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Translation, Cross-cultural adaptation and Establishment of psychometric properties of the Gujarati version of the knee injury and osteoarthritis outcome score (KOOS) scale in subjects with knee painin south gujarat

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INTRODUCTION

Knee joint is the most important weight bearing joint of the body which is involved in various day to day activities and hence is the commonest to undergo much wear and tear and damage.[1]

Knee pain is a common musculoskeletal symptom among working-age people. The prevalence of knee pain varies from 10 to 60%.[(2)]. Knee pain is common in Indians than other ethical groups with 6 months prevalence of 31%. In younger age groups, knee pain is commonly secondary to increased activity, injury or contact sports.[3]As the prevalence of knee OA increases with age it can have marked impact on the quality of life of individual's thus threatening community health. [(4)] There is risk of knee pain, particularly with respect to occupational physical loading and exercises. Patients with ACL or meniscus injury have a higher than average risk of developing osteoarthritis, and about 50% have radiological signs of osteoarthritis 10-15 years after injury.[(7)]

In the elderly population, the Western Ontario and McMaster Osteoarthritis Index (WOMAC) is the self-administered instrument most commonly used to measure pain, stiffness and function in daily living. However, in younger and/or more physically active subjects, joint injuries cause knee problems more often than primary knee OA. Younger patients also often have higher expectations regarding physical functioning. Thus, the WOMAC may not be used for these subjects. Partly for this reason, the Knee injury and Osteoarthritis Outcome Score (KOOS) was developed in the late 1990s as an extension of the WOMAC index to address problems associated with knee injuries and/or knee OA.[5]The KOOS is a knee-specific instrument, developed to assess the patients' opinion about their knee and associated problems. The KOOS evaluates both short-term and long-term consequences of knee injury. It holds 42 items in 5 separately scored subscales; Pain, other Symptoms, Function in daily living (ADL), Function in Sport and Recreation (Sport/Rec), and knee-related Quality of Life (QOL). KOOS has been found to be a valid, reliable and responsive outcome measure in different patient populations with varying knee injuries (of 4 menisci, ACL or cartilage), [9] knee OA [10] and total knee replacement. [11] Currently, KOOS is available in 50 different languages and language variants. [8] The validity and reliability of the Gujarati version of KOOS in subjects with different knee problems has yet not been reported. Hence, the need of this study is to produce a Gujarati version of KOOS and to evaluate its psychometric properties in patients with knee injuries.

SIGNIFICANCE OF STUDY-˙ translation, cross cultural adaptation and psychometric evaluation of Gujarati version of KOOS will help researchers to examine functional status across abroad spectrum of people and permit the exchange of information across cross cultural and linguistic barrier. Hence aim and objective of the study were To translate and cross culturally adapt KOOS into Gujarati version of KOOS in subjects with knee pain. AndTo evaluate the psychometric properties of Gujarati version of KOOS in subjects with knee pain.

MATERIALS AND METHODOLOGY-Study design was Biphasic observational study. Population consisted Subjects with 13-79 years of age with knee pain[15,16] , Sampling technique was Purposive sampling, Study duration-1 year ,Sample size- the sample size was calculated by using the formula[17]). Study setting was SPB physiotherapy college O.P.D. and different clinical O.P.D.s of South Gujarat. Inclusion criteria was Age 13 to 79 years[15, 18]• Diagnosed and referred case of knee pain by 0rthopaedic surgeon •

Fractures around knee joint within 3 months. • Anterior cruciate ligament injury treated conservatively and reconstruction, meniscus injury (conservative or repair) and Total Knee Replacement in last 3 months[14]• Patellofemoral syndrome[13]• Medial patella femoral ligament reconstruction within 3 months. • Post traumatic Osteoarthritis patients according to ACR criteria[19]• Ability to communicate Gujarati and English language.

Exclusion criteria was presence of any hip or ankle pathology, knee joint contracture or deformity in past six months • Patients with cognitive impairments affecting their ability to consent and complete the questionnaires or • Subjects with any neurological, respiratory, cardiac, or other conditions that would significantly compromise their ability to complete the questionnaire.[4]

Outcome measure

- ❖ Reliability of Guajarati version of Knee injury and Osteoarthritis Outcome Score(KOOS)
- ❖ Content validity of Guajarati version of KOOS
- ❖ Face validity of Guajarati version of KOOS
- ❖ Construct validity of Guajarati version of KOOS parallel with SF-12 [20], LEFS[18] and VAS [21] scale

- ➢ **PROCEDURE**
- ➢ Ethical clearance was taken from institutional ethical committee and all procedures was conducted in accordance with declaration of Helsinki. [22] Referred Knee pain subjects diagnosed and referred from orthopaedic surgeon were included in the study. They were screened on the basis of inclusion and exclusion criteria. The purpose of the study was explained and a written informed consent and demographic detail was obtained from all subjects.
- ➢ **Translation and cross cultural adaptation-(phase-1)**A cross-cultural adaptation of the measure was performed in accordance with the recommendations by Beaton et al. (2000). [12] The American-English KOOS was translated into Gujarati by two translators independently; one translator is (T1) and the other a professional translator with no medical background or special knowledge of the concepts in question (T2). Both versions will be then collected in a consensus meeting. This consensus version translated back into English independently by two Gujarati-speaking translators of English origin (BT1 and BT2) unfamiliar with the original questionnaire or concepts therein. The

translations into Gujarati and back translations into English and thereafter be discussed and collected in a second consensus meeting. The committee's considerations are around four areas: semantic equivalence (the meaning of words), idiomatic equivalence (equivalent expression for idioms and colloquialisms), experiential equivalence (the target cultural context), and conceptual equivalence (the validity of the concept). Pre final version tested with 30 knee pain subjects to confirm if all the items in the questionnaire were understandable and whether the subjects experienced problems in answering any of them.

