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Mmed Urology

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CAN PETROLEUM JELLY BE USED TO OBTAIN SATISFACTORY RENAL ULTRASOUND IMAGING?

Thelle Mogoerane Regional Hospital

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa, in partial fulfilment of the requirements for the degree of Master of Medicine in the division of Urology.

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Objectives (which must start with 'To...' and be followed by a simple statement of the objectives,

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Declaration of original work:

This MMed research report is my own original work. It has not been submitted for examination to this or any other university before.

This research work has not been submitted for possible publication to any journal before. This MMed is written in the submissible format according to the instructions to authors for possible publication by the British Journal of Urology International (BJUI).

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15 January 2020

Dear Editor of BJUI,

Please find attached our manuscript entitled: “Can petroleum jelly be used to obtain satisfactory renal ultrasound imaging” for consideration to possibly published in the prestigious British Journal of Urology International.

This urology research work was encouraged by working in a country with limited health care finances and resources. Ultrasound gel is not always available and led us to investigate the possibility of using another cheaper and readily available ultrasound coupling medium instead. Petroleum jelly proved to be a good alternative to the more expensive gold standard ultrasound gel in these financial and resource strained situations.

Kindly contact the corresponding author if there are further questions or comments.

With kindest regards,

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10 January 2020

Author Contribution Statement

Title of Manuscript: "Can petroleum jelly be used to obtain satisfactory renal ultrasound imaging?"

Name of corresponding author: Dr Reuben Ras

Herewith all three authors declare that each author had made a significant contribution to this manuscript as detailed below, have seen and approved the final manuscript, and have agreed to its submission to British Urology Journal International. None of the authors had any conflict of interest.

Dr Reuben Ras:

Execution of the research work, analyses of data, drafting the manuscript.

10 January 2020

Professor Mohammed Haffejee:

Original idea, conceptual design, clinical supervision and final approval of the manuscript.

10 January 2020

Dr Marietha Nel

Research design, academic supervision, final writing, proofreading and editing of the manuscript.

10 January 2020

Conflict of interest:

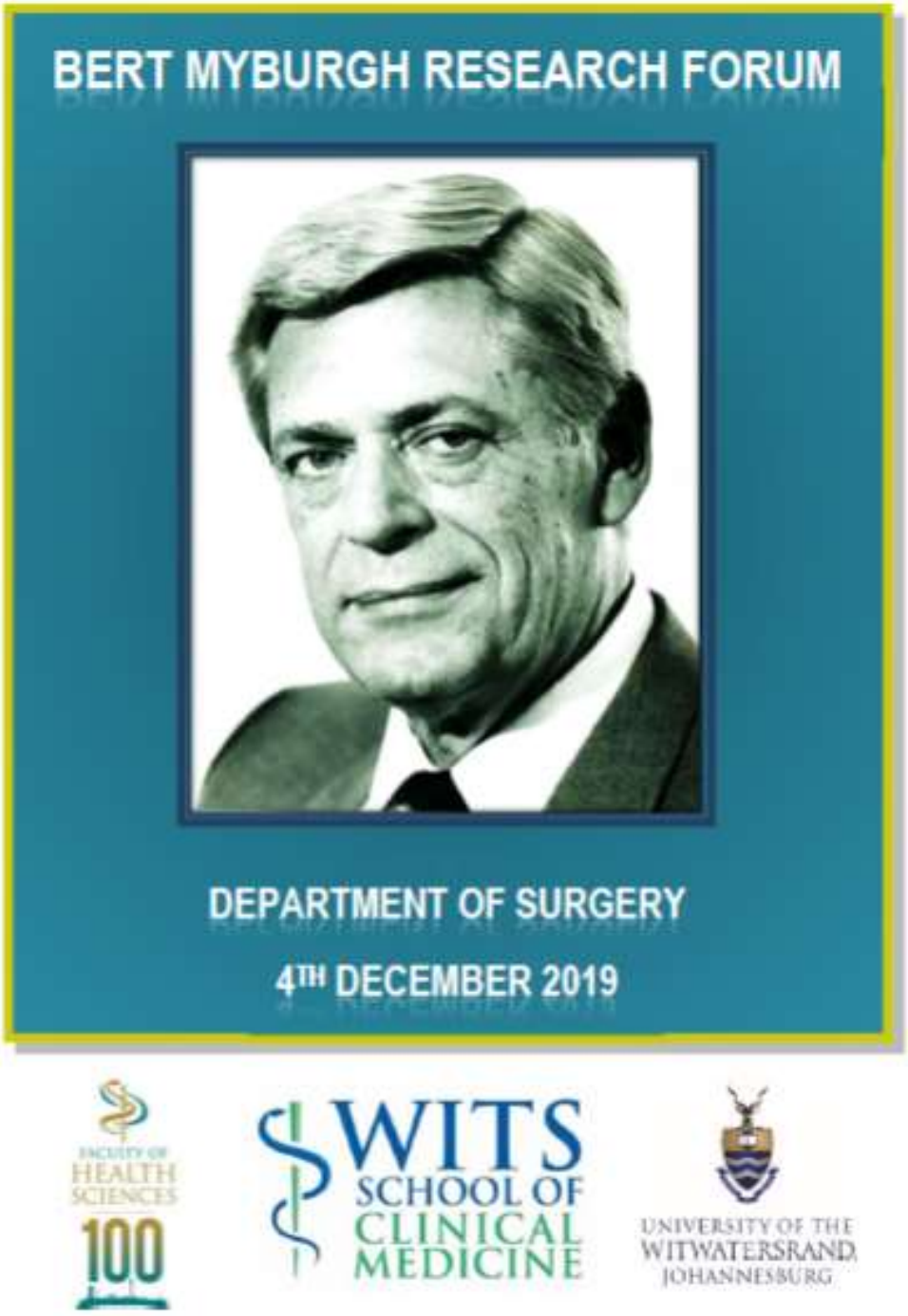
None.

Dedication

To my loving wife Adéle: Thank you for standing by me and sacrificing so much during the period of this research project. I am ever grateful.

