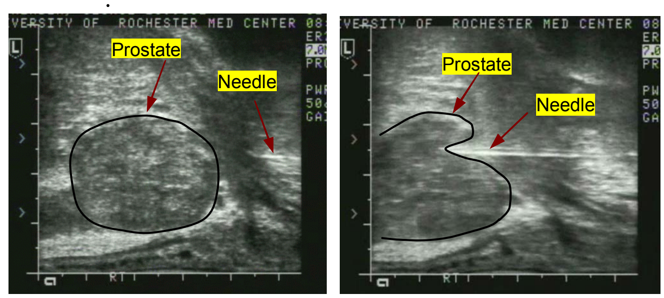
Abstract – **Placement accuracy of different types of surgical needles in soft biological tissues depends on a variety of factors. The needles used for prostate brachytherapy procedures are typically about 200mm in length and 1.27-1.47mm in diameter. These needles are prone to deflection and thereby depositing the seeds at a location other than the planned one. Thus tumorous tissues may not receive the planned dose whereas the critical organs may be over-dosed. A significant amount of needle deflection and target movement is related to some procedure-specific criteria and some patient-specific criteria. In this paper we have developed needle insertion force models taking both procedure-specific criteria and patient-specific criteria. These statistical models can be used to estimate the force that the needle will experience during insertion and thereby control the needle to reduce the needle deflection and enhance seed delivery accuracy.**

I. INTRODUCTION

In various medical diagnostic and therapeutic procedures like tissue biopsy, brachytherapy, anaesthesia, vaccinations, blood/fluid sampling, abscess drainage, catheter insertion, accurate intervention of surgical needles is very important. However, precise insertion of needles in soft tissue is challenging because of several reasons such as tissue heterogeneity and elastic stiffness, tissue deformation and movement, unfavorable anatomic structures, needle bending, inadequate sensing, and poor maneuverability. Some of the factors such as tissue deformation and movement, target deflection, and needle bending are directly related to the force experienced by the needle during insertion. A portion of these forces and deformations depend on the needle geometry and insertion techniques. Significant tissue/organ deformation and movement (both translational and rotational) are observed during capsule puncturing of inner organs like prostate (Fig. 1), liver, or the skin of external organs like breast. The undesired deformation and movement can cause deflection of the needle and the target resulting in clinical complications such as vital tissue damage, misdiagnosis, under/over dosing with radiation, tumor seeding, to mention a few. Although the biological tissue relaxes and regains the position partially, there are some organ rotation and deformation which do not recover during surgery and consequently the original pre-operative surgical plan becomes erroneous for actual surgery.



(a) Prior to capsule puncture *(b) During capsule puncture*

Figure 1: Ultrasound (U/S) images showing prostate deformation in capsule puncturing taken during prostate brachytherapy procedure in the operation room; during this imaging the U/S probe did not move, thus both the images have the same reference frames.

Over the past several years, researchers have been investigating the effects of needle insertion in soft tissue and developing models and techniques to improve needle insertion accuracy [1]-[7]. Okamura *et al.* [1] have developed empirical models for needle insertion force comprising of tissue stiffness force, friction force, and cutting force. The overall shape of the model simulation data is similar to the measured data in bovine liver; they have concluded that perfect match was impossible because of the significant variations in liver geometry and internal structure of the liver. DiMaio *et al.* [2] have also developed analytical models for estimating needle forces and soft tissue deformation using FEM using linear elastic modulus. Although the simulation results reasonably matched with experimental data while inserting the needle into polyvinylchloride (PVC) phantom, they have pointed out that the models might not be amenable to real-time simulation or agreeable with *in vivo* measurement. Glozman *et al.* [3] have developed an optimal trajectory for flexible needle steering into viscoelastic materials using virtual spring concept. The effect of velocity modulation on surgical needle insertion is relatively a less studied area. Recently, Podder *et al.* [4] , Yan *et al.* [5] and Crouch *et al.* [6] have reported the efficacies of velocity (linear insertion velocity and rotational velocity) modulation in reduction of total force and phantom deformation during insertion of brachytherapy needles. Kiss *et al.* [7] and Taylor *et al.* [8] have developed models for stress using fractional derivative approach and verified with *ex-vivo* experiments.

