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Reliability and validity of new instrument measuring pelvic floor muscle squeeze pressure

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Abstract
Background and Purpose: Present study was conducted to assess the validity and reliability of a new instrument measuring pelvic floor muscle contraction pressure projected as the strength of pelvic floor muscles (PFM).
Perineometers are usually available in foreign markets, which are high in cost and so, it is not commonly used by physiotherapists in India. This perineometer is an Indian version which is indegeniously designed to assess the PFM strength which will be cost effective and easily available in the markets.
Objectives: To assess inter and intra reliability and validity of the new instrument measuring PFM contraction pressure. To assess the specificity and sensitivity of the indegeniously designed instrument used for measuring pelvic floor muscle strength. To assess the difference of PFM strength amongst nulliparous, primiparous and multiparous women between the age group of 18-35 years.
Methodology: A cross sectional study was conducted in which 120 women comprising nulliparous, primiparous and multiparous asymptomatic women between the age group of 18-35 years were enrolled via convenient sampling (N=120, n=40). Women were evaluated for PFM strength by per-vaginal digital assessment and also by using new instrument measuring pelvic floor muscle contraction pressure. The digital PFM strength was graded using Laycock (Modified Oxford) scale of grading. An indigeniously designed perineometer was used by two investigators to assess the PFM strength in the form of PFM squeeze pressure measured in mm of Hg. Thereafter, the instrument was assessed for the reliability, validity and accuracy in the form of specificity and sensitivity.
Results: The mean difference in PFM Perineometer readings for nulliparous and primiparous women recorded by two investigators was 0.32mm Hg, in multiparous women was 0.15mm HG.
Difference between inter and intra perineometer readings was statically insignificant at p=0.75, Interclass correlation coefficient (ICC) inter and intra-rater agreement measure shows a value of 0.941 and 0.94 respectively which signifies excellent reliability of the indigenously designed Perineometer. Sensitivity and Specificity was assessed for Grades 2, 3, and 4 of Modified Oxford Scale with respect to the Perineometer readings. The co-ordinated values of Perineometer with Modified Oxford Scale was found to be 23.5mmHG for Grade 2, 28.5mmHG for Grade 3 and 29.5 mmHG for Grade 4 Oxford Scale of PFM strength assessment. Validity was assessed based on the findings of Bland Altman graph and the ROC graphs. The graphical representation in Bland Altman graph suggest that all the observations lie in the range mean difference +/- 1.96 x SD which is in the acceptable range, while the ROC curves confirms the accuracy of the tool.
The mean pelvic floor muscle squeeze pressure in nulliparous women was 31.58 mm Hg, primiparous women was 31.25 mm Hg and multiparous women was 26.28 mm Hg. Anova test revealed significant difference between the three parity groups.

Keywords: pelvic floor muscle (PFM), PFM strength, modified oxford scale grading, indigenous, perineometer, parity, reliability and validity

Introduction
Evaluation of the pelvic floor is crucial to identify dysfunctions that may affect the quality of life of women and contribute to problems such as stress urinary incontinence (SUI), faecal incontinence and sexual dysfunction [1]. It is used as a tool for monitoring the clinical results that are achieved through rehabilitation methods of the muscles of the pelvic floor (PFM). It is also used as a teaching tool and as motivation for carrying out the training exercises [2, 3].
Several methods have been recommended by different authors for the evaluation of PFM, such as electromyography, vaginal cones, digital palpation, perineometer measurements, ultrasonography and magnetic nuclear resonance [4, 5].
The function of the PFM is evaluated clinically using a simple, well tolerated and minimally invasive method that identifies whether there is correct muscular recruitment and predicts PFM dysfunction [6, 7].
Pelvic floor muscle strength can be measured with a manometer or a dynamometer. However since dynamometer are not commercially available [8, 9] strength is common measured by digital muscle testing and manometers. Several vaginal palpation rating scales have been used in clinical practice8 but most commonly used tool in physical therapy seems to be modified oxford grading scale [9, 10].
Evaluation with a perineometer is a reliable method to objectively assess the strength of the PFM [11, 12].