Presentations originating from this research:

Bert Myburgh Research Forum 2019:



PROGRAM FOR THE BERT MYBURGH RESEARCH FORUM

LEN MILLER LECTURE THEATRE, DEPARTMENT OF SURGERY

4th December 2019

	13:00 - 13:10	**WELCOME - PROF MARTIN SMITH** - *Chairman of the 2019 Bert Myburgh Research Forum*
1	13:10 - 13:20	**DR MFUNDISO ZONDO** *Lunar Cycle, Seasonal Variations and Emergency Urological Presentations*
2	13:20 - 13:30	**DR REUBEN C RAS** *Can Petroleum Jelly Be Used to Obtain Satisfactory Renal Ultrasound Imaging?*
3	13:30 - 13:40	**DR ZAKIYAH GAIBIE** *Urethral Ratio as a Predictor of Successful Posterior Urethral Valve Ablation – A Systematic Review*
4	13:40 - 13:50	**DR JAMES NONDE** *The World of Validated Suprapubic Catheter Insertion Simulation Trainers From Head-Blocks to 'Lunch Boxes' - A Systematic Review*
5	13:50 - 14:00	**MR JARED McDOWALL** *Is The History of Erectile Dysfunction a Reliable Risk Factor for New Onset Acute Myocardial Infarction? - A Systematic Review and Meta-Analysis*
6	14:00 - 14:10	**DR YUSUF MOOLLA** *'Prostate Cancer' Information on the Internet: Fact or Fiction?*
7	14:10 - 14:20	**DR UDEY DANIEL UGARE** *Early Onset Malignant Solid Tumours in Young South Africans (16-40 Years) - A 5 Year Audit Based on Histopathological Records of Patients Seen in Three Academic Hospitals of the University of The Witwatersrand Circuit*
8	14:20 - 14:30	**DR CATHARINA POTHAS** *Time to First Health Care Contact, Referral Pathways and Stage at Presentation – The Experience from Four South African Breast Units*
9	14:30 - 14:40	**DR BOITUMELO PHAKATHI** *Survival of South African Women with Breast Cancer Receiving Anti-Retroviral Therapy for HIV*
10	14:40 - 14:50	**DR SARAH NIETZ** *Quality Indicators for Breast Cancer Diagnosis and Surgery in South Africa*
11	14:50 - 15:00	**PROF AYLWYN MANNELL** *A Prospective Study of 112 Newly Diagnosed Breast Cancer Patients to Identify Discordance Between the Receptor Profile of the Primary Tumour and the Ipsilateral Axillary Lymph Node Metastases*

Abstract:

Introduction:

Ultrasound is widely used in the medical field and has also become an integral part of daily practice in urology. Ultrasound gel is the gold standard coupling medium, but it is not always readily available. Petroleum jelly (Vaseline) was proposed as an alternative coupling medium when performing renal ultrasound.

Objectives:

To compare renal ultrasound imaging obtained by using petroleum jelly (test) versus conventional ultrasound gel (control).

To determine if petroleum jelly ultrasound imaging is adequate for clinical use.

Patients:

Patients aged 18 to 75 years presenting to Thelle Mogoerane Regional Hospital (TMRH) Urology OPD, volunteered and took part in the study. Patients with wounds or skin conditions affecting the flank and abdominal area were excluded.

Methods:

A prospective pilot study was conducted. Forty two patients had renal ultrasounds done of their left kidney, using ultrasound gel and petroleum jelly respectively. Renal ultrasound is a routine procedure in urological practice. A single ultrasonographer performed the renal ultrasounds and scored each image 1 to 3 (1-worst, 3- best) with regards to penetration, detail and total image quality. The ultrasonographer also determined which one of the paired images was better and whether the images were adequate for clinical use.

Results:

Ultrasound imaging adequate for clinical use was obtained in 95.24 % (n=40) of patients when using ultrasound gel and in 88.10% (n=37) patients using petroleum jelly. Vaseline produced better imaging in 28.57% (n=12) of patients. Ultrasound gel had statistically significant better mean scores ($p< 0.05$) in all the evaluated categories vs Vaseline: Penetration: 2.8 vs 2.6, detail: 2.6 vs 2.4 and total image quality: 2.7 vs 2.5. This statistically significant difference could be due to the small sample size. The cost of performing a renal ultrasound with Vaseline was 30% cheaper per patient (42c) compared to ultrasound gel (60c).

Conclusion:

Although ultrasound gel remains the gold standard coupling medium for renal ultrasound, in a setting where ultrasound gel is not available, Vaseline is a good affordable alternative to obtain renal ultrasound imaging.

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Manuscript word count: 2046

Key words: Ultrasound, Ultrasound gel, Petroleum jelly, Vaseline, Kidney, Renal

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Thank you Prof Mohamed Haffejee and Dr Marietha Nel for your assistance, guidance and invaluable input during the conceptualization and execution of this research study. I also want to thank Ms Busisiwe Mapoko who performed all the renal ultrasounds and Mr Gbenga Olorunfemi who assisted me with the statistical analysis.

List of contents:

Title page	1
BJUI author guidelines	2
Declaration of original work	5
Cover letter to the editor of BUJI	7
Letter signed by co-authors stating the contribution of the candidate	8
Conflict of interest statements from all authors	9
Dedication	10
Presentation originating from this research	11
Abstract	13
Acknowledgements	15
List of contents	16
List of figures	17
List of tables	18
Abbreviations	19
Introduction	20
Materials and methods	23
Results	26
Discussion	36
Conclusion	37

References 38

Appendices:

Appendix 1: Approved research protocol and review of the literature 40

Appendix 2: Ethics clearance certificate 62

Appendix 3: Turnitin report cover page 64

List of figures:

Figure 1: Total scores for the 'penetration' parameter for ultrasound gel and petroleum jelly images. 30

Figure 2: Total scores for the 'detail' parameter for ultrasound gel and petroleum jelly images. 31

Figure 3: Total scores for the 'total image quality' parameter for ultrasound gel and petroleum jelly images. 32

