

Reliability and Concurrent Validity of 5cm-Microplastic Meter Ruler and 5mm Diameter-Nozzle Syringe for Dosage specification using Topical Diclofenac Gel and Methyl Salicilate Cream formulations

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Reliability and Concurrent Validity of 5cm-Microplastic Meter Ruler and 5mm Diameter-Nozzle Syringe for Dosage specification using Topical Diclofenac Gel and Methyl salicylate Cream formulations

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Project title: Reliability and Concurrent Validity of 5cm-Microplastic Meter Ruler and 5mm Diameter-Nozzle Syringe for Dosage specification using Topical Diclofenac Gel and Methyl salicylate Cream formulations

Abstract

Background: Finger Tip Unit (FTU) is used for dosage specifications of topical medications but has no metric value, hence, there is risk of over-dosage. Portable tools are being proposed but there is dearth of empirical data to support their reliability. The study aimed to determine the reliability and concurrent-validity of a 5cm-Microplastic ruler and a 5mm-diameter nozzle syringe.

Methods: 621 patients with musculoskeletal disorders participated in the correlation study. The test instruments were 5cm-Microplastic ruler, 5mm-diameter nozzle syringe, methyl salicylate cream and diclofenac gel. Each participant (Tester 1) measured the Finger Tip Unit Metric Length (FTUML) and the investigators (Tester 2) re-measured. Both testers ejected the cream from a standard tube on a 5cm-Microplastic ruler to reproduce the initial FTUML, and quantified the length of cream ejected. Both testers were blinded to each other's measurements. The same procedures were adopted for the gel. The modified syringe with simulated 5mm opening was filled to 6mL with the cream or gel, and both Testers ejected the medication to produce one FTU. The difference between 6mL and the remaining volume was recorded as the quantity of cream or gel ejected. Measurements were documented on two testing days, with test-retest interval of 4 weeks. Data were analyzed using descriptive statistics and Pearson's product-moment correlation co-efficient.

Results: Both within and across the testers, significant correlations were obtained for the quantification the length of the cream and gel using the 5cm-Microplastic ruler, ranged from $r = 0.23$ to 0.88 ($p = 0.001$). Using the syringe, significant correlations were also observed for the cream and gel ($r = 0.41$ to 0.91 , $p = 0.001$). There were low negative correlations with the amount cream and gel formulations ejected for both tools ($r = -0.10$, $p = 0.01$; $r = -0.09$, $p = 0.02$).

Conclusion: Moderate intra- and inter-tester agreement was observed for cream and gel dosages when measured with the 5cm-Microplastic ruler and 5mm-diameter syringe over a 4-week test-retest interval. This indicates potential reliability, noting that correlation coefficients alone do not confirm reliability. However, there was no strong evidence of agreement between the two measurement tools.

Keywords: Topical medications, Dosage specificity, Reliability, Validity, microplastic ruler, 5mm-diameter nozzle syringe

1 Background

There is increasing popularity in the usage of topical medications among physiotherapists, nurses, patients, caregivers and other health professionals. The administration of topical medications in different formulations had been proven to be an effective means of drug delivery, with minimal systemic side effects because it avoid gastrointestinal irritation and hepatic first-pass effect, but reaches the lesion directly without much adverse reactions [1,2]. According to Zhao et al (2024), [1], Topical medications are in four categories, namely; 1. those where absorption is unnecessary, 2. medications where is no spreading in the skin tissue, 3. a class of those that reaches the deeper tissues and 4. drugs that cross the skin into blood vessels and other tissues or organs. Of utmost clinical importance to physiotherapists are

the second and third classes. However, it has been a huge challenge to quantify the specific dose for topical medications for specific regions of the body in clinical physiotherapy practice; and it is pertinent to use the precise dosage in order to avoid the risk of side effects [3]. Despite the importance of transdermal administration of topical medications, limited focus is placed on adequacy of dosage specification and this has been the major bane of providing qualitative care for clients[4]. The Finger Tip Unit (FTU) that was postulated by Long and Finlay (1991)[5] to be a means of quantifying dosages is considered to be rough guides for the application of topical medications but it is associated with several setbacks[6]. Buttressing this, is the report of Matsuki et al (2025) [7] who observed that over one-third of patients in Japan that participated in a cross-sectional survey had faulty FTU-based prescription, and application insufficiency for the usage of topical corticosteroid.