The evaluation of PFM is important to provide prophylaxis and improve treatment of Pelvic floor muscles dysfunction.
The Peritron manometer (Cardio-Design, Victoria) is available in the foreign markets [12]. The cost and availability of the equipment makes it difficult for its use in clinics in India. Hence the need of the hour warranted making an indigenous design of Perineometer to be made easily available and cost effective for use by the Indian therapists.
If more than one examiner is to assess the participants in clinical studies, it is essential to assess the inter-rater reliability of the measurement method. Whether a measurement tool should be used in clinical practice or in research depends on its reliability [13].
Intra-rater reliability refers to one researcher measuring the same procedure in the same subject twice, while inter-rater reliability refers to two or more clinicians or researchers conducting measurements of the same subject [14]. Also any new diagnostic device needs to be checked for its sensitivity and specificity with respect to the measurement tool used currently in the clinics.
It was found that pelvic muscle strength declined from ante partum to postpartum in women with vaginal births [15]. Studies done in the past have concluded that Nulliparous women had the highest pelvic floor muscle strength and there was no significant difference in pelvic floor muscle strength between women with normal vaginal delivery and those with caesarean section [16].
During pregnancy, the female body undergoes several adaptive modifications. The effects of normal gestation on the physiology of the urinary tract have not been completely elucidated. The evaluation of the PFM is important to provide prophylaxis and improve treatment of PFM dysfunctions [17].
The primary aim of this study was to evaluate the inter-rater reliability of the indigenously designed Perineometer. A secondary aim was to compare the scores obtained with the Perineometer for squeeze pressure measurement in nulliparous, primiparous and multiparous women.

Aim

Reliability and validity of indigenously designed perineometer measuring PFM contraction pressure in mm Hg.

Materials and methodology

A cross-sectional study was conducted; comprising 120 asymptomatic women in the age group of 18-35 years were divided equally into nulliparous, primiparous and multiparous individuals.

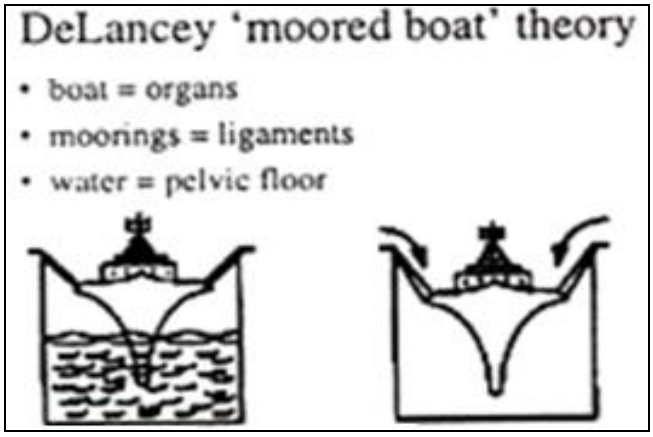

Fig 1: Description of the pelvic floor muscles using the De Lancey's 'moored boat' theory

All the women recruited for the study were individually given a very simple description of the pelvic floor muscles, and its functions in lay terms, using the De Lancey's 'moored boat' picture; (Refer Fig. 1) and were fully explained the method and benefits of the procedure via a written information sheet. A written consent was obtained from each patient before proceeding with the assessment procedures. The entire study protocol was validated by the Ethical department of School of Physiotherapy, D.Y.Patil University, Nerul, Navi Mumbai.
Fig 2 shows the flowchart of the methodology in brief.
The principal investigator noted the participant's age, weight, height, use of oral contraceptives, level of physical activity, participation in pelvic floor muscle training, parity and urinary incontinence.
A detailed maternal history including the number and type of deliveries, other medical/surgical histories/complaint of stress urinary incontinence, were included in the assessment Performa. Also, the menstrual history in brief comprising of the duration of the cycle, amount of bleeding, sexual history in brief were also noted in the proforma.
After verifying that the participants were eligible to take part in the study, pelvic floor muscle strength was assessed. Examinations were conducted with the participants in a crook lying position. All women were evaluated twice, first by one examiner and 7 days later by a second examiner. Both examiners were trained in this specific protocol of pelvic floor muscle assessment by a Gynaecologist from the Obstetrics and Gynaecology department of D.Y.Patil Hospital and Research centre, Nerul, Navi Mumbai.

Assessment of the pelvic floor muscles

1. Per-vaginal digital examination

The subject was placed in a comfortable, crook line position as seen in the picture. Sterilized rubber gloves were used and sterilized Gauze pieces to cleanse the female perineal surface with savalon solution. The ability to contract and relax the

pelvic floor muscles was first evaluated digitally, asking the subject to pull her pelvic floor muscles in and up as strongly as possible and then to relax them completely. When a correct contraction was verified, the examiner scored it according to the modified Oxford Grading Scale [7]. A best of three contractions was noted down and recorded [18, 19].