Figure 4: Total scores for 'adequate for clinical use' parameter for ultrasound gel and petroleum jelly images. 33

Figure 5: Best renal ultrasound image obtained (per patient) using ultrasound gel and petroleum jelly respectively. 34

Figure 6: Mean scores of each parameter. 36

List of tables:

Table 1: Price comparison of petroleum jelly and ultrasound gel. 22

Table 2: Patient demographics and results of the renal ultrasounds that were performed with ultrasound gel and petroleum jelly respectively at TMRH (n=42). 27

Table 3: Total and mean scores of renal ultrasound performed with ultrasound gel and petroleum jelly respectively (n=42). 29

Table 4: Total number of images obtained that were adequate for clinical use when using ultrasound gel and petroleum jelly respectively (n=40) vs (n=37) 32

Table 5: Best renal ultrasound image obtained (per patient) using ultrasound gel and petroleum jelly. 33

Abbreviations:

TMRH	Thelle Mogoerane Regional Hospital
CEO	Chief Executive Officer

Introduction:

Ultrasound was first used for medical diagnosis in 1937 by Dr Karl Dussik to perform a cranial ultrasound.[1,2] He was a neurologist who aimed to visualize the cerebral ventricles.[1] Dr Dussik placed ultrasound transducers on either side of the patient's head which was partially submerged in water. Water was thus the coupling medium. Ultrasound has developed since then and is now used in various medical fields such as obstetrics, cardiology and urology.[1]

A coupling medium is used when performing an ultrasound to improve the sound wave conduction between the probe of the instrument and the patient's tissue.[3] Today ultrasound gel is commonly used as a coupling agent. Conventional ultrasound gel is water based and typically contains an agent that retains water, a preservative and colouring agent.[4]

Renal ultrasound plays an important role in the management of urology patients. Ultrasound gel is often out of stock in rural hospitals as it is frequently used, suppliers may have difficulty distributing to remote locations and hospital funds are limited. Thus, cheaper, more readily available alternatives warrant consideration.

Although there is paucity on possible ultrasound alternatives in the literature, a few alternative ultrasound media have been investigated. Riguzzi *et al*., (2017) used a home-made cornstarch-based gel to obtain ultrasound imaging with similar image quality compared to conventional ultrasound gel.[3] However, this cornstarch medium should be used within 2 days of preparation as the starch and water may separate.[3] Sterility is also uncertain as it is home-made.[3] Mueller and Theoharis (2013) reported the successful use of mineral oil, 0.9% saline

and water as alternative coupling agents when performing a venous duplex ultrasound.[4] Alternatives were sought as a patient who needed a duplex doppler ultrasound for a suspected deep vein thrombosis, reported an allergic reaction after a previous ultrasound was performed. Possible allergens in ultrasound gel are polypropylene glycol, propylene glycol and parabens.[4] The alternatives considered did not contain any of these substances.[4] Luewan *et al.,* (2007) found that olive oil can be used to obtain ultrasound images that are of similar quality compared to conventional ultrasound gel.[3, 5]

The researcher proposed using petroleum jelly as an alternative to conventional ultrasound gel when performing a renal ultrasound, as it is cheaper and more readily available than ultrasound gel. According to the International Programme on Chemical Safety and the Commission of the European Communities petroleum jelly consists of hydrocarbons with carbon numbers greater than 25 (2002).[6] Conventional ultrasound gel is made up of a gelling agent (i.e.etherified hydroxyethylcellulose), a solvent (i.e.1,3-propanediol), water and an antimicrobial agent (i.e. benzalkonium chloride).[7]

A PubMed database search restricted to the human species and English language was done. The following search strategies were used with the keywords: “ultrasound” and “petroleum jelly”, “sonar” and “petroleum jelly”, “ultrasound” and “Vaseline”, “sonar” and “Vaseline”. No literature was found with regards to the use of petroleum jelly to perform ultrasound in general, or in renal ultrasound specifically. However, petroleum jelly has reportedly been used for ocular ultrasound in an Emergency Department setting by Engelbert and Palma in 2015. Engelbert and Palma (2015) only reported that petroleum jelly did not damage the ultrasound

probe, but did not report on the quality of such images on its own or in comparison to ultrasound gel images.[8]

Cost comparison:

An initial Internet search was done on 21 April 2018 on the cheapest petroleum jelly, ultrasound gel and wooden spatulas (to apply petroleum jelly to the ultrasound probe) available in South Africa. The results were updated on the 9th of August 2018 with results as shown in Table 1 below.

Table 1: Price comparison of petroleum jelly and ultrasound gel.

MERCHANT:	**PRODUCT:**	**PRICE PER CONTAINER**	**AMOUNT USED PER PATIENT**	**PATIENTS PER CONTAINER**	**PRICE PER PATIENT**
Clicks	**Vaseline blue seal original [9] (Petroleum jelly)**	R49.95 for 450ml	5ml	90	56c+25c (spatula) = 81c
Clicks	**Vaseline blue seal original [10] (Petroleum jelly)**	R32.99 for 250ml	5ml	50	66c+25c (spatula) = 91c
Afrimedics	**Ultrasound gel [11]**	R25 for 250ml	15ml	16	R1,67

Afrimedics	**Wooden spatula [12]**	100 spatulas for R25	1	100	25c

A saving of 86cents per patient, equating to a saving of almost 50% (48.5%) per patient could possibly be achieved by using petroleum jelly instead of ultrasound gel.

Materials and Methods:

Equipment and supplies:

A Philips Clear Vue 550 ultrasound instrument was used.

The following supplies were bought at Dischem as Afrimedics could not supply the ultrasound gel in time: Brunel laboratoria ultrasound gel at R75.95c per 500ml container. On average approximately 3.93ml was used per patient at a cost of about 60c. Petroleum jelly (Blue Seal brand) bought at a cost of R27.95c per 250ml container. On average approximately 1.07ml was used at a cost of 12c per patient. A box of 100 tongue depressors bought for R29.98, thus a price of 30c per tongue depressor per patient. The total cost of petroleum jelly and one tongue depressor came to 42c per patient.