Some mechanical properties such as modulus of elasticity (Young's modulus), Poisson's ratio, relaxation, stress and strain, measured from *ex vivo* human tissues, are also available in the literature [9]-[11]. Although *ex vivo* measurement can be more accurate for a small piece of sample, there are three main differences between *ex vivo* and *in vivo* measurements, especially for PSI: (1) during *in vivo*, i.e. actual brachytherapy in the OR, the needle traverses through different types of tissues/organs having very different nonlinear viscoelastic properties, (2) factors such as the boundary conditions acting on the organ, organ/tissue interlace, blood flow, temperature, and (3) tissue properties also depend on some patient-specific criteria such as age, body-mass index (BMI), ethnicity, prior treatment, stage of cancer, prostate-specific agent (PSA), Gleason score.

However, perhaps none of the existing models, either empirical or analytical including the FEM, along with *ex vivo* measurements can accurately assess the forces and tissue deformations while the needle is inserted into the prostate gland through different types of organs and tissues. But, to the best of our knowledge, to date no *in vivo* force measurement data for needle insertion in human soft tissue, especially in prostate gland, has been reported. In this study we have developed statistical models of needle insertion force using *in-vivo* measured procedure-specific criteria, and patient-specific criteria. These models can be used to predict the needle insertion force responsible for tissue/organ deformation and target deflection during various surgical procedures and virtual reality based surgical simulations.

II. MATERIAL AND METHOD

A. In-vivo Force-Motion Measurement

We have collected procedure-specific data from 25 patients in the OR using a hand-held adapter (Fig. 2), that we designed and developed, equipped with a 6 DOF force-torque (F-T) sensor (Nano17, ATI Ind. Auto., Apex, NC).

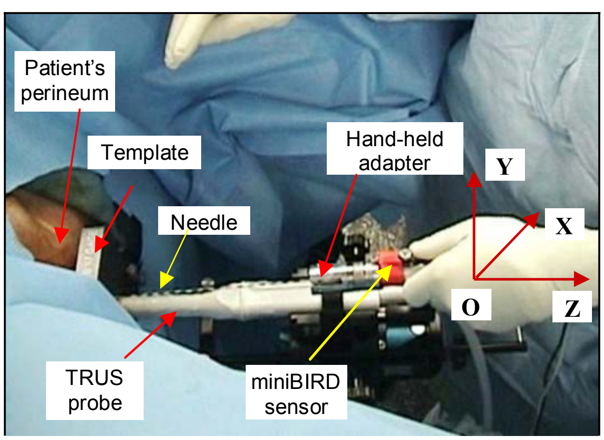


Fig. 2. Force/torque and position data collection during actual brachytherapy procedure in the OR.

In this *in vivo* measurement, the needle progression into the soft tissue (perineum, prostate and other organs) is registered using ultrasound (US) imaging technique. A 6 DOF electromagnetic (EM)-based position sensor (miniBIRD® from Ascension Technology Corporation) is attached to the hand-held adapter to measure 3D positions and orientations of the F/T sensor and the corresponding time stamps are recorded automatically for calculating the needle insertion velocity and acceleration. To have synchronized data, we have integrated EM-based position sensor (miniBIRD®) with the F-T sensor so that F-T sensor can trigger the position sensor. We have collected F-T data during prostate brachytherapy procedure in compliance with the Research Subject Review Board (RSRB) approved protocol and with patient's informed consent. The handheld adapter was operated by an experience surgeon. Details about the procedure and results are available in [12].

B. Mathematical Framework

Multi-variable Ordinary Least Square (OLS) linear regression model is given by

$$y_i = \beta_0 + \beta_1 x_{1i} + \beta_2 x_{2i} + ... + \beta_p x_{pi} + \varepsilon_i \qquad (1)$$

where y_i is the dependent variable, β_k $(k = 0,1,....,p)$ are the coefficients of the independent variables for the population, p is the number of independent variables, and ε_i is the error term.