Grading of Pelvic floor Muscles: Modified Oxford/ Laycock (1998) [19].

0 - No contraction of Contraction of the Pelvic floor muscles
1 - Slight Flicker of Contraction of the Pelvic floor muscles
2 - Weak Contraction of the Pelvic floor muscles
3 - Moderate Contraction of the Pelvic floor muscles
4 - Good Contraction of the Pelvic floor muscles
5 - Strong Contraction of the Pelvic floor muscles

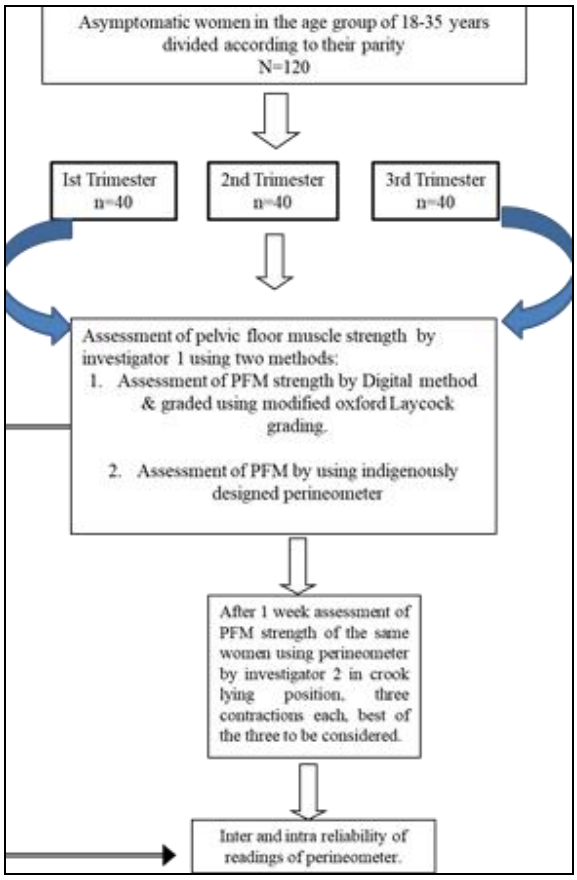

Fig 2: Flowchart of the methodology of the study

2. Assessment of PFM strength by indigenously designed perineometer

After vaginal palpation, the indigenously designed perineometer was placed with the middle of the probe 3.5 cm inside the vagina [20].

Examination was performed with the subject in crook lying position using a vaginal pressure measurement instrument. The new instrument (Figure 3) is a simple pneumatic device consisting of a vaginal sensor (vaginal probe) which recorded the contraction in mm of Hg. The resistance chamber (vaginal sensor) measured about 2.5cm in diameter and 8cm in length and is made of silicon. The vaginal sensor was covered with the condom before it was used for the assessment. The perineometer was inserted into the vaginal canal until the full extent of the compressible portion of the device was above the level of hymen ring [21].

The device was calibrated to zero before each measurement. An intentional pressure of 5 mm Hg was maintained before inserting the sensor into the vagina for each woman. Once the sensor was inserted into the vagina, the digital reading was set to zero before recording the compression pressure [21].

The women were instructed to undertake three maximal pelvic floor muscle contractions sustained for 5 seconds with an interval of 30 seconds, as reported in a previous study [21].

Three squeezes were recorded with a 30 sec rest between efforts, best of the three readings were considered. Only contractions with visible inward movement of the perineum were considered to be valid [22].

Co-contraction of the gluteal and hip adductor muscles was discouraged, as was the Valsalva manoeuvre [23, 24, 25].

Similar assessment was performed by the 2nd investigator after duration of 1 week. The observations were computed and statistical analysis was done to assess the intra and inter reliability and validity of the new indigenously designed perineometer.

Observation and results

120 asymptomatic women were randomly selected for the study by convenience sampling technique. These were divided according to their parity status.

Table 1 shows the general observations of the study; firstly, age wise distribution of nulliparous, primiparous and multiparous women in the age group of 18-35 years of age.