Most previous rehabilitative clinical trials in physiotherapy, speculated dosages for topical medications using the Finger Tip Unit (FTU) to provide evidences for the efficacy of transdermal application of some drugs especially in pathologies with neuropathic pains, musculoskeletal disorders, spasticity and decubitus ulcers[7,8,9,10]. Onigbinde et al (2021)[11] considered FTU to have no metric value, hence, the use of Finger Tip Unit Metric Length (FTUML) was introduced using a flexible tape rule to measure the length of topical medications from the crease to the tip of the index finger as described by Long and Finlay (1991)[5]. Few studies had made attempts to establish the Inter-rater reliability of the Tape ruler but the major problems observed with the usage are the clumsy longer length and loose flexibility; making it in-appropriate for clinical application, especially in obese and patients with musculoskeletal disorders[12,13]. There is also speculation that the use of physiotherapist's FTUML to quantify the dose of topical medications for clients might be inappropriate with the likely risk of either under or over dosage[14].

The use of a clinical syringe tube with a modified and simulated 5mm opening is also being speculated to be another versatile means of volumetric quantification of topical medications[11]. Although, Onigbinde et al (2021)[11] established the reliability of the modified syringe but the external validity is in doubt because of the small sample size ($n = 50$). In view of these, there is the need to develop a standard micro-plastic meter ruler and 5mm nozzle syringe that will be useful for clinical application of topical medications. The few available reliability and validity studies did not involve patients but utilized apparently healthy individuals.

Furthermore, Onigbinde and Aliyu (2022)[15] found that the mean volume of gel and cream expelled from a syringe differed and were at variance, despite using the same tool (Onigbinde et al, 2021)[11]. The methyl salicylate cream used in the study was a semi-solid emulsion or mixture of oil-soluble drug and hydrophilic (water-soluble) base whereas the diclofenac gel is a semisolid dosage form with viscosity and consistency that consists of a network of small molecules or polymers, dispersed within a liquid medium[1, 16]. The implication of this is that same dosage of topical medications cannot be prescribed for drugs of different

formulations, hence, the need to establish appropriate doses for different topical formulations. In addition, the 5mm diameter nozzle syringe tube was found to be reliable as a tool but it has no concurrent validity with the plastic meter ruler to quantify diclofenac sodium gel[15]. Most test-retest intervals in previous studies were within two weeks, whereas, a very short interval creates an easy carryover effect, whereas a longer duration, increases the chances that a change in status could occur, hence, creating a better reliability evaluation[17,18]. The gaps, inconsistencies, limitations and veridancy of topical dosage specification for topical medications necessitated this study. The objectives of this study were to determine the intra-tester and inter-tester reliability of the a 5cm-Microplastic ruler and 5mm nozzle syringe to quantify dosage of topical medications (cream and gel) on two testing days with a test-retest interval of 4 weeks

2 Materials and Methods

2.1 Study settings

There are five studying settings, namely, Unimed Teaching Hospital, Ondo, Ondo state; State hospital, Ondo, Ondo state, Uniosun Teaching Hospital, Osogbo, Osun state, Unimed Teaching Hospital, Akure, Ondo state and State hospital, Ila, Osun state, Nigeria.

2.2 Participants

Six hundred and twenty one patients with musculoskeletal disorders participated in the study.

2.3 Inclusion and Exclusion criteria

Included in the study were patients with musculoskeletal dysfunctions whose ages were between 5 and 80 years and were literate enough to read measurements on any scale. Excluded were patients with Hand or finger deformity, recent musculoskeletal injuries to the lower extremities, history of congenital or acquired deformity, polyarthritis or Rheumatoid Arthritis of the hand.

2.4 Instruments

One thousand pieces of 5cm-Microplastic rulers (Tesonigmeter- Figure 1) with a width of 5mm, to simulate the width of a standard nozzle tube of a cream/gel. The pieces were

produced from 1000 standard 15cm-Plastic rulers, using Slicers which had been heated in an Electric oven. Similarly, 1000 pieces of standard 10mL of syringe tube was restructured by removing the needle nozzle, and an opening was bored to simulate the width of a standard nozzle tube of a cream/gel [Tesonig-syringe], (Figure 2). The opening was bored using a heated 5mm width iron rod. The plastic metre ruler was calibrated in centimeters(cm) and measured to the nearest 0.1 centimeter while the 5mm diameter Nozzle syringe was in milliliter (mL).