Excluding the error term, we get the regression equation as

$$E(y_i \mid \{x_{1i}, x_{2i}, ..., x_{pi}\}) = \beta_0 + \beta_1 x_{1i} + \beta_2 x_{2i} + ... + \beta_p x_{pi} \qquad (2)$$

where partial regression coefficients are

$$\beta_j = \frac{\partial y}{\partial x_i}, \quad j = 1,2,......., p, \quad i = 1,2,...., n \qquad (3)$$

Here the OLS assumptions are: (i) the model is correctly specified, (ii) estimated errors, $E[\varepsilon_i] = 0$ for all i, (iii) homoscedasticity, i.e. constant variance for the errors, $Var[\varepsilon_i] = \sigma^2$ for all i, (iv) errors are not correlated, $Corr[\varepsilon_i, \varepsilon_j] = 0$ for all $i \neq j$, (v) errors are normally distributed, i.e., $\varepsilon_i \sim N(0, \sigma^2)$, and (vi) the independent variables are not perfectly correlated with one another, i.e. no multicollinearity. We can plot the residuals (or standardized residuals) to verify whether these assumptions are satisfied. For the least square estimates, the error function is minimized as follows:

$$Min \sum_i^n \hat{\varepsilon}_i = Min \sum_i^n (y_i - \hat{y}_i)^2 \qquad (4)$$

where $\hat{y}_i$ is the estimate of the dependent variable given by the following equation:

$$\hat{y}_i = b_0 + b_1 x_{1i} + b_2 x_{2i} + ... + b_p x_{pi} \qquad (5)$$

In this equation (Eq. 5) b_k are sample statistics or the estimates of β_k that are derived from a set of random samples.

In this study we investigate whether a Best Linear Unbiased Estimator (BLUE) for needle insertion force can be developed using both procedure-specific criteria and patient-specific criteria. The general form of the estimation model that we propose is given as-

$$F = b_0 + b_1 age + b_2 BMI + b_2 PSA + ...+ b_p needle_{size} \quad (6)$$

where F is the needle insertion force; *age, BMI, PAS* are patient-specific criteria, and $needle_{size}$ is procedure-specific criteria.

III. RESULT AND DISCUSSION

A. Procedure-Specific Criteria

In this study, we have considered three procedure-specific criteria; size, velocity and acceleration of the needle as independent variables for the model. *In-vivo* data were collected from 25 patients for a total of 72 insertions during actual PSI procedures in the OR. There were 2-3 insertions of either 17G needles or 18G needles for each patient; the average value for each patient is presented in Table I. In our model, we have used all data for all 72 insertions.

TABLE I
IN-VIVO DATA MEASURED IN THE OR

		At Perineum			In Prostate		
Patient No.	Needle Size (mm)	Avg. Max. Needle Vel. (cm/s)	Avg. Max. Needle Accen. (m/s^2)	Avg. Max. Force (N)	Avg. Max. Needle Vel. (cm/s)	Avg. Max. Needle Accen. (m/s^2)	Avg. Max. Force (N)
1	1.47	1.3	1.87	12.5			
2	1.27	18.1	7.5	12.8	1.7	-0.6	5.95
3	1.27	17.1	6.5	5.2	0.94	-0.9	4.49
4	1.27	27.6	2.8	7.9	0.7	0.67	
5	1.47	21.1	11.3	8.75	4.0	0.79	6.86
6	1.47	21.5	9.58	11.7	0.6	-0.2	7.63
7	1.47	40.4	17.7	11.5	10.3	5.52	6.08
8	1.47	7.0	-0.9	9.8	9.2	1.6	8.32
9	1.27	27.5	6.0	3.4	1	0.04	5.37
10	1.47	31.6	10.3	14.2	3.4	0.31	7.7
11	1.27	11.9	16.4	5.6	12.8	9.87	4.95
12	1.47	50.4	74.8	12.7	4.8	0.33	7.84
13	1.47	50	23	12.1	4.0	0.23	9.6
14	1.27	11.1	0.27	6.6	3.0	0.59	5.18
15	1.47	27.3	5.79	13.7	2.1	0.38	7.09
16	1.47	50	38.1	15.3	4.0	0.89	7.52
17	1.27	1.6	0.23	9.44	1.4	-0.2	4.62
18	1.27	8.7	-7.8	8.6	2.0	0.46	3.92
19	1.27	2.6	-0.1	8.01	1.2	-0.4	5.05
20	1.27	24	2.06	9.9	5.9	0.2	4.44
21	1.47	64	34.8	15.7	3.0	-2.9	9.72
22	1.27	24	5.73	8.46	4.0	0.34	4.64
23	1.27	3.8	0.15	7.32	17.8	0.78	6.43
24	1.47	55.5	48.1	16.7	54	14.2	7.16
25	1.47	1.1	-0.1	9.83	11.6	3.11	7.08