It was observed that in the age group of 18-25 years, 27 women were nulliparous, 14 women were primiparous and 5 women were multiparous. In 25-30 years of age 9 women were nulliparous 21 women were primiparous and 11 women were multiparous whereas in 30 -35 years of age 4 women were nulliparous, 5 women were primiparous 24 were multiparous individuals.

Table 1: General Observations

Age wise distribution of subjects based on parity of women.			
	18 to 25	**25 to 30**	**30 to 35**
Nulli-Parous	27	9	4
Primi-Parous	14	21	5
Multi-Parous	5	11	24
Distribution of study subjects according to parity and Oxford scale grading of PFM strength			
Oxford Grades	**Nulli-parous**	**Primi-parous**	**Multi-parous**
2	2	2	4
3	9	12	28
4	29	26	8
Total	40	40	40
Mean values of perineometer readings (mm of Hg) in nulliparous, primiparous and multiparous women as assessed by two investigators			
Parity		**Investigator 1**	**Investigator 2**
Nulli-parous	Mean	31.58	31.9
	SD	+ 4.33	3.9
Primi-parous	Mean	31.25	30.95
	SD	+ 4.05	3.93
Multi-parous	Mean	26.28	26.13
	SD	+ 4.34	4.15

Further, the subjects were assessed for digital pelvic floor strength assessment and it was noted that, Oxford scale Grade 2 comprised 2 nulliparous, 2 primiparous and 4 multiparous women, Grade 3 comprised 9 nulliparous, 12 primiparous and 28 multiparous women, while Grade 4 comprised 29 nulliparous, 26 primiparous and 8 multiparous women.

Mean values of perineometer readings in nulliparous, primiparous and multiparous women as assessed by the two investigators is depicted in the Table 1

The mean difference in PFM Perineometer readings for nulliparous and primiparous women recorded by two investigators was 0.32mm of Hg, in multiparous women was 0.15mm of Hg.

The relationship of Modified Oxford Scale grading and Perineometer readings is depicted in Graph 1, Figure 3

Statistical analysis was performed using Statistical Package of Social Sciences (SPSS) (version 16.0) under the guidance of Mr.Pratap Jadhav, biostatistician from GSMC and KEMH Hospital, Parel, Mumbai.

Cronbach's alpha test was used to assess internal reliability. Intra Item Correlation (ICC) matrix was used to analyse inter and intra reliability of the Perineometer designed indigenously.

T test was used to analyse the differences in the readings of the two investigators. Bland Altman test was used assess the relative agreement between the readings of the two investigators.

Sensitivity and Specificity was assessed by plotting the Receiving Operating Characteristic (ROC) curves. Validity was assessed based on the findings of the ROC curves.

To compare difference between the means of PFM squeeze pressure as assessed by the indigenously designed Perineometer amongst nulliparous, primiparous and multiparous women One-Way ANOVA test is used. To find out difference of PFM squeeze pressure as assessed by the indigenously designed Perineometer within nulliparous primiparous and multiparous women Post hoc test was performed.

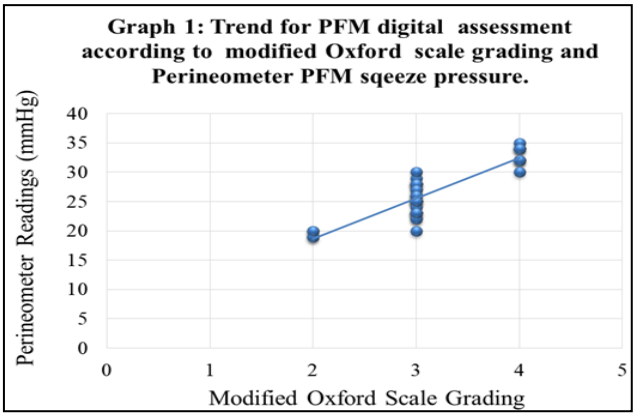

Fig 3: Relationship between Perineometer readings in mm of Hg and Modified Oxford Scale assessment grades

Table 3 shows the mean values of Perineometer readings recorded by the two investigators. The mean perineometer reading recorded by the first Investigator was 29.7mm Hg, while that of the second investigator was 29.65mmHg.