- **Assessment of psychometric properties (phase -2)**
- Total sample subjects completed KOOS-G along with VAS, LEFS AND SF-12 at initial visit and again only on 30 subjects repeated KOOS-G after 48 hours from baseline.
- **psychometric testing**
- **Test retest Reliability**-Test retest reliability of the questionnaire was performed on 30 subjects for the KOOS-G. Subjects completed the relevant questionnaire twice with an interval of 48 hour to reduce any memory of previous answers and any variations in clinical status.[23] Test-retest reliability was determined by intra class coefficient (ICC). ICCs can vary from 0 to 1 and values above 0.8 are considered as proof of excellent reliability. Exploratory factor analysis was performed to determine the dimensionality of the items of the scale. Factor component analysis by using the principal component analysis with varimax rotation method, Eigen value greater than or equal to 1 were retained and item with loading equal to or greater the 0.4 was considered satisfactory.[24]
- **Internal consistency** - of KOOS-G was assessed by Cronbach's α coefficient. Cronbach's α value range from 0 to 1. Where value above 0.7 indicate adequate internal consistency of the scale.[25] Agreement The standard error of measurement (SEM) was used to determine the measurement error. The SEM is derived from the square root of the within subject variance obtain from the analysis of the variance. The variance was computed with analysis of variance for random effects. The SEM was converted in to the minimal detectable change (MDC), which expresses the minimal magnitude of change rather than measurement error. The MDC was established from the SEM and calculated as 1.96 $\sqrt{2}\times$ SEM[26] Face Validity Face validity was assessed by asking one question to each of the

patients, 'Do you think this scale is relevant to your condition.' The answer was noted as 'yes' or 'no'. Face validity of the KOOS was established when all the patients questioned about the relevance of the scale to their condition.

- **Content Validity-Content equivalence** was assessed under two headings: 1. Are the words in the translated Gujarati version of KOOS presented fluently and correctly as in the original version? 2. Do the words and phrase in the translated Gujarati version of KOOS have the same semantic meaning compared with the original version? For this answers from expert panel member's fall between "mostly agree" to "strong agree"
- This was assessed by an expert panel and they assessed the KOOS-G for content equivalence and content relevance on 5 point likert scale.[27] Content relevance Content relevance was evaluated by expert judges or panels: How the Gujarati version of KOOS statement is relevant to assessing function in knee pain subjects? For this answers from expert panel members' fall between "mostly agree" to "strong agree".[28]
- **Construct validity** is frequently measured as convergent and divergent validity and factor analysis. In this study, convergent validity was evaluated by a parallel questionnaire LEFS. Divergent validity was tested by Spearman's correlation coefficient (rs),showing that the KOOSG measurement concept was different from that for severity of pain on VAS, functional assessment by LEFS and quality of life by SF – 12. Exploratory factor analysis was performed to determine the dimension ability of the items of the scale. Principal component analysis with Varimax rotation method was performed, Eigen values greater than or equal to 1 were retained and item with loading equal to or greater than 0.4 were considered satisfactory. In addition, factor analysis was done for construct validity. Construct validity was assessed by calculating Spearman's correlation coefficient (rs) and comparing the extent to which expected relationships between the various constructs were fulfilled using the KOOS-G. Expected relationships were based on the literature. A correlation coefficient of zero indicates that no linear relationship exists between two continuous variables, and a correlation coefficient of -1 or +1 indicates a perfect linear relationship. The strength of relationship can be anywhere between - 1 and +1. The stronger the correlation, the closer the correlation coefficient comes to ±1. If the

- Coefficient is a positive number, the variables are directly related (i.e., as the value of one variable goes up, the value of the other also tends to do so). If, on the other hand, the coefficient is a negative number, the variables are inversely related (i.e., as the value of one variable goes up, the value of the other tends to go down).[29]
- **STATISTICAL ANALYSIS-** Statistical analysis for Descriptive statistics (percentages, means, and standard deviations) was used to describe demographic characteristics within the study. All analyses of reliability and validity described in the research methods were conducted using SPSS version 20.0 (IBM, Armonk, NY, USA) for Windows with a 95% confidence interval (CI).

Tests of Normality

	Kolmogorov-Smirnov[a]		
	Statistic	**df**	**Sig.**
AGE	0.097	105	0.017
PAING	0.166	105	0
SYMPTOMSG	0.125	105	0
ADLG	0.113	105	0.002
SPORTG	0.152	105	0
QQLG	0.139	105	0
PAINE	0.165	105	0
SYMPTOMSE	0.122	105	0.001
ADLE	0.113	105	0.002
SPORTSE	0.152	105	0
QQLE	0.139	105	0
SF12	0.125	105	0
LEFS	0.072	105	.200*
VAS	0.081	105	0.089

- **RESULT**-Data were checked for normality using Kolmogorov Smirnov test. P-value was less than 0.05; hence data was not normally distributed. (TABLE -6.1) Descriptive statistics
- Were used to describe demographic characteristics within the study. (TABLE – 6.2) The demographic and clinical characteristics of the patients are presented. (TABLE -6.3) A total 105 patients with knee pain (male – 47, female – 58) participate in the study (GRAPH-6.1). Different diagnoses of the knee pain are presented. (TABLE-6.4)

❖ TABLE – 3 ILLUSTRATES TABLE FOR NORMALITY DISTRIBUTION OF KOOS – G

Descriptive Statistics					
	N	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
AGE	105	19	70	44.90	12.502
PAING	105	11	97	62.46	18.251
SYMPTOMSG	105	21	82	52.84	11.383
ADLG	105	15	94	62.27	20.091
SPORTG	105	0	100	48.38	35.359
QQLG	105	13	88	45.40	17.433
SF12	105	22	36	29.22	3.527
LEFS	105	5	71	43.89	15.336
VAS	105	2.10	7.50	4.6124	1.16798
Valid N (listwise)	105				