Patients:

Patients aged 18 to 75 years who presented to the Out Patient Department of TMRH, Department of Urology voluntarily consented to be part of this study. Renal ultrasound is a routine procedure in urology practice. Patients who had wounds or skin conditions affecting their abdominal- or flank area, were excluded from the study.

Study aim:

The aim of the study was to investigate whether petroleum jelly may be used to produce renal ultrasound images of similar quality to those obtained with conventional ultrasound gel.

Study objectives:

Primary objectives

To compare renal ultrasound imaging obtained by using petroleum jelly (test) *versus* conventional ultrasound gel (control).

To determine if petroleum jelly ultrasound imaging is adequate for clinical use.

Secondary objective

To stimulate interest in further research of petroleum jelly as a cost-effective alternative ultrasound medium.

Study design and population

This was a prospective study conducted during June 2019 at Thelle Mogoerane Regional Hospital (TMRH) in Vosloorus. It is one of the four academic hospitals of the University of the Witwatersrand. The hospital has 821 beds and delivers level 1 and level 2 health care to the East Rand of Johannesburg.

Patients were assigned a study number to insure anonymity. Although the patient consent form displayed the patient name and hospital number, the consent forms were kept separate from the data collection sheets in a safe locked drawer to which only the principal investigator had access.

Each patient had two renal ultrasounds of the left kidney with conventional ultrasound gel (control) and with petroleum jelly (test) respectively. Patients who had wounds or skin conditions that affect their abdominal or flank areas were excluded from the study.

Data collection

Two ultrasounds of the left kidney were performed using conventional ultrasound gel and petroleum jelly respectively. One ultrasonographer performed all the ultrasounds and scored each image from 1 to 3 (1-worst, 3- best) with regards to the following criteria.[13]

1. Penetration: Demonstration of the kidney at increasing depth.
2. Detail: Sharpness of the outline of the solid and fluid filled areas.
3. Total image quality: Contrast between solid and fluid areas and absence of artifact or noise.

The ultrasonographer also commented on whether the imaging was adequate for clinical use (yes/no) and which one of the two images' quality was better.

The data was captured on an image evaluation sheet and entered into an Excel spreadsheet. A picture was taken of each ultrasound image. Each patient file contains the image evaluation sheet and the printed images of the renal ultrasounds.

Statistical analysis:

The assistance of a biostatistician was obtained to determine the minimum patient sample size needed in each of the two groups for this study. No similar study had been done before and a statistical estimate was done. It was determined that a minimum of 40 patients were needed per

group to enable meaningful statistical data analyses. Data were entered into a codebook and analysed using Stata Version 14.2. The parameters compared were penetration, detail, total image quality, adequacy for clinical use and which image was better. Numerical variables were described using measures such as mean, standard deviation, minimum and maximum. Categorical variables were reported with frequencies and graphs Inferential statistics were applied to the parameters scored out of 3, using the paired T-test. A confidence interval of 95% and a p value of <0.05 were used to determine statistical significance.

Ethics:

Ultrasound gel and petroleum jelly posed no risk to the participants. For infection control, a clean tongue depressor was used to apply petroleum jelly to the ultrasound probe for each patient. The probe was cleaned after each use, according to the specifications of the manufacturer of the ultrasound instrument.

The Human Research Ethics Committee (HREC) (medical) of the University of the Witwatersrand approved this study (Certificate No: M181131). Permission to conduct the research was granted by The Thelle Mogoerane Regional Hospital management team (CEO) and by Dr TM Kasapato (Head of Department of Urology at Thelle Mogoerane Regional Hospital).

Results:

Forty-two patients volunteered to have ultrasound imaging of their left kidney done with ultrasound gel (control) and petroleum jelly (test) respectively (Table 2).

Table 2: Patient demographics and results of the renal ultrasounds that were performed with ultrasound gel and petroleum jelly respectively at TMRH (n=42).

Patient ID:	**Age (years)**	**Gender**	**Ultrasound Gel: Penetration**	**Detail**	**Total image quality**	**Adequate for clinical use**	**Petroleum jelly: Penetration**	**Detail**	**Total image quality**	**Adequate for clinical use**	**Best image**	**Comment**
1	54	M	3	2	3	Y	2	2	2	Y	US	
2	38	M	2	3	2	Y	3	3	3	Y	V	
3	56	M	3	2	2	Y	2	2	2	N	US	
4	62	M	3	3	3	Y	1	1	1	N	US	
5	57	M	3	3	3	Y	3	2	3	Y	US	
6	55	M	3	2	2	Y	2	2	2	Y	US	
7	37	M	3	3	3	Y	3	2	2	Y	US	
8	64	M	3	3	3	Y	2	2	2	Y	US	
9	54	M	3	2	2	Y	2	2	1	Y	US	
10	54	M	3	3	3	Y	3	2	2	Y	US	
11	55	M	3	3	3	Y	2	2	3	Y	US	
12	20	M	3	3	3	Y	3	3	3	Y	US	
13	60	M	3	3	3	Y	2	3	3	Y	US	
14	75	M	1	1	1	N	2	1	1	N	V	Central obesity
15	62	M	3	3	3	Y	3	3	3	Y	Equal	
16	53	M	3	3	3	Y	2	3	3	Y	US	
17	44	M	3	3	3	Y	3	3	3	Y	US	
18	48	M	3	3	3	Y	2	3	3	Y	US	
19	51	M	2	2	2	Y	3	2	2	Y	V	
20	65	M	3	3	3	Y	3	3	3	Y	Equal	
21	67	M	2	2	3	Y	2	2	2	Y	US	
22	67	F	3	3	3	Y	2	1	2	N	US	
23	68	M	3	3	3	Y	2	3	3	Y	US	
24	67	M	3	3	3	Y	3	2	3	Y	US	
25	66	M	3	3	3	Y	3	2	2	Y	US	
26	54	F	3	3	3	Y	3	3	3	Y	V	
27	67	M	2	2	2	Y	1	1	1	N	V	
28	65	M	3	3	3	Y	3	2	3	Y	US	
29	69	M	3	3	3	Y	3	3	3	Y	US	
30	66	M	3	3	3	Y	3	3	3	Y	Equal	