The 5cm-Microplastic rulers and the modified syringe were produced by a Technologist (Research Assistant) at the Orthotic unit of the University of Medical Sciences, Ondo, Ondo state, Nigeria. Other instruments used were Diclofenac sodium gel and 85g Methyl salicylate cream. The practicality of patients understanding quantification of dosages using micro-plastic meter ruler and syringe tube might be a challenge, hence, a 3- minute tutorial video clip was produced for the patients to understand the usage of a 5cm-Microplastic ruler and modified syringe to measure one FTU.

The video production involved the usage of the Touchscreen Professional Video Camera 4K with relevant components. A script was prepared ahead of the shooting and it was perused and edited by 10 physiotherapists until it was certified to be appropriate for video production. Similarly, the video produced was edited by the principal investigator and a studio engineer for content validity for the purpose of teaching the usage of 5cm-Microplastic ruler and 5mm diameter-nozzle syringe to quantify topical medications. Post video evaluation was also done by the 10 physiotherapists who prepared the initial script.

2.5 Sample Technique

The sample size of 1000 patients was obtained using Cochran's sample size formula as reported by Lonas (2025)[19] using 95% confidence level ($Z = 1.96$), a maximum variability ($p = 0.5$), and a 3% margin of error ($e = 0.03$) equation. However, only six hundred and twenty one patients completed the study. The study suffered attrition because of the test-retest interval of 4 weeks. Most patient did not turn up for re-evaluation, making the overall response rate to be 62.2% at the end of the 4th week. Sample of convenience was used to select 5 hospitals in the south west of Nigeria while purposive sampling technique was used to select patients who met the inclusion criteria.

2.6 Research design

The research design was a Correlation study.

2.7 Procedures

Ethical approval was obtained from the Health Research and Ethics Committee of the University of Medical Sciences, Ondo, Ondo state, Nigeria (UNIMED-HREC-Apv/2025/180). Consent to participate was also sought from the patients and the caregivers of children who were below the age of 18 years. The purposes and procedures of the of the research work was explained to each patients or caregivers. The height and weight of each patient were measured using standard procedures as described by Macinuis et al (2003). The Body Mass Index (BMI) was computed by dividing the weight by the square of the height(weight/height² (kg/m²). Prior to data collection, all the patients were given the opportunity to watch the 3-minutes video clip until it was acknowledged that the method of application of the topical medication was well understood

The 5cm-micro-plastic ruler was used to measure the Finger Tip Unit Metric Length (FTUML) and this is the distance between the distal skin-crease of the index finger to the tip[12]. The length of both Diclofenac gel and methyl salicylate cream ejected to cover one FTU was also measured after application.

2.8 Procedure for measuring the Finger Tip Unit Metric Length (FTUML) using the 5cm-Microplastic ruler

1. The patients measured self length of the Finger Tip Unit (FTUML) and the investigators also re-measured (blinded).
2. The patients applied the cream to make one FTU (from the distal crease to the tip of the index finger). The 5cm-Microplastic ruler was then used to measure the length of the cream. The value obtained was documented as the Finger Tip Unit Metric Length (FTUML) .
3. The investigator also measured the same length of the cream using the ruler but was blinded to the previous measurements of the patients.
4. The cream was applied on the 5cm-Microplastic ruler to make up the amount of FTUML initially measured by both the patients and the investigator, blinded to each others measurements (Figure 3). Both then re-read the exact amount that was reflecting on the ruler, irrespective of the previous values. The measurements were recorded as the FTUML for the cream using micro-plastic ruler. The same procedure was adopted for the measurements of the FTUML for the diclofenac gel, and there were 2 testing days with test-retest interval of 4 weeks.



Figure 1: 5cm-Microplastic Meter Ruler



Figure 2: 5mm diameter Nozzle syringe (mL)



Figure 3: Quantification of 1 FTU of cream on a Micro-plastic Meter Ruler

2.9 Procedure for the volumetric quantification of topical medication using the 5mm Nozzle Syringe

1. Each patient filled the modified syringe to 6mL with the cream, after the tube had been cleared of air by pressing the piston against a closed tube., using the thumb.
2. This was followed by ejecting the cream or gel (Figures 4 [a & b] and 5) on the index finger from the distal crease to the tip, to make up one FTU.
3. The new level of the cream on the tube was recorded. The difference between the new level and 6mL was recorded as the volume of cream that made up one FTU. There were also 2 testing days with test-retest interval of 4 weeks for both testers. All the measurements for children below 18 years were taken by the parents or Caregivers for those who were unable to quantify accurately. All the measurements of the patients were documented as that of the Tester one (1) while those of the investigators were recorded to be that of Tester 2.