Table 4 shows the values of Cronbach's alpha test for reliability. Cronbach's Alpha value was found to be 0.97 which shows relatively high internal consistency

Table 3: Mean values of Perineometer readings recorded by two investigators

	Mean (mmHg)	Std. Deviation	N
Investigator 1	29.70	4.86	120
Investigator 2	29.66	4.71	120

Table 4: Cronbach's Alpha Test for Reliability

Reliability Statistics		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	No. of Items
0.97	0.97	2

Table 5: Inter-Item Correlation Matrix

	Inter	Intra
Interrater	1.000	.941
Intrarater	.94	1.000

Interclass correlation coefficient (ICC)- inter and intra-rater agreement measure shows a value of 0.941 and 0.94 respectively which signifies excellent agreement in between the readings of PFM squeeze pressure assessed by two investigators at different times and in between the readings of a single investigator at a time. (Refer Table 5)

Statistical analysis of Inter and Intra class correlation coefficients analysed using the Fisher's test shows a significant value of 0.00 at 95% confidence interval (CI). (Table 6) Therefore, the occurrence of ICC values being excellent is not just by chance and is true at 95%CI.

Table 6: Intra-class Correlation Coefficient

Intra-class Correlation		95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	
Single Measures	.94[b]	.92	.96	32.73	119	119	.000
Average Measures	.97[c]	.96	.98	32.73	119	119	.000

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. Type C intraclass correlation coefficients using a consistency definition-the between-measure variance is excluded from the denominator variance.
b. The estimator is the same, whether the interaction effect is present or not.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

Table 7: One-Sample t Test used to compare the difference of PFM squeeze pressure recorded by Investigator 1 & 2

	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Difference of perineometer readings of the two investigators	0.28	119	0.78	0.042	-0.26	0.34

One sample t test was used to compare the difference between mean values of the PFM squeeze pressure recorded using perineometer by the two investigators. Table 7 shows that a p value of 0.78, i.e., >0.05, therefore, we can ascertain that the difference between the readings of the two investigators are similar and the difference is not statistically significant at 95 % CI. Graph 2 in Figure 4 depicts Bland and Altman graph. The graph represents scatter of points in this plot which lies near the line of mean, it indicates that the two inter and intra readings of PFM strength are similar.

It is evident that the scatterplot falls close to the mid line which suggests that the two observers are measuring the same characteristic of the instrument. The graphical representation suggests that all the observations lying in the range mean difference +/- 1.96x SD which is in the acceptable range. [95% confidence interval] Graph 5

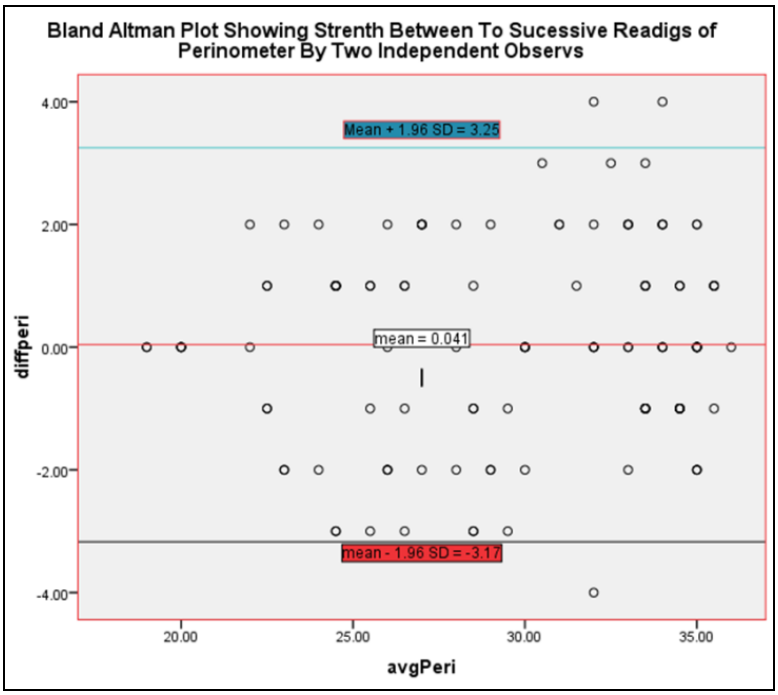

Fig 4 (Graph 2): Bland Altman test showing strength between two observers

Sensitivity and specificity of the perineometer

Sensitivity and Specificity was assessed for Grades 2, 3, and 4 of Modified Oxford Scale with respect to the Perineometer readings, as the data sample presented with these grades of subjective PFM strength.