31	65	M	3	1	2	Y	3	3	3	Y	V	
32	67	M	3	2	3	Y	3	3	3	Y	V	
33	62	M	3	3	3	Y	3	2	3	Y	US	
34	68	M	2	1	2	Y	2	2	2	Y	V	
35	51	M	3	3	3	Y	3	2	3	Y	V	
36	64	M	3	3	3	Y	3	3	3	Y	V	
37	56	M	3	3	3	Y	3	3	3	Y	US	
38	45	M	2	1	2	N	3	2	3	Y	V	
39	63	M	3	3	3	Y	3	3	3	Y	Equal	
40	66	F	3	3	3	Y	3	2	2	Y	US	
41	52	M	3	3	3	Y	3	3	3	Y	US	
42	45	M	3	3	3	Y	3	3	3	Y	V	

The following mean scores were obtained when using ultrasound gel and petroleum jelly respectively: Penetration: 2.8 vs 2.6, detail: 2.6 vs 2.4 and total image quality: 2.7 vs 2.5 respectively (Table 3, Figure 1, Figure 2 and Figure 3).

Standard deviations of the three parameters when using ultrasound gel and petroleum jelly were as follows: Penetration: 0.5 vs 0.6, detail: 0.7 vs 0.7, total image quality: 0.5 vs 0.7 (Table 3).

Ultrasound gel scored 3 (best score) more often than petroleum jelly for each respective parameter: Penetration 83.33% (n=35) vs 61.90% (n=26), detail 71.43% (n=30) vs 45.24% (n=19) and total image quality 76.19% (n=32) vs 61.90% (n=26) for ultrasound gel and petroleum jelly respectively (Table 3).

Table 3: Total and mean scores of renal ultrasounds performed with ultrasound gel and petroleum jelly respectively.

Penetration	**Ultrasound gel**	**Petroleum jelly**
1	1 (2.38%)	2 (4.76%)
2	6 (14.29%)	14 (33.33%)
3	35 (83.33%)	26 (61.90%)
Mean	2.8	2.6
Standard deviation	0.5	0.6

Detail	**Ultrasound gel**	**Petroleum jelly**
1	4 (9.52%)	4 (9.52%)
2	8 (19.05%)	19 (45.24%)
3	30 (71.43%)	19 (45.24%)
Mean	2.6	2.4
Standard deviation	0.7	0.7

Total image quality	**Ultrasound gel**	**Petroleum jelly**
1	1 (2.38%)	4 (9.52%)
2	9 (21.43%)	12 (28.57%)
3	32 (76.19%)	26 (61.90%)
Mean	2.7	2.5
Standard deviation	0.5	0.7

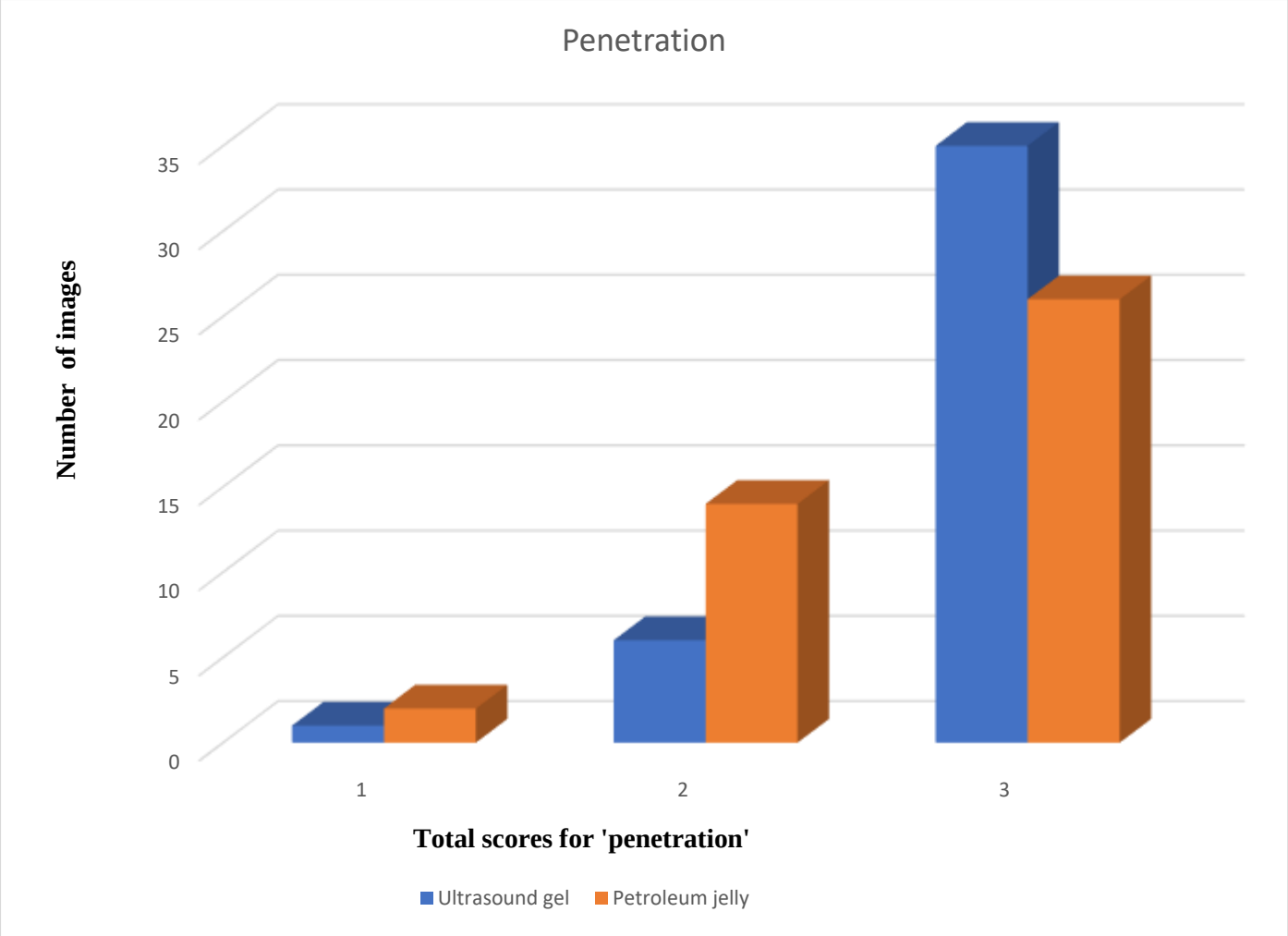

Figure 1: Total scores for the 'penetration' parameter for ultrasound gel and petroleum jelly images.