❖ TABLE – 4 ILLUSTRATES DESCRIPTIVE STATISTICS OF KOOS – G

BASELINE CHARACTERISTICS OF KNEE PAIN PATIENTS	**VALUES**
Subject	105
Age in years- mean (SD)	44.90±12.502
Female	58
Male	47

DIAGNOSIS OF KNEE PAIN SUBJECTS	**N**	**%**
FRACTURE AROUND KNEE JOINT	20	19.047
ACL RUPTURE - RECONSTRUCTION	23	21.9
MENISCUS REPAIR - MENISECTOMY	14	13.33
TKR	11	10.47
OSTEOARTHARITIS	37	35.23
TOTAL	105	

TABLE – 6 ILLUSTRATESDIAGNOSIS OF KNEE PAIN SUBJECTS

RELABILITY –

For the 5 subscale of KOOS-G , the Interclass Correlation Coefficient (ICC**)** were for pain 0.999 , for symptoms 0.995, for Activities of Daily Living (ADL) 1.000, for Sport and Recreation Function – 1.000, for Knee-related Quality of Life (QOL) 0.997.(TABLE -7)

KOOS-G	**Baseline score**	**Retest score**	**Cronbach's alpha**	**ICC (95% CI)**	**SEM**	**MDC**	**% of Floor / ceiling**
KOOS – PAIN	63.43	63.27	0.999	0.999 (0.998-1.000)	1.781	4.935	0/0
KOOS-SYMPTOMS	51.53	51.90	0.995	0.995 (0.989-0.997)	1.111	3.079	0/0
KOOS-ADL	64.30	64.17	1.000	1.000 (1.000-1.000)	1.961	5.434	0/0
KOSS-SPORT	49.17	48.83	1.000	1.000 (0.999-1.000)	3.451	9.564	22.85/0
KOOS-QQL	48.03	47.83	0.997	0.997 (0.994-0.999)	1.701	4.714	0/0
TOTAL	55.29	55.2	0.9982	0.9952	2.001	5.548	

TABLE 7 – ILLUSTATES TEST-RETEST RELABILITY, SEM AND MDC OF KOOS – G

Based on the 95% confidence interval of the ICC estimate, values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent reliability, respectively.[26] Hence the ICC for all the subscales ranged between 0.995-1.000, which suggests that KOOS G have excellent reliability

Internal consistency, as measured by Cronbach's alpha, for the subscale Pain was0.999, for Symptoms was 0.995, for Activities of Daily Living (ADL) was 1.000, for Sport and Recreation Function was 1.000, and for Knee-related Quality of Life (QOL) was 0.997.(TABLE – 5) George and Mallery (2003) provide the following rules of thumb: "_ > .9 – Excellent, _ > .8 – Good, _ > .7 – Acceptable, _ > .6 – Questionable, _ > .5 – Poor, and _ < .5 – Unacceptable"(42) Hence the KOOS G scale showed excellent internal consistency in all the subscales pain, symptoms, ADL, Sports and recreation function.

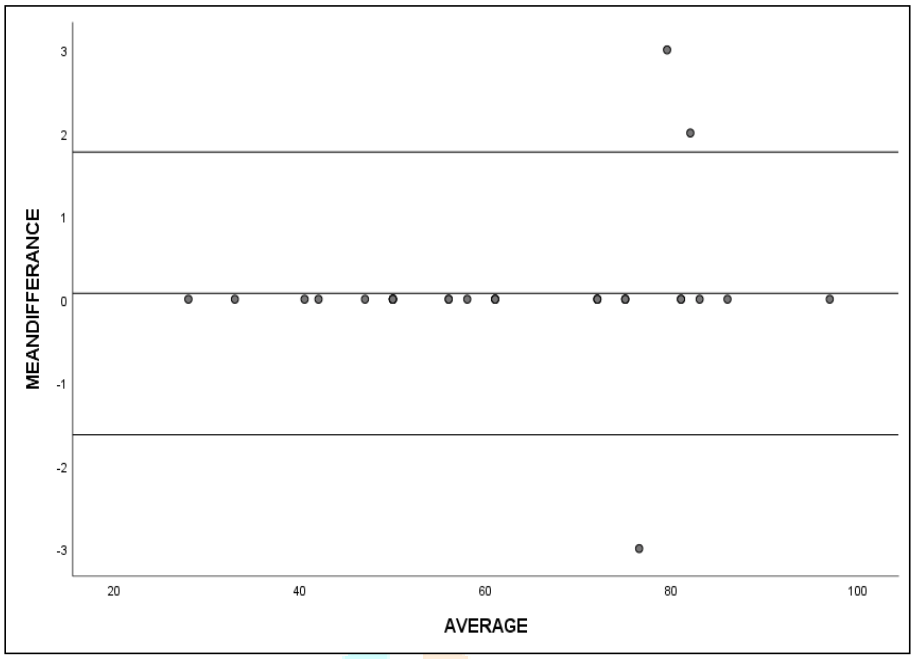
Table -7 shows the (Standard Error Mean) SEM which is a measure of absolute reliability, the smaller the SEM, the more reliable measurement, SEM value calculated for variability in measurements scale of baseline and retest score. SEM values range between 1.111 -3.451 which suggest that KOOS G is a reliable measurement scale. The MDC was calculated as 1.96 √2× SEM. MDC value range between 3.079 – 6.564.