B. Patient-specific Criteria

The patient-specific criteria that we considered for developing the estimation model are age, BMI, ethnicity, prostate volume, physical activity, prior treatments, cancer stage, PSA, and Gleason score (Table II). These data were gleaned from the 25 patients from whom we collected the force and motion data in the OR. We have considered hormonal therapy (HT), external beam radiation treatment (EBRT) and partial prostatectomy (PROS) as prior treatments for the patients in this study.

TABLE II
PATIENT-SPECIFIC CRITERIA

Patient No.	Age (yr)	BMI (kg/m^2)	Ethnicity	Prostate Vol. (cm^3)	Physical Activity	Prior Treatment	Cancer Stage	PSA	Gleason Score
1	63	22.9	W	25	N	EBRT	T2c	45	3+3
2	69	26.3	W	28	N	None	T2c	5.0	3+3
3	61	26.0	W	28	A	EBRT	T1c	3.1	3+3
4	75	27.1	W	40	A	EBRT	T2a	47	4+3
5	69	30.5	W	55	A	None	T1c	11	3+3
6	62	24.8	B	35	A	EBRT	T1c	4.6	3+3
7	76	25.6	W	30	A	EBRT	T1c	6.7	4+4
8	70	25.1	W	26	N	EBRT	T2a	8.2	4+3
9	70	27.0	W	24	N	EBRT	T2a	5.6	3+3
10	76	24.5	W	40	N	EBRT	T1c	6.4	3+3
11	80	26.0	W	30	N	None	T2a	5.2	3+4
12	70	26.4	B	29	A	None	T1c	4.9	3+3
13	72	25.9	W	45	N	HT	T2	8.3	3+4
14	64	27.2	W	33	N	EBRT	T1b	2.9	3+3
15	70	29.4	W	25	N	EBRT	T2c	5.0	4+3
16	71	31.2	W	28	N	EBRT	T2b	10	3+4
17	72.3	25.6	W	30	N	PROS	T1c	5.1	3+3
18	78.8	24.0	W	20	A	None	T1c	9.8	3+3
19	75.5	27.8	W	35	N	None	T2a	1	3+3
20	72.5	31.9	W	42	N	None	T2	7.3	3+3
21	77.6	26.7	W	37	N	EBRT	T2c	5.8	3+3
22	67.8	27.2	W	31	N	None	T1c	6.2	3+3
23	65.6	33.7	W	45	A	None	T1c	9.5	3+4
24	73.4	24.7	W	38	N	HT	T1c	8.9	3+3
25	88.3	26.3	W	50	N	HT	T2c	10	3+3

Note: W-white, B-black, A-physically active, N-physically not active.