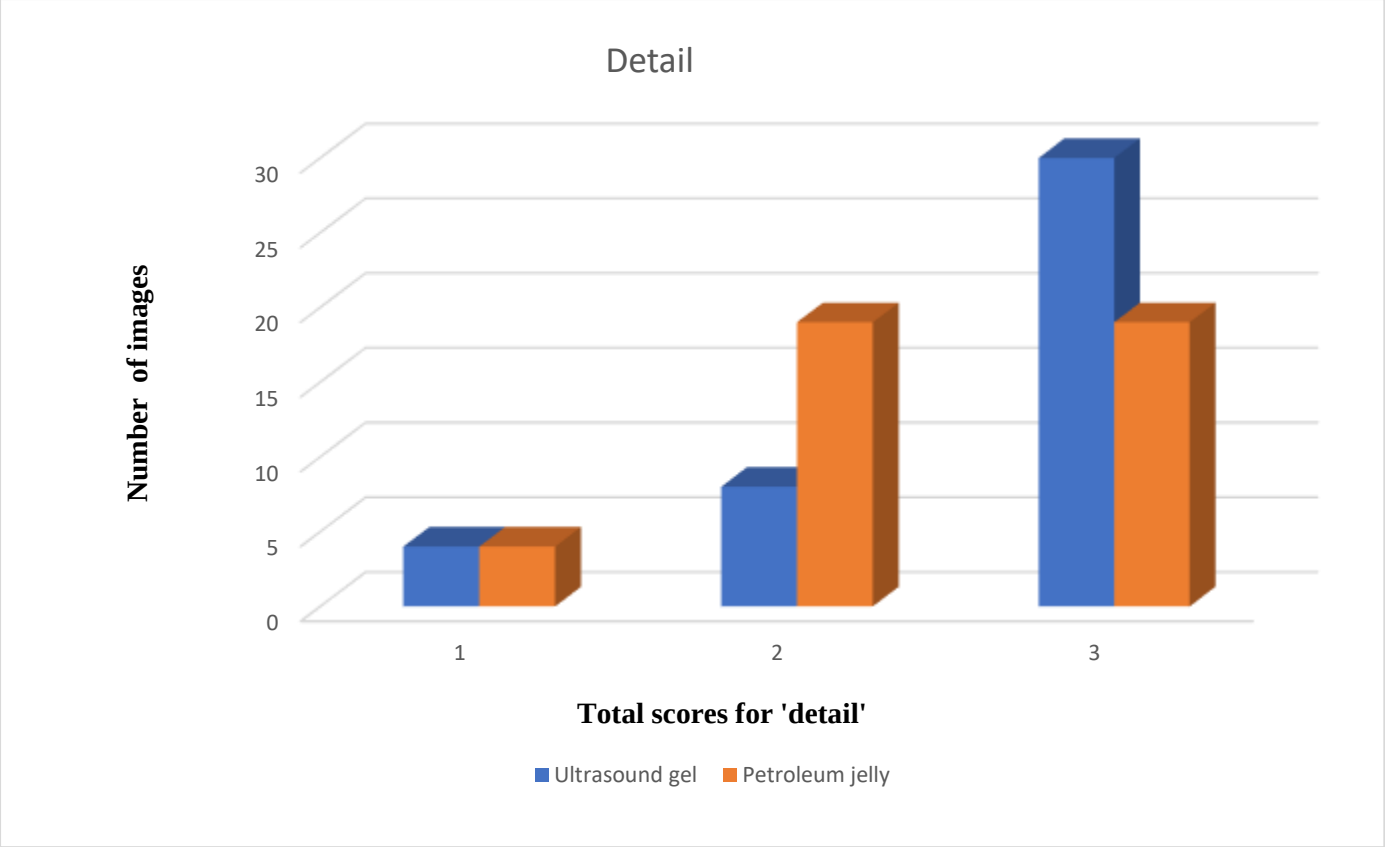

Figure 2: Total scores for the ‘detail’ parameter for ultrasound gel and petroleum jelly images.

Figure 3: Total scores for the 'total image quality' parameter for ultrasound gel and petroleum jelly images.

Ultrasound gel produced images that were adequate for clinical use more often than petroleum jelly: 95.25% (n=40) vs 88.10% (n=37) (Table 4, Figure 4).

Table 4: Total number of images obtained that were adequate for clinical use when using ultrasound gel and petroleum jelly respectively.