The Bland–Altman limits of agreement analysis between two measurements

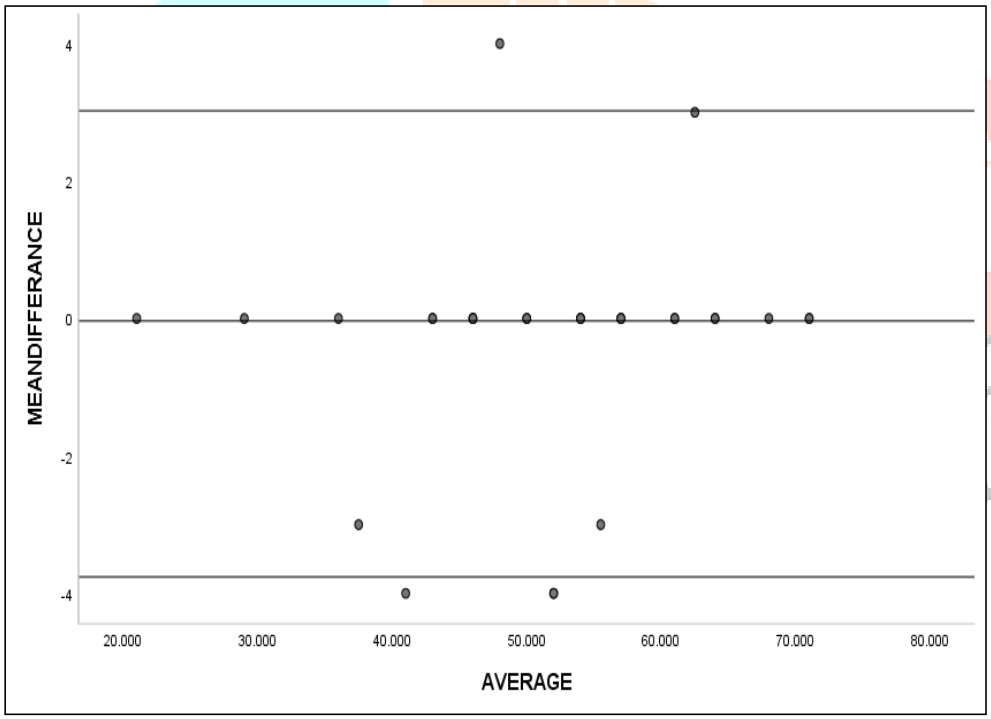
The bland and Altman plot indicated that measure of within subject variation, the bias was very minimal as the mean difference was close to zero and the limits of agreements were excellent. [27]

KOOS – G SUBSCALE	MEAN	S.D	UPPER LIMIT (MEAN +1.96×S.D)	LOWER LIMIT (MEAN-1.96×S.D)
KOOS – PAIN	.07	.868	1.77	-1.631
KOOS-SYMPTOMS	-.37	1.732	3.024	-3.7608
KOOS-ADL	.13	.571	1.249	-0.989
KOSS-SPORT	.000	.000	.000	.000
KOOS-QQL	.000	.000	.000	.000

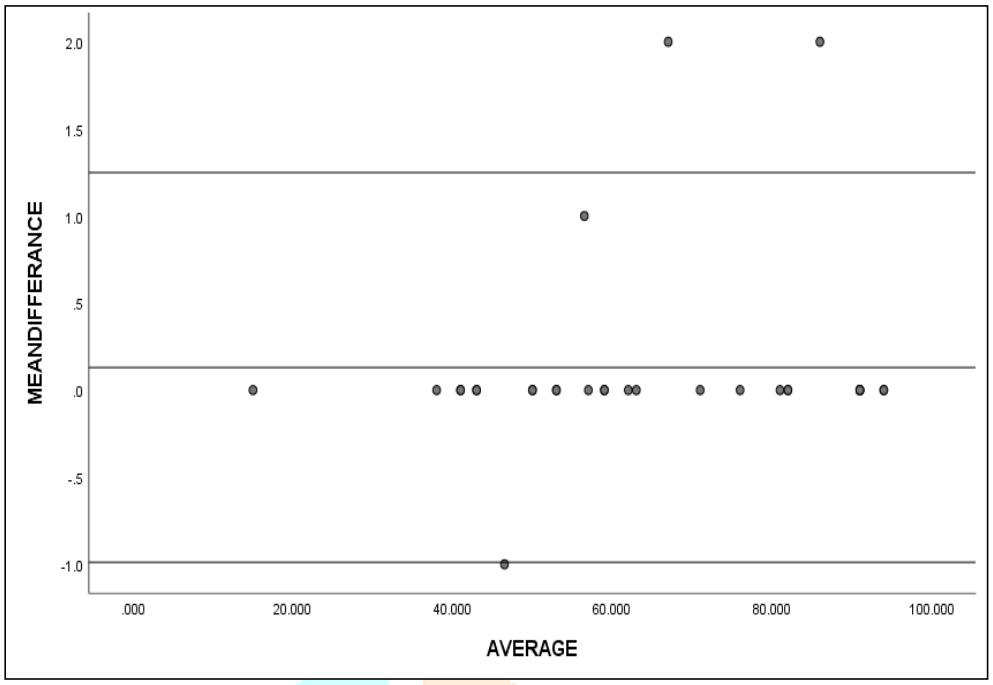
TABLE-8 ILLUSTRATED BLAND AND ALTMAN PLOTTING WITH LIMITS OF AGGREMENT OF KOOS – G