Figure 4: Ejection to make one 1 FTU for the cream and gel from the 5mm diameter nozzle syringe

2.10 Data analysis

The data were analyzed using descriptive statistics of mean and standard deviation. The Pearson's product moment correlation was used to determine the relationship between the Fingertip Unit Metric Length (FTUML) obtained from the micro-plastic meter ruler at onset and after 4 weeks. Similarly, the volume of gel expelled from the 5mm diameter of the syringe tube on day one and after 4 weeks were also determined using the Pearson's product moment correlation co-efficient. The level of significance was set at $p < 0.05$.



Figure 5: Ejection to make one 1 FTU for the cream and gel from the 5mm diameter nozzle syringe (detail)



Figure 6: Ejection to make one 1 FTU for the cream from the standard 5mm-diameter tube

3 Results

3.1 Age, Gender, Anthropometry and selected Anatomic Girths of patients

The mean age of the patients was 38.42 ± 22.16 years. The minimum and maximum age, height and weight are presented in Table 1. There are 279 male (44.93%) and 342 (55.1%) female.

3.2 Finger Tip Unit Metric Length (FTUML) using the 5cm-Microplastic ruler for the Cream and Gel

Cream and Gel

The mean Finger Tip Unit Metric Length (FTUML) measured using the 5cm- Micro-plastic ruler by both the patients (Tester 1) and the investigators (Tester 2) was 2.39 ± 0.31 cm (Table 2). Following application of the cream formulation by the patients (Tester 1) to make one FTU on the first testing day, the mean length of the cream obtained using the 5cm-Microplastic ruler was found to be 2.36 ± 0.31 cm by tester 1 while after 4 weeks, it was found to be 2.41 ± 0.36 cm (Table 2). On the first and second testing days, the second group of testers (tester 2) obtained a mean FTUML of 2.37 ± 0.31 cm and 2.45 ± 1.05 cm length of cream using the 5cm-Microplastic ruler for both days

The measurements for the FTUML for gel formulation for the first testing day were found to be 2.69 ± 0.95 cm and 2.61 ± 1.26 cm by the patients (Tester 1) and the investigators (Tester 2) respectively. Similarly, after 4 weeks, the measurements were 2.63 ± 0.76 cm and 2.56 ± 0.65 cm by the patients and the group of testers, respectively (Table 2). Other mean values obtained for the cream and gel are presented in Table 2.

Table 1: Age, weight height and BMI of participants

	Minimum	Maximum	Mean	Std. Deviation
Age (years)	5.00	80.00	38.42	22.16
Height (m)	0.90	1.85	1.61	0.18
Weight (kg)	11.00	121.00	65.85	22.39
BMI (kg/m ²)	13.33	42.97	24.67	6.63

3.3 Volumetric Quantification of the Cream and Gel using the 5mm diameter Nozzle Syringe

On the first testing day, the mean volume of cream formulation ejected from the 5mm diameter Nozzle Syringe to make one FTU by both testers were 1.13 +/- 0.59mL (Tester 1) and 1.02 +/- 0.54mL (Tester 2). At the 4th week, the mean volume of cream ejected to make one FTU by both the patients and the investigators were 1.12 +/- 0.59mL and 1.01 +/- 0.53mL respectively. Other values obtained for the volumetric quantification using the 5mm-diameter nozzle syringe are presented in Table 2.

For the gel formulation, the mean volume ejected from the 5mm diameter Nozzle Syringe to make one FTU by both the patients and the investigators on the first testing day were 1.30 +/- 0.59mL and 1.26 +/- 0.77mL respectively (Table 2). At the 4th week, the volume of cream ejected to make one FTU by both the patients and the investigators were 1.30 +/- 0.59mL and 1.24 +/- 0.63mL respectively.