Adequate for clinical use	Ultrasound gel	Petroleum jelly
Yes	40 (95.24%)	37 (88.10%)
No	2 (4.76%)	5 (11.90%)

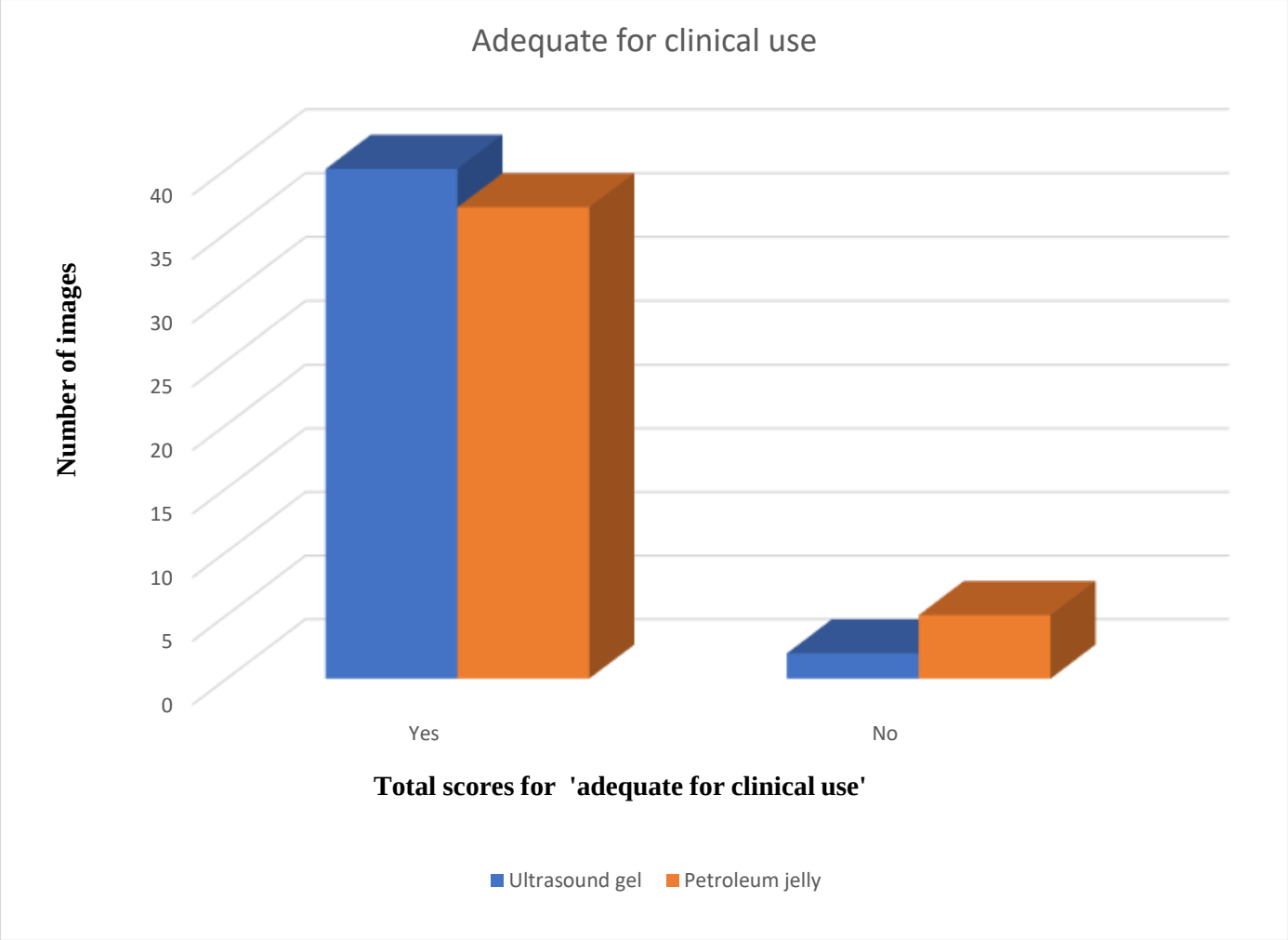

Figure 4: Total scores for 'adequate for clinical use' parameter for ultrasound gel and petroleum jelly images.

The best imaging was most often obtained using ultrasound gel (61.90%, n=26). However, petroleum jelly occasionally produced better imaging (28.57%, n=12). The image quality was seldom equal (9.52%, n=4) (Table 5, Figure 5).

Table 5: Best renal ultrasound image obtained (per patient) using ultrasound gel and petroleum jelly.

	Ultrasound gel	**Petroleum jelly**	**Equal**
Best image	26 (61.90%)	12 (28.57%)	4 (9.52%)

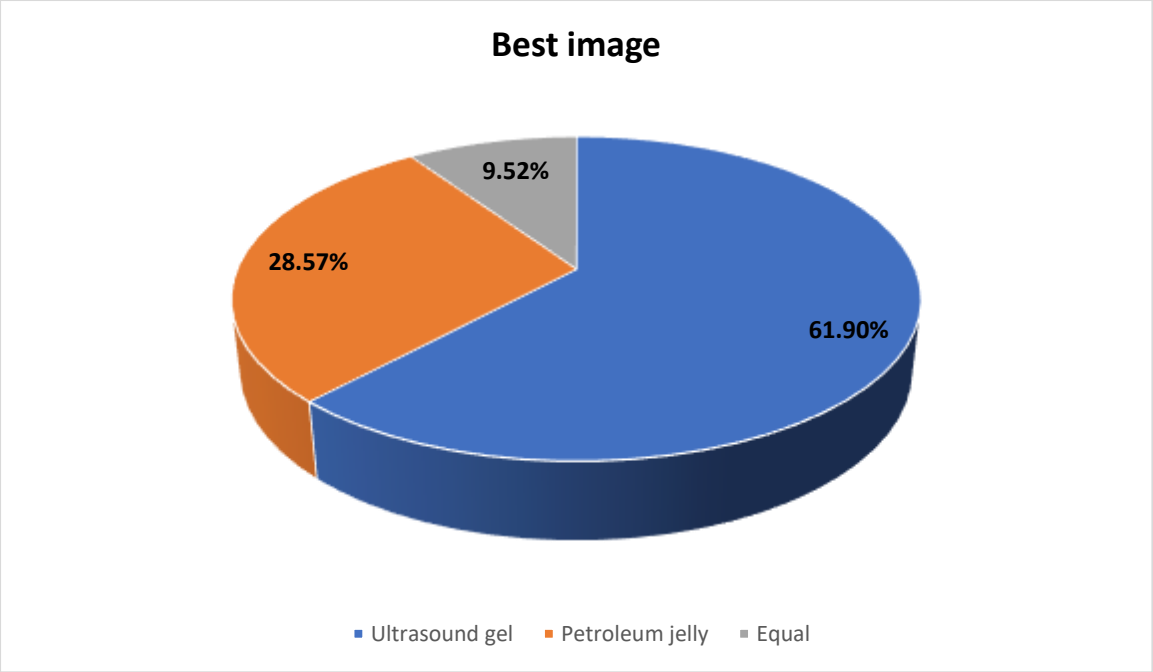

Figure 5: Best renal ultrasound image obtained (per patient) using ultrasound gel and petroleum jelly.