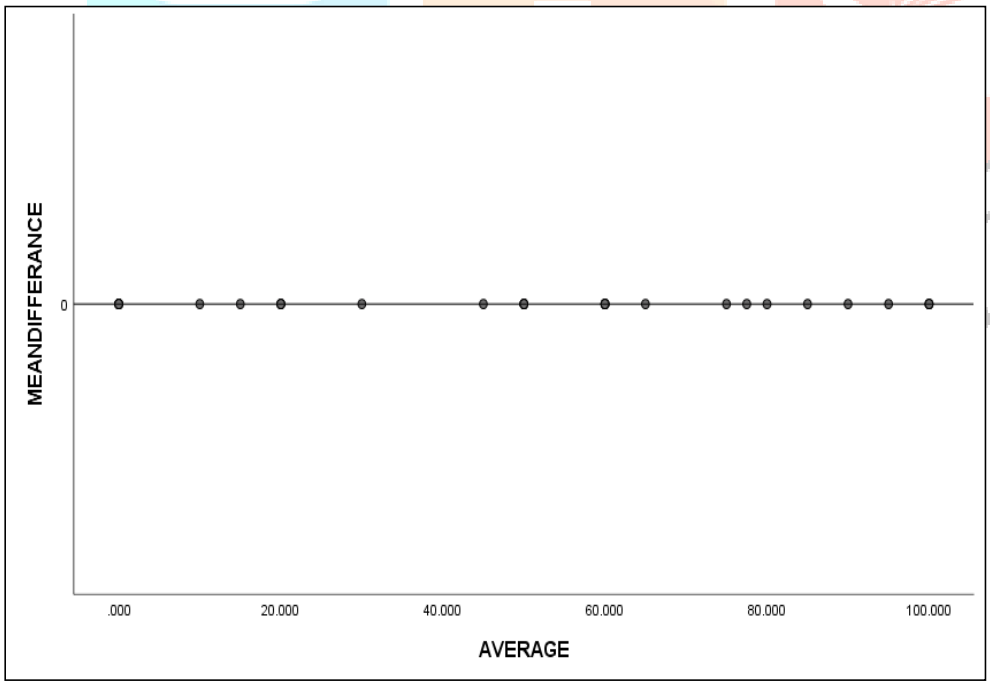
GRAPH 2 - ILLUSTRATES BLAND AND ALTMAN PLOTTING FOR KOOS-G PAIN.



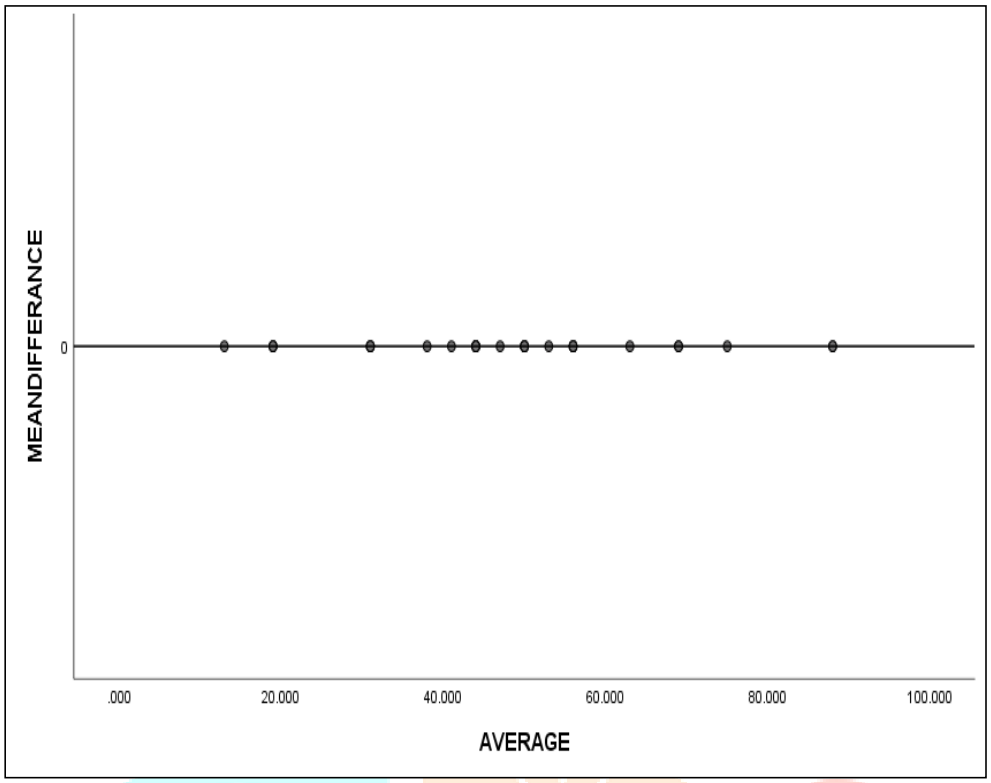
GRAPH 3 - ILLUSTRATES BLAND AND ALTMAN PLOTTING FOR KOOS-G SYMPTOMS.



GRAPH 4 - ILLUSTRATES BLAND AND ALTMAN PLOTTING FOR KOOS-G ADL.



GRAPH 5 - ILLUSTRATES BLAND AND ALTMAN PLOTTING FOR KOOS-G SPORTS.



GRAPH 6 - ILLUSTRATES BLAND AND ALTMAN PLOTTING FOR KOOS-G QQL.

FACE VALIDITY–face validity of the KOOS G was established when all the 105 patients questioned about the relevance of the scale answered YES.i.e 100%

CONTENT VALIDITY -

Content equivalence was assessed under two headings:

1. Are the words in the translated Guajarati version of KOOS presented fluently and correctly as in the original version? For this answers from expert panel member's fall between "strongly disagree" to "strongly agree" on a 5 point likert scale. (Average= 4.25)

2. Do the words and phrase in the translated Gujarati version of KOOS have the same semantic meaning compared with the original version?