Table 8: Digital assessment (Modified Oxford Scale) Grade 2 Area under the curve

Area	Std. Error	Asymptotic Sig.	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
0.985	0.01	0	0.966	1.005

Table 8 shows the area under the curve (AUROC) for Grade 2 of Modified Oxford scale which is a digital examination of assessing the PFM strength. The AUROC value is 0.985 that signifies excellent sensitivity of the equipment for grade 2 on digital examination.

Table 9 shows the co-ordinated value of the curve, which is the value that nears 1 for sensitivity and 0 for specificity. 23.5mmHg of PFM squeeze pressure on the Perineometer would match with Grade 2 of modified Oxford Scale. Also, Table 10 shows that the values of AUROC are significant with 0 p value at 95% CI.

Grade 2 Oxford Scale would concur with 23.5mmHG on the Perineometer for a minimum of 96% of the cases and maximum 100% cases during clinical evaluation of PFM strength.

Similarly, Table 10 shows the area under the curve (AUROC) for Grade 3 of Modified Oxford scale which is a digital examination of assessing the PFM strength. The AUROC value is 0.890 that signifies good sensitivity of the equipment for Grade 3 on digital examination. Table 11 shows the co-ordinated value of the curve. 28.5mmHg of PFM squeeze pressure on the Perineometer would match with Grade 3 of modified Oxford Scale. Also, Table 10 shows that the values of AUROC are significant with 0 p value at 95% CI. Grade 3 Oxford Scale would concur with 28.5mmHG on the Perineometer for a minimum of 81% of the cases and maximum 96% cases during clinical evaluation of PFM strength.

Table 9: Co-ordinates of the Curve

Positive if Less Than or Equal To	Sensitivity	1 - Specificity
18	0	0
19.5	0.25	0
21	0.625	0.009

22.5	0.875	0.036
23.5	1	0.08
24.5	1	0.098
25.5	1	0.196
26.5	1	0.241
27.5	1	0.295
28.5	1	0.384
29.5	1	0.42
31	1	0.473
32.5	1	0.554
33.5	1	0.634
34.5	1	0.812
35.5	1	0.938
37	1	1

Table 10- Digital 3 area under curve

Area	Std. Error	Asymptotic Sig.	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
0.89	0.036	0	0.819	0.961

Table 11: Coordinates of the Curve

Positive if Less Than or Equal To	Sensitivity	1 - Specificity
18	0	0
19.5	0	0.028
21	0.02	0.07
22.5	0.082	0.099
23.5	0.184	0.113
24.5	0.224	0.113
25.5	0.449	0.113
26.5	0.551	0.113
27.5	0.673	0.113
28.5	0.878	0.113
29.5	0.959	0.113
31	1	0.169
32.5	1	0.296
33.5	1	0.423
34.5	1	0.704
35.5	1	0.901
37	1	1

Table 12 shows the area under the curve (AUROC) for Grade 4 of Modified Oxford scale which is a digital examination of assessing the PFM strength. The AUROC value is 0.999 that signifies excellent sensitivity of the equipment for Grade 4 on digital examination.

Table 12: Digital 4 Area under the curve

Area	Std. Error	Asymptotic Sig	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
0.999	0.01	0	0.996	1.001

Table 13 shows the co-ordinated value of the curve, that the value that nears 1 for sensitivity and nearing 0 for specificity. 29.5mmHg of PFM squeeze pressure on the Perineometer would match with Grade 4 of modified Oxford Scale. Also, Table 12 shows that the values of AUROC are significant with 0 p value at 95% CI. Grade 4 Oxford Scale would concur with 29.5mmHG on the Perineometer for a minimum of 99% of the cases and maximum 100% cases during clinical evaluation of PFM strength.

To summarize: The co-ordinated values of Perineometer with Modified Oxford Scale is as follows:- Grade 2- 23.5mmHG, Grade 3- 28.5mmHG, Grade 4- 29.5mmHG

Table 13: Coordinates of the Curve

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
18	1	1
19.5	1	0.965
21	1	0.895
22.5	1	0.807
23.5	1	0.702
24.5	1	0.667
25.5	1	0.474
26.5	1	0.386
27.5	1	0.281
28.5	1	0.105
29.5	1	0.035
31	0.937	0
32.5	0.794	0
33.5	0.651	0
34.5	0.333	0
35.5	0.111	0
37	0	0

Anova test was used for comparison of perineometer in parity. Table 14 shows a significant difference in the perineometer readings in nulliparous, primiparous and multiparous women with a p value is 0.00 at 95% CI.