*Tester 1: Patients Tester 2: Principal investigator

3.4 Intra and Inter Rater Reliability of the 5cm-Microplastic ruler and 5mm-Diameter Nozzle Syringe

There was significant correlation between the length of methyl salicylate cream quantified using the 5cm-Microplastic ruler when the values obtained for Tester 1 on day 1 and day 2 were correlated ($r = 0.54$, $p = 0.001$). Also, for tester 2, there was significant correlation when day 1 and 2 values were correlated ($r = 0.23$, $p = 0.001$). There was also significant correlation between the length of methyl salicylate cream quantified across the testers using the 5cm-Microplastic ruler on both day 1 and day 2 ($r = 0.75$, $p = 0.001$ and $r = 0.32$, $p = 0.001$ respectively). The values of other correlation coefficients obtained for the quantification of the cream and gel are presented in table 3. Furthermore, there was significant correlation between the volume of methyl salicylate cream expressed from the 5mm-diameter nozzle

Table 2: Finger Tip Unit Metric Length (FTUML) and Volumetric Quantification using 5cm-Microplastic ruler and 5mm diameter Nozzle of Syringe

Measurements	*Measured By	FTUML (cm)	Min	Max	Mean	Std. Deviation
5cm- Micro-plastic ruler	Tester 1	Actual	1.30	3.50	2.39	0.31
	Tester 2		1.40	3.10	2.39	0.31
DAY 1	Tester 1	Cream	1.40	3.20	2.36	0.31
	Tester 2		1.50	3.50	2.37	0.31
DAY 2	Tester 1		1.20	3.30	2.41	0.36
	Tester 2		1.10	2.70	2.45	1.05
DAY 1	Tester 1	Gel	1.60	8.20	2.69	0.95
	Tester 2		0.40	2.80	2.61	1.26
DAY 2	Tester 1		0.80	8.00	2.63	0.76
	Tester 2		0.40	7.60	2.56	0.65
5mm Nozzle Syringe		Volume (mL)				
DAY 1	Tester 1	Cream	0.31	3.10	1.13	0.59
	Tester 2		0.10	3.20	1.02	0.54
DAY 2	Tester 1		0.31	3.00	1.12	0.59
	Tester 2		0.20	3.20	1.01	0.53
DAY 1	Tester 1	Gel	0.36	4.20	1.30	0.59
	Tester 2		0.20	4.00	1.26	0.77
DAY 2	Tester 1		0.20	3.90	1.30	0.59
	Tester 2		0.24	4.50	1.24	0.63

when the values obtained for Tester 1 on day 1 and day 2 were correlated ($r = 0.91$, $p = 0.001$). Also, for tester 2, there was significant correlation when day 1 and 2 values were correlated ($r = 0.86$, $p = 0.001$). Similarly, across the testers there was significant correlation between the volume of gel expelled out using the 5mm-diameter nozzle of the syringe on both day 1 and day 2 ($r = 0.46$, $p = 0.001$ and $r = 0.48$, $p = 0.001$ respectively). Other results for cream and gel formulations are presented in Table 3.

3.5 Concurrent Validity of the Micro-plastic Meter Ruler and 5mm-diameter Nozzle Syringe

There was no significant correlation between the FTUML quantified by the patients, using the 5cm-Microplastic ruler on the first testing day and the volume of cream ejected from the 5mm-diameter nozzle syringe on the second testing day by either the patients (Tester 1) or the investigators (Tester 2), excluding the negative correlation with the amount ejected by Tester 2 ($r = -0.10$, $p = 0.01$). Similar correlation was found between the FTUML and the volume of gel ejected using the syringe by the investigators (Tester 2) between the 2 testing days ($r = -0.09$, $p = 0.03$), and between the FTUML of the patient on day 2 and the volume of gel ejected using the syringe by the investigators on day 2 ($r = -0.09$, $p = 0.02$), (Table 4).

Table 3: Intra and Inter Rater Reliability of the 5cm-Microplastic ruler & 5mm Diameter Nozzle Syringe

		Testers	Formulations	Days	r	p
FTUML	Within (Intra)	1	Cream	Day 1 Vs Day 2	0.54	0.001
		2			0.23	0.001
		1	Gel	Day 1 Vs Day 2	0.23	0.001
		2			0.46	0.001
	Across (Inter)	1 vs 2	Cream	Day 1	0.75	0.001
				Day 2	0.32	0.001
		1 vs 2	Gel	Day 1	0.23	0.001
				Day 2	0.88	0.001
Volume	Within (Intra)	1	Cream	Day 1 Vs Day 2	0.91	0.001
		2			0.86	0.001
		1	Gel	Day 1 Vs Day 2	0.68	0.001
		2			0.55	0.001
	Across (Inter)	1 vs 2	Cream	Day 1	0.46	0.001
				Day 2	0.48	0.001
		1 vs 2	Gel	Day 1	0.42	0.001
				Day 2	0.41	0.001