For this answers from expert panel member's fall between "strongly disagree" to "strongly agree". (Average =4.25)

Content relevance

This was assessed by asking this question: how the Guajarati statement is relevant to assessing KOOS questionnaire in knee pain patients? For this answers from expert panel member's fall between "strongly disagree" to "strongly agree" on a 5 point Likertscale. (Average = 4.25)

Potential floor and ceiling effects were thought to be present if more than 15% of the respondents attained the highest or lowest possible score, respectively.[30]

The number of patients receiving floor and ceiling effect was zero for the KOOS – G, with one exception, for the subscale sport/Rec, 24 subjects (22.85 %) reported worst possible score. (TABLE – 7)

CONSTRUCT VALIDITY

Construct validity is frequently measured as convergent and divergent validity and factor analysis. In this study, convergent validity was evaluated by a parallel questionnaire LEFS. Divergent validity was evaluated with spearman correlation coefficient by showing that KOOS G concept of measurement is different from severity of pain, symptoms, ADL, Sports and Recreation Function and QOL.

SPEARMAN' S CORRELATIONS					
			PAIN	SYMPTOMS	VAS
Spearman's rho	PAIN	Correlation Coefficient	1.000	.307	-.097
		Sig. (2-tailed)		.001	.326
	SYMPTOMS	Correlation Coefficient	.307	1.000	-.159
		Sig. (2-tailed)	.001		.105
	VAS	Correlation Coefficient	-.097	-.159	1.000
		Sig. (2-tailed)	.326	.105	

TABLE – 10 ILLUSTATES SPEARMAN'S CORRELATION OF ADL AND SPORTS COMPONENT OF KOOS G WITH LEFS.

In convergent validity there was a positive correlation of ADL and sports with LEFS. There was a positive correlation between LEFS and ADL (r=0.85) and between LEFS and sports (r=0.17). (Table -10)

SPEARMAN'S Correlations				
			QQL	SF12
Spearman's rho	QQL	Correlation Coefficient	1.000	.083
		Sig. (2-tailed)		.400
	SF12	Correlation Coefficient	.083	1.000
		Sig. (2-tailed)	.400	

TABLE – 11 ILLUSTATES SPEARMAN'S CORELATION OF QOL COMPONENT OF KOOS G WITH SF -12.

In convergent validity there was a positive correlation of QQL with SF-12. Which show that with SF-12 there was a positive correlation between SF-12 AND QQL (R=0.083). (Table - 11)

SPEARMAN' S Correlations					
			PAIN	SYMPTOMS	VAS
Spearman's rho	PAIN	Correlation Coefficient	1.000	.307	-.097
		Sig. (2-tailed)		.001	.326
	SYMPTOMS	Correlation Coefficient	.307	1.000	-.159
		Sig. (2-tailed)	.001		.105
	VAS	Correlation Coefficient	-.097	-.159	1.000
		Sig. (2-tailed)	.326	.105	

TABLE - 12 ILLUSTATES SPEARMAN'S CORRELATION OF PAIN AND SYMPTOMS COMPONENT OF KOOS G WITH VAS.

Table 12 shows the divergent validity correlation of pain and symptoms of KOOS with VAS. Which was confirmed by negative correlation between VAS AND PAIN(R = -.097) AND SYMPTOMS AND VAS (R= -0.159)

SPEARMAN'S Correlations					
			ADL	SPORTS	LEFS
Spearman's rho	ADL	Correlation Coefficient	1.000	.620	.085
		Sig. (2-tailed)		.000	.389
	SPORTS	Correlation Coefficient	.620	1.000	.017
		Sig. (2-tailed)	.000		.865
	LEFS	Correlation Coefficient	.085	.017	1.000
		Sig. (2-tailed)	.389	.865	

TABLE.13 – ILLUSTRATES SPEARMAN'S CORRELATION OF ADL AND SPORTS COMPONENT OF KOOS G WITH LEFS.

Convergent validity was confirmed by positive correlation of ADL AND SPORTS with LEFS. Correlation between LEFS and ADL was (R=0.85) AND between LEFS and SPORTS (R=0.17). (TABLE.13)

SPEARMAN'S Correlations				
			QQL	SF12
Spearman's rho	QQL	Correlation Coefficient	1.000	.083
		Sig. (2-tailed)		.400
	SF12	Correlation Coefficient	.083	1.000
		Sig. (2-tailed)	.400	

TABLE - 14 ILLUSTATES SPEARMAN'S CORELATION OF QOL COMPONENT OF KOOS G WITH SF -12.

Convergent validity was supported by a positive correlation of QQL with SF-12, SF-12 and QQL (R=0.083). (Table14)

FACTOR ANALYSIS

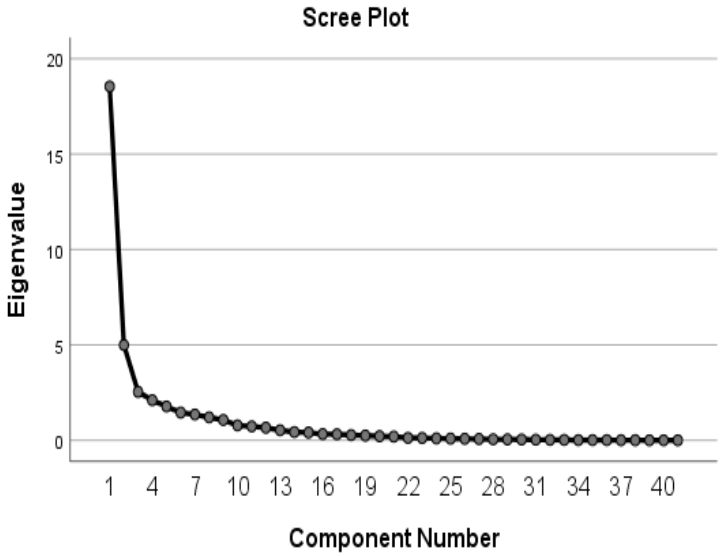
Exploratory factor analysis was performed to determine the dimensionality of the items of the questionnaires. Factor structure was analyzed using principal component analysis (PCA) with varimax rotation method. A PCA was run to establish construct validity of the items in the scale. In Factor analysis, the scree plot indicates that two factors may be adequate to describe the data. The initial solution accounted for 45.25 % of the total variance for the Gujarati version of the KOOS questionnaire (Eigen value of 18.54 for the first factor and 4.9 for the second factor). Many items loaded on both factors when the two factor solutions are used. Therefore, a forced one-factor solution was chosen which accounted for 53.3% of the variance.