Table 14: Difference of Perineometer readings between groups of parity assessed by Anova Test

		Sum of Squares	Df	Mean Square	F	Sig.
Perineometer	Between Groups	705.95	2	352.98	19.6	0
	Within Groups	2103.3	117	17.98		

Post Hoc analysis was done to assess the difference in between each of the groups.

Table 15 shows Post Hoc multiple comparison tests. It suggests perineometer readings when compared with nulliparous and primiparous is statistically not significant as p value is 1 whereas between perineometer squeeze pressure in nulliparous and multiparous is statistically significant as p value is 0, finally, comparison of readings of perineometer between primiparous and multiparous is statistically significant as p value is 0

Table 15: Difference of Perineometer readings in between each of the groups of parity assessed by Post Hoc test

Dependent Variable	(A) Deliverycat	(B) Deliverycat	Mean Difference (A-B)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Perineometer	Nulliparous	Primiparous	0.325	0.95	1	-1.98	2.63
		Multiparous	5.30*	0.95	0	2.99	7.60
	Primiparous	Nulliparous	-0.325	0.95	1	-2.63	1.98
		Multiparous	4.98*	0.95	0	2.67	7.28
	Multiparous	Nulliparous	-5.30*	0.95	0	-7.60	-2.99
		Primiparaous	-4.98*	0.95	0	-7.28	-2.67

A statistical significant difference was obtained in perineometer squeeze pressure between Nulliparous and Multiparous, Primiparous and Multiparous women.

Validity of the Perineometer was ascertained by the significant and highly agreeable values of PFM squeeze pressure measured by the two investigators. Modified Oxford Scale measures categorical attributes while, the indigenously designed Perineometer record objective measures which are continuous. Therefore, validity of the tool can be established on the basis of its highly significant inter and intra reliability and excellent sensitivity and specificity.

Discussion

A total of 120 women in the age group of 18-35 years included in the study, were divided as nulliparous, primiparous and multiparous women. The aim of the study was to ascertain the reliability and validity of indigenously designed perineometer measuring PFM contraction pressure in mm HG.

The present study found the sensitivity and specificity of the indigenously designed perineometer used to measure PFM strength; further the difference of PFM strength in terms of PFM muscle contraction pressure amongst nulliparous, primiparous and multiparous women was assessed. Therefore, the first part of the study was concerned with inter and intra reliability of the new instrument measuring PFM contraction pressure.

Cronbach's alpha test was used for reliability. Cronbach's Alpha value was found to be 0.97 which shows relatively high internal consistency. The value 0.97 which falls in the acceptable range of the test suggest that the instrument has a good internal reliability [26].

In previous studies authors assessed inter-rater reliability of the Peritron manometer which found high correlation between the results of the two examiners [11]. The study included 100 women (18 nulliparous and 82 parous). However, a subgroup analysis showed that correlation between examiners was unaffected by parity [11]. The authors explained issues that may have influenced their results, including the short interval between the two examinations and the fact that the examinations were performed by multiple examiners. Furthermore, not all subjects were evaluated by the same examiners [11]. The statistical methods used in the present study were different from the study mentioned above, making comparison difficult. Bland and Altman's limits of agreement were used in the present study as it has been demonstrated that the use of correlation tests is inappropriate for the determination of reliability and may overestimate the results [27, 28, 29]. In the present study, all subjects were examined by the same two examiners, with a rest period of 30 secs between each contraction; three readings of contraction were taken and the best of the three were recorded.

Interclass correlation coefficient (ICC)- inter and intra-rater agreement measure shows a value of 0.941 and 0.94 respectively which signified excellent agreement in between the readings of PFM squeeze pressure assessed by two investigators at different times and in between the readings of a single investigator at a time. Statistical analysis of Inter and Intra class correlation coefficients analysed using the Fisher's test shows a sig value of 0.00 at 95% confidence interval (CI). Therefore, the occurrence of ICC values being excellent is not just by chance and is a true value at 95%CI [26].

Bland and Altman's limits of agreement were used in the present study as it has been demonstrated that the use of correlation tests is inappropriate for the determination of reliability and may overestimate the results [19, 27, 28] In the present study, all subjects were examined by the same two examiners, with a rest period of 30 secs between each contraction three contraction were taken and the best of the three were recorded.