Table 4: Concurrent validity of the 5cm-Microplastic ruler and 5mm-diameter Nozzle of the Clinical Syringe

		Cream	Cream	Cream	Cream	Cream	Gel	Gel	Cream	Cream
Measurements	Measurements	Day 1 Micro-plastic Tester 1	Day 1 Micro-plastic Tester 2	Day 1 Syringe Tester 1	Day 2 Syringe Tester 1	Day 1 Syringe Tester 2	Day 1 Syringe Tester 1	Day 2 Syringe Tester 2	Day 2 Micro-plastic Tester 1	Day 2 Micro-plastic Tester 2
Cream: Day1 Micro-plastic Tester 1	r									
Cream: Day1 Micro-plastic Tester 1	p									
Day 1 Micro-plastic Tester 2	r	0.75**								
Day 1 Micro-plastic Tester 2	p	0.001								
Day1 syringe Tester 1	r	0.006	0.01							
Day1 syringe Tester 1	p	0.87	0.80							
Day 2 syringe Tester 1	r	0.02	-0.03	0.91**						
Day 2 syringe Tester 1	p	0.59	0.41	0.001						
Day 2 syringe Tester 2	r	-0.02	-0.006	0.46**	0.48**					
Day 2 syringe Tester 2	p	0.62	0.88	0.001	0.001					
Gel: Day 1 syringe Tester 2	r	-0.03	-0.01	0.22**	0.25**	0.20**				
Day 2 syringe Tester 2	p	0.53	.857	.001	0.001	0.001				
Day 2 syringe Tester 2	r	-0.010**	-0.009*	0.38**	0.38**	0.33**	0.55**			
Cream: Day 2 Micro-plastic Tester 1	p	0.01	0.03	0.001	0.001	0.001				
Day 2 Micro-plastic Tester 1	r	0.54**	0.55**	-0.077	-0.08*	-0.052	-0.042	-0.09*		
Day 2 Micro-plastic Tester 2	p	0.001	0.001	0.06	0.04	0.20	0.29	0.02		
Day 2 Micro-plastic Tester 2	r	0.21**	0.23**	-0.04	-0.06	-0.03	0.005	0.003	0.32**	
Day 2 Micro-plastic Tester 2	p	0.001	0.001	0.30	0.17	0.52	0.90	0.94	0.001	-

4 Discussion

The average age of the patients in this study was almost 40 years, implying that they were matured enough to understand and quantify the readings of the 5cm-Microplastic ruler and the 5mm-diameter Nozzle of the clinical syringe. Only very few of the patients (17.85%) who were within the age range of 5 to 15 years needed assistance to quantify the dosage specification by parents or caregivers. The relationship between age, cognitive and arithmetic decisions cannot be neglected, hence, the need for older adults to supervise the quantification of topical medications[20]. The decision to allow older caregivers to do topical dosage quantification using the Finger Tip Unit (FTU) of the children was justifiable because young children are at higher risk of side effects of some medicines because of poor arithmetic decision and they are also with smaller body mass and shorter FTU.

Matsuki et al (2025)[7] emphasized the need to ensure that adequate and effective amount of topical medications are used by patients according to the required FTU. Onigbinde et al (2017)[12] advocated the use of a tape ruler to measure FTUM but recent developments have shown that the length is too long and may not be clinically useful and there are recent documentations that short rulers are easier to read and they offer versatility, precision and minimal movement for accuracy[21].

This study found a very strong correlation between the actual quantification of the length of FTU by both testers on both testing days. Significant correlation were also found between the Finger Tip Unit Metric Lengths of methyl salicylate cream obtained from using the 5cm- Micro-plastic ruler by both testers on the first and second testing days, either within or across each tester (intra or inter-tester reliability). Most correlations obtained for both testers using the 5cm- Micro-plastic ruler were considered to be moderate. There were also significant correlations between the lengths of the cream measured by both the patients and the investigators for quantifying the diclofenac gel formulation, although, the correlation values were lower than the values obtained for the cream. This might be because the gel is a semi-solid preparation with higher water content, hence it may easily widen and also flow beyond the crease of the index finger that marks the anatomical end point for the application of FTU. Similar results were obtained for the volumetric quantification of the cream and gel formulations using 5mm-diameter Nozzle Syringe to make one FTU by both testers both at onset and after 4 weeks This also implied that the syringe also has moderate intra-tester and inter-tester reliability for quantifying dosage specification for cream and gel formulation. These findings were consistent with that of Onigbinde et al (2021)[11]. A higher intra-rater reliability was observed for second group of testers for the quantification of gel using the microplastic ruler while it was lower for the gel and cream using the 5mm-diameter nozzle syringe. Afzal et al (2021)[22] reported that awareness of application was usually high among experts. Furthermore, our current findings corroborated that of Speeckaert et al, (2019)[6] who