Kaiser-Meyer-Olkin Value ID was 6.14,which suggested a moderate sampling Adequacy .(TABLE 15)

The acceptable level of communalities and factor loadings for items was kept at 0.5. (31)Five factors were extracted for the KOOS G. The five factors were identified as pain(factor 1),symptoms(factor2),activities of daily living(factor 3),sports and recreation (factor 4) and quality of life (factor 5).

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.614
Bartlett's Test of Sphericity	Approx. Chi-Square	7247.146
	df	820
	Sig.	.000

TABLE –15 ILLUSTRATES KMO VALUE FOR SAMPLING ADEQUACY



GRAPH –7 ILLUSTRATES SCREE PLOT OF FACTOR ANALYSIS

Rotated Component Matrix[a]

	Component				
	1	2	3	4	5
q29	.785*				
q11	.761*				
q22	.759*				
q21	.753*				
q16	.718*				
q26	.697				
q27	.650				
q42	.645				
q28	.626				
q23	.597				
q15	.595				
q25	.573	.536			
q9	.557				

q18	.530				
q6	.530				
q17	.528			.513	
q36		.869*			
q34		.868*			
q35		.861*			
tq38		.828*			
q37		.816*			
q32		.760*			
q33		.673			
q1		.645			
q30		.548			
q31		.508			
q7					
q20			.765*		
q12			.745*		
q24			.737*		
q14			.699*		
q10			.660		
q13			.594		
q4					
q8				.774*	
q39				.678*	
q3				.666	
q19				.508	
q2					.682*

q41					.668*
q5					.536
Extraction Method: Principal Component Analysis. ,Rotation Method: Varimax with Kaiser Normalization factor loading of 0.5 or more are displayed here.					
*factor upon which item loaded most heavily					

TABLE – 16 ILLUSTRATES FACTOR ANALYSIS

DISSCUSION

There is a need for a reliable and valid instrument of Gujarati version of KOOS that can be used to research and measure outcome in people with knee pain. There is at present no valid and tested version of Gujarati KOOS for use in Gujarati speaking country; therefore our aim wascross-cultural adaptation and translation of KOOS into Gujarati language and establish its Reliability and validity in patients with knee pain. The Psychometric properties of the translated version were evaluated and found satisfactory. The rigorous testing for the questionnaire could provide reliable result for other studies.

The results indicated that the Gujarati version of KOOS has good validity, and that the questionnaire is a reliable measure of pain, symptoms, Activities of daily living, sport and recreation, and quality of life in patients with knee injuries of different kind.

The acceptability of Gujarati version of KOOS was in general very good, no disturbing questions, few confusing items, very low percentage of missing data for items and scales, and the time taken to complete the questionnaire was relatively short. These facts confirm the absence of problems related to translation, and that it is a reliable and valid measure for Gujarati patients with a variety of knee pain. The mean score of the sport and recreation function subscale was markedly higher than the scores of other KOOS subscales, and have been previously reported.[32, 33]

Reliability

The present study determined test- retest reliability of KOOS –G scale in patients with knee pain. The intra rater reliability of the KOOS – G scale was tested by Intraclass correlation coefficient. ICC for KOOS G Pain was 0.99 ,for Symptoms was 0.995, for Activities of daily living (ADL) was1.000, for Sport and recreation function was 1.000, for knee-related quality of life (QOL) was 0.997. ICC value greater than 0.90 indicate excellent reliability of KOOS – G subscales. (26)This is comparable to findings in studies done in other languageswith similar conditions including the original study 0.75 - 0.93 by Roos et al.(31) and 0.75 - 0.89 by Seo et al.(20), 0.61 - 0.91 by Salavati et al.(30), 0.85 - 0.95 and by Monticone et al.[21]

This result is comparable to observations in other languages and patient populations, such as in the Swedish version with preoperative patients [31], the Dutch version with patients with focal cartilage defects [38], the Persian version with patients with knee injuries [30], and the Singapore English and Singapore Chinese [33], Dutch [34], French [35]versions with knee OA patients.

The internal consistencywas satisfactory for all of five subscales, with the correspondent items properly correlated with each other.

The Cronbach's alpha, for the subscale pain was 0.999, for symptoms was 0.995, for Activities of daily living (ADL) was 1.000, for Sport and recreation function was 1.000, and for knee-related quality of life (QOL) was 0.997. According toGeorge and Mallery *(2003)* [35] rules of thumb there is excellent reliability of KOOS – G scale. The authors concluded that this might be due to the relative homogeneity of patient. Accordingly, it has been claimed that, for clinical application, high Cronbach's α values, of at least 0.90, are needed [36]. In this study, the high value for Cronbach's alpha indicates good internal consistency of the items in the scale.

The MDC value of 5.5 points at the group level indicates that the Gujarati version of the KOOS has an ability to detect a minimum change of 5.5 points between the measurements. The MDC should be smaller than the minimal important change (MIC), which is regarded as the smallest change score needed for the effect to be considered clinically relevant. [38]

For the different KOOS subscales a MIC of 8–10 points has been considered to be appropriate. [38] Thus the Gujarati version of the KOOS is applicable to detect such a change without difficulties.