C. Models for Needle Insertion Forces

In our model the estimates, i.e. the dependent variables are the needle insertion forces at perineum and in prostate. We have developed the model to estimate the maximum force that the needle will experience during insertion into a patient. We used statistical software package called "SWstat+" to formulate the models considering all the procedure-specific criteria and patient-specific criteria. After extensive computer simulations we found the BLUE for the perineum force model as follows:

$$F_{perineum} = -14.210 + 0.354\ BMI - 0.153\ Vol + 3.182\ HT + 0.871\ Gleason + 0.062\ Needle_{Accn} + 0.075\ Needle_{Vel} + 17.823\ Needle_{Size}$$

The prostate force estimation model is as follows:

$$F_{prostate} = -10.577 + 0.056\ Vol + 0.883\ EBRT + 0.672\ Gleason + 0.158\ Needle_{Accn} + 0.06\ Needle_{Vel} + 10.570\ Needle_{Size}$$

TABLE III
OVERALL SIGNIFICANCE OF THE MODELS

	Perineum force model	Prostate force model
p-value	<0.0001	<0.0001
F-ratio	8.50	11.55
R-squared	0.46	0.41
Adj. R-squared	0.41	0.37
Durbin-Watson No.	1.61	1.50

TABLE IV
SIGNIFICANCE OF INDIVIDUAL COEFFICIENTS OF THE DEPENSENT VARIABLES FOR THE MODELS

	BMI	Vol	HT	EBRT	Gleason	Needle accen.	Needle velocity	Needle size
perineum	.057	.023	.032	---	.05	.054	.041	.001
prostate	.061	.054	---	.045	.04	.001	.05	.0001

The overall significance of the models are shown in Table III (p-value and F-ratio). The R-squared and adjusted R-squared are quite close to each other which indicates goodness of fit as well as proper selection of number of independent variables. The Durbin-Watson numbers in both the models are 1.61 and 1.5 which are far away from 0 and 4 indicating no autocorrelation, i.e. the models are properly specified; no significant information is left with the residuals. We observe that the model coefficients (coefficients of independent variables) are also individually significant (Table IV). Residuals plots for both the models are presented in Figs. 4 and 5. Plots of standardized residuals versus fitted values indicate that the OLS assumption of homoscadasticity is not violated (Figs. 3(a) & 4(a)); however, Fig. 4(a) exhibits slight diverging residuals. The residual plots also show that the errors are normally distributed (Figs. 3(b) & 4(b)). Multicollinearity was checked from VIF (variance inflation factors) values which were below 3 for all the coefficients in the models. Thus, the models appear to be the BLUE and can be used for estimating needle insertion force for actual prostate brachytherapy procedures.

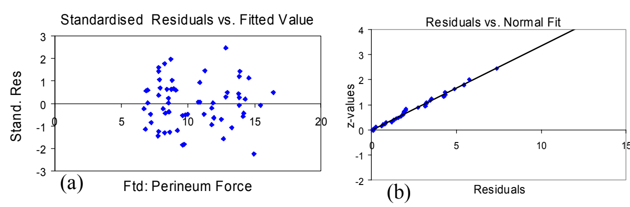


Fig. 3. Residuals plots for perineum force estimation model – (a) standardized vs. fitted value, (b) normal distribution of the residuals.

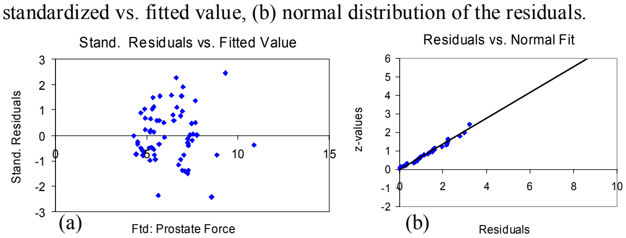


Fig. 4. Residuals plots for prostate force estimation model – (a) standardized vs. fitted value, (b) normal distribution of the residuals.

IV. CONCLUSION AND FUTURE WORK

In this paper, we have presented *in-vivo* brachytherapy procedure-specific data and patient-specific data from 25 patients. Then, we have used this data to develop statistical models to estimate needle insertion force. The overall significance of the models are quite high (p-value <0.0001). The models satisfied all the OLS assumptions. It appears that both procedure-specific criteria and patient-specific criteria can be used to estimate needle insertion force during surgical procedures. These models may be used to develop robot controllers and predictive deformation models of the prostate to enhance accuracy. With the collected random data set, relatively small number patient-specific criteria were statistically significant for the model development. We will be collecting more *in-vivo* and *ex-vivo* data to improve the models further.

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