found that there were inter-rater and intra-rater agreements when a picture-based tool and Body Surface Area computation in order to provide quantification for FTU. The reliability values obtained in our study have clinical implications because volumetric quantification for topical medications is considered to be the consistent standard[23]. Aside this, the use of syringe in pharmacy is recommended for the quantification of medications of small volumes, and it provides a high degree of precision and accuracy for patient safety[24].

There was a diffuse reports in the concurrent validity obtained when the dosage specifications obtained from the two tools were considered. While there was no significant correlation between the FTUML quantified by the patient using the 5cm-Microplastic ruler on the first testing day and the volume of cream ejected from the 5mm-diameter nozzle syringe on the second testing day by either the patient or the investigators, there was a negative correlation with the amount ejected by the second testers. Similar negative correlations were found between the FTUML and the volume of gel ejected using the syringe by the second tester between the 2 testing days, and between the FTUML of the patient on day 1 and the volume of gel ejected using the syringe by the former after 4 weeks. Statistically, the absence of significant or presence of negative correlation in the outcomes of two tools does not necessarily meant absence of concurrent validity, either may be valid. The outcome might be because they measured different formulations or there were behavioural differences during quantification. It is noteworthy, that the 5cm-Microplastic ruler measured length while the 5mm-diameter nozzle syringe measured volume, and one of the most prevalent misconceptions is that both metric indices are directly proportional[25]. Furthermore, it could also implied that the tools are independent of one another. The few measurement with very low negative correlation obtained between the 5cm-Microplastic ruler and the 5mm-diameter nozzle syringe might implied that the tools are not measuring the intended construct.

The moderate reliability obtained in this study for the 5cm-Microplastic ruler and 5mm-diameter nozzle syringe is an eye opener for effective application of topical medications because it would provide clear and standard means of dosage specification; and this will empower patients' treatment adherence, and equally allows clinicians to develop nuanced, long-term strategies for managing cases that requires transdermal application of different drug formulations[26]. Moreover, with increasing advocacy, the current use of 5cm-Microplastic ruler and modified clinical syringe may give health-care professionals the grace to providing guidance on application doses that align with appropriate use of FTU. Above all, our current findings may also be a pointer of need for manufacturers of both topical medications and syringe to embark on the production of 5cm-Microplastic ruler and 5mm-diameter nozzle syringe considering the portability and versatility of the two instruments for clinical use. The limitation of this study was that there are different investigators at the study settings, hence, there may be variations in the methods and accuracy of using the tools, and there was no check for consistency in the quantification of the topical formulations among the investigators. Also,

the gel formulation spread easily, and this may limit accuracy of reading after application. Another limitation is that the study used only Pearson’s correlation coefficient to imply reliability whereas it is not conclusive enough to use it.

5 Conclusion

There was moderate intra- and inter-tester agreement for cream and gel dosages when measured with the 5cm-Microplastic ruler and 5mm-diameter syringe over a 4-week test-retest interval. This indicates potential reliability, noting that correlation coefficients alone do not confirm reliability. However, there was no strong evidence of agreement between the two measurement tools

6 Declarations

Clinical trial number: Not applicable.

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Authors’ contributions: O.A.T led the conceptualization, methodology development, production of tools & supervision, data collection, analyses and drafting of the original manuscript

.A.O.E contributed to methodology, data collection, collation, supervision and manuscript review. O.M was involved in data collection and manuscript review. O.I.A and O.A were involved in data collection, literature review, data entry proof reading and manuscript editing. All authors reviewed and approved the final version of the manuscript.

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Authors' contributions: O.A.T led the conceptualization, methodology development, production of tools & supervision, data collection, analyses and drafting of the original manuscript. A.O.E contributed to methodology, data collection, collation, supervision and manuscript review. O.M was involved in data collection and manuscript review. O.I.A and O.A were involved in data collection, literature review, data entry proof reading and manuscript editing. All authors reviewed and approved the final version of the manuscript.

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