In studies of patients with knee injury, the MDC ranges for KOOS pain ranged between 6-6.1, for KOOS symptoms ranged between 5-8.5, for KOOS ADL ranged between 7-8, for KOOS sport/rec ranged between 5.8-12, and for KOOS QOL ranged between 7-7.2 (39).

A study including patients with knee OA, the MDC'S for KOOS pain was 13.4, for KOOS symptoms was15.5, for KOOS ADL was 15.4, for KOOS Sport/Rec was 19.6, and for KOOS QOL was 21.1 (39)However, it is important to note that the mentioned MDC values apply to patients and not to individual patient.

This is fact that all measurement fell within the 95% of Confidence interval around the mean difference during the Bland and Altman plotting. Analysis point out very strong agreement between the measurements on two occasions with very minimal within subject variation s. In sports and QOL, the mean difference was 0.000,which indicate strong agreement between measurements.

Construct validity

Validation of instruments assessing patient-relevant outcomes is difficult since no golden standard is available for comparisons. instead, construct validity has been assessed by correlating the new measure to already existing well-validated measures measuring similar constructs (convergent construct validity) and dissimilar constructs (divergent construct validity). [31]

The construct validity of the KOOS G was determined by comparing the KOOS G subscales with the scales of SF- 12, LEFS and VAS.

The KOOS G subscales are as representative as those of the measuring scale. It was therefore expected that correlations between the KOOS and other scales would be found.

Construct validity was supported by the presence of positive correlation between KOOS G ADL/Sports and LEFS(convergent validity) and there was negative correlation between KOOS-G Pain/Symptoms/QOL and SF-12(divergent validity) .These findings are similar to those of the original developers and most cross-national adaptations.[30, 40]When the KOOS and SF-36 were compared for construct validity, we found strong correlations between the KOOS subscales and those of the SF-36 that measured similar constructs. The highest correlations were observed between the SF-36 subscale of Physical Functioning and the KOOS subscales of ADL and Pain. The SF-36 subscale of Bodily Pain and the KOOS subscales of Pain and ADL

also showed strong correlations. In contrast, the KOOS subscale of Symptoms showed the lowest correlations with all the SF-36 subscales. This is in line with the findings of Salavati et al. (2008) in patients with knee injuries, and of Roos et al. (1998) in subjects with knee OA. In fact, Roos et al. concluded that the KOOS Symptoms subscale is not as important as the other four subscales as a determinate of Physical Health. The authors suggested that symptoms and functional limitations should be reported separately and not aggregated into a single score [31].All in all, the construct validity for the patients in our study was at more or less the same level as observed in patients with knee injuries[30]and less severe forms of OA, but higher than that obtained in elderly patients with advanced OA eligible for total joint replacement. [33, 41]

The visual analogue scale used in this study measures the intensity of pain experienced in general as well as in specific body regions. As expected, strong and moderate correlations was found between all the KOOS-G Subscales and VAS, particularly those focus [42]using on the lower extremities and the knee region. These findings, in conjunction with the fact that self-reported knee pain was more severe than pain in any other body region, confirm the utility of the KOOS-G as a lower-extremity PRO measure in subjects with diverse knee problems. It was also noted that there was strong correlations between the Pain VAS, and LEFS and the KOOS Activities of Daily Living subscale. This is understandable, given that the knee is a large weight-bearing joint with a large range of movements, and that managing the activities of daily living presumes an extensive repertoire of pain-free weight-bearing movements. However, somewhat surprisingly, the KOOS Pain subscale correlated only strongly instead of, as expected, very strongly with the Pain-VAS . This is most likely due to only partial similarity between the constructs in the two subscales. While the nine-item KOOS Pain subscale is designed to elicit the prevalence and degree of pain during different activities and rest, the Pain-VAS consists of a single item in asking about the intensity of pain experienced during the past week. Nevertheless, the use of the Pain-VAS yielded new information, since to our knowledge no previous KOOS validation studies have investigated the correlations between the KOOS-G PAIN subscale and Pain-VAS ..

The results of factor analysis of 42 items of the KOOS G are mentioned in table .total 5 components were extracted which are similar to 5 subscales of KOOS E. The 5 factors were identified as pain(items loaded were q6,q9,q11,q15,q16,q17q18q22,q23,q25,26,q27,q28,q42) and maximum loading was on Q29.,symptoms(items loaded were Q30,31,32,33,34,35,36,3738) and maximum loading was on Q34,35

,36.,ADL(items loaded were Q 10,12,13,14,20,24) and maximum loading was on Q20,Sports and recreation(items loaded were Q3,8,19,39) and maximum loading was on Q 8.Quality of life(items loaded were Q2,5,41) and maximum loading was on Q 2. The result of the item analysis also suggests that all five subscales are acceptable for inclusion in the Gujarati version of KOOS. This demonstrates the appropriateness and comprehensiveness of the questionnaire for a patient population with relatively moderate knee pain and other knee injury symptoms.

8. CONCLUSION

The result of this current study provided us with preliminary evidence that the KOOS-G version is reliable and valid measure to assess the knee pain in Gujarati-speaking subjects. This study result suggest that the KOOS-G has been successfully translated and cross culturally adapted from English to Gujarati, The preliminary evidence generated by the psychometric testing show that the Gujarati version of KOOS demonstrates psychometric properties similar to English version.

LIMITATION OF THE STUDY- Sample size was small.

- Study does not present with entire spectrum of knee OA and some common knee complaints affecting pain, such as patella femoral pain syndrome, rheumatoid arthritis, Plica syndrome, banker cyst and bursitis.
- **FUTURE RECOMMENDATION**
- In future this study can be recommended for further validation and consideration of its responsiveness with a larger number of patients with knee complaints in all prospective
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