We used a sample T Test to compare the difference between mean values of the perineometer recorded by two investigators. The difference obtained by using T test was 0.78 which is statistically insignificant as p value is > 0.05. It suggest that the difference between the two investigators are similar and so, the difference is not statistically significant [26] Bland Altman limits of agreement was used to compare the mean of inter and intra readings obtained by the new instrument which was used to measure the pelvic floor contraction pressure which is measured in mmHg.

All the observations by the two investigators lie in the range mean difference +/- 1.96xSDwhich suggests that they are measuring same characteristic of the instrument There was a good agreement observed between the investigator 1 and investigator 2 of the perineometer readings which were statistically significant and suggested that the instrument has a good reliability [27, 28].

The modified Oxford Grading Scale was used in this study because it is commonly used in clinical physical therapy to assess the PFM strength. To assess the diagnostic screening of the tool was analysed using Receiver operating characteristics curve.

Sensitivity and Specificity was assessed for Grades 2, 3, and 4 of Modified Oxford Scale with respect to the Perineometer readings for the results of the diagnostic validity of the perineometer with regard to digital palpation was calculated using the ROC analysis.

One way ANOVA test was performed to find out the difference present in perineometer amongst the nulliparous, primiparous and multiparous women which showed a positive

significance with p value 0.00 at 95% CI.

Further, post hoc were performed to test difference present amongst the various parity, in which it was observed that perineometer when compared with nulliparous and primiparous is statistically not significant as p value is 1, whereas nulliparous with multiparous is statistically significant as p value is 0. Primiparous and multiparous is statistically significant as p value is 0. There was a statistical difference present between nulliparous and multiparous, primiparous and multiparous.

Validity of the Perineometer was ascertained by highly significant agreeable values of PFM squeeze pressure measured by two investigators, and it also confirms the excellent sensitivity and specificity of the tool by receiver operating analysis, Thus the study results indicates that the inter-rater reliability and validity of the Perineometer is acceptable and it can be used in re-evaluations performed by different examiners in clinical practice.

The findings of Bo and Finckenhagen [30] showed that palpation scores using the modified Oxford Grading Scale did not differ from pelvic floor muscle strength. In the present study we could not establish the relationship between PFM digital scoring and PFM Perineometer readings statistically. Modified Oxford Scale grading is a categorical data while Perineometer readings are objective data measured as PFM squeeze pressure in mm of mercury.

Also many studies in the past have done similar studies with different types of perineometers. The use of different types of perineometer generates different results that should not be compared [21, 31] In contrast, Isherwood and Rane [32] found good agreement between the modified Oxford Grading Scale and the PFX9100C perineometer (Cardio-Design, Victoria). However, the perineometer they used reported squeeze pressures on a 0 to 12 point scale, and in contrast with the present study, one examiner only used the modified Oxford Grading Scale and the other performed the evaluations with the perineometer.

Other authors have found good correlation between different vaginal palpation scales and vaginal squeeze pressure [11, 33, 34].

The present study recorded data of PFM strength both subjectively and objectively amongst nulliparous, primiparous and multiparous asymptomatic women at young age, and the results may differ in older women with pelvic floor disorders. Therefore, further studies need to be conducted amongst older women with pelvic floor dysfunctions. Since the women were asymptomatic none reported with extremely weak pelvic floor muscles. The range of Oxford Scale varied from Grade 2 to Grade 4. Dietz *et al*. [34] found that almost half of young and nulliparous women contracted their pelvic floor muscles unsatisfactorily or not at all unless they received instructions. This indicates that the evaluation of pelvic floor muscles in young nulliparous women is essential, not only in research aiming to determine normal values of pelvic floor muscle strength, but also to evaluate preventive guidelines related to improvement of the ability to contract the pelvic floor muscles and to pelvic floor muscle training programmes in this population.

With a perfectly valuated sample size, the excessive homogeneity of the sample and the long interval between evaluations, the present results indicate that the inter-rater reliability of the indigenously designed perineometer is acceptable and it can be used in re-evaluations performed by different examiners in clinical practice

Conclusion

The results suggest good reliability and validity of the perineometer, because of its simplicity, quickness, inexpensive and high reliability and validity appears to be an appropriate objective instrument for measuring PFM strength.

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