For one patient adequate ultrasound imaging could not be obtained with either ultrasound gel or petroleum jelly due to central obesity (Table 2). When images were not adequate for clinical use all three parameters were affected, whether using ultrasound gel or petroleum jelly (Table 2).

A paired T-test was performed on the scores (out of 3, 3 is the maximum score) obtained for each category when performing renal ultrasound with ultrasound gel and petroleum jelly respectively, generating the following results (Figure 6).

Penetration:

Regarding the ultrasound penetration, the ultrasound gel scored 2.81 ± 0.45 compared to petroleum jelly's score of 2.57 ±0.59 with a statistically significant higher mean score for ultrasound gel of 0.2381 (95% CI, 0.0338 to 0.4424) (p = 0.0235).

Detail:

The ultrasound gel scored 2.62 ±0.66 compared to petroleum jelly's score of 2.36±0.66 with a statistically significant higher mean score for ultrasound gel of 0.2619 (95% CI, 0.0229 to 0.5009) (p = 0.0325), on the ultrasound image detail.

Total image quality:

For the ultrasound image quality, the ultrasound gel scored 2.74±0.50 compared to petroleum jelly's score of 2.52 ±0.67 with a statistically significant higher mean score of 0.2143 (95% CI, 0.0254 to 0.4032) (p = 0.0272) for the ultrasound gel.

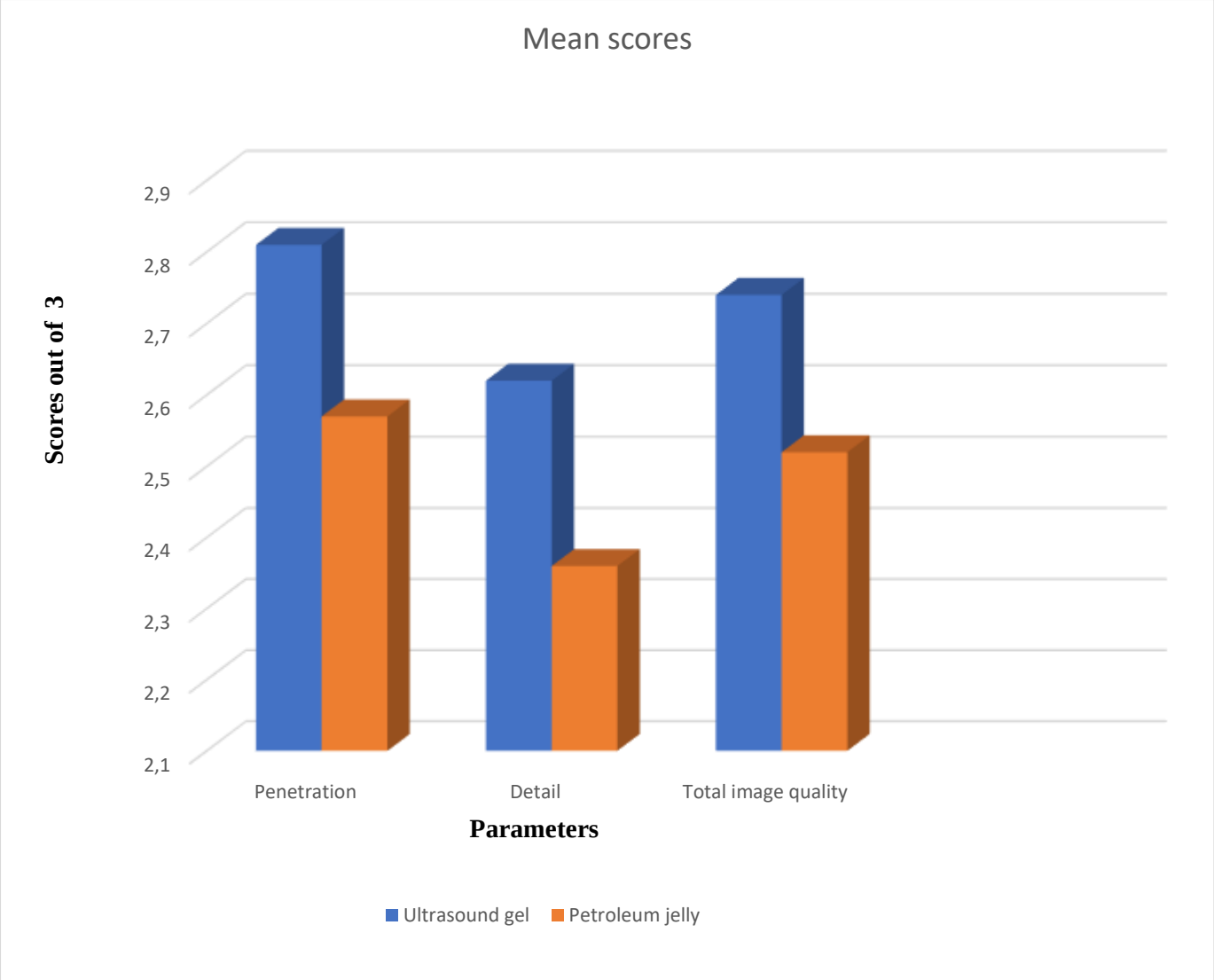

Figure 6: Mean scores for each parameter

Demographics:

The age of the youngest participant was 20 years and that of the oldest patient was 75 years. The mean age was 57.7 years and the median age was 61 years (Table 2).

Three female patients and thirty-nine male patients took part in the study.

Discussion:

Ultrasound gel performed better overall with statistically significant better mean scores in each category (Table 3). The statistically significant differences might be attributed to a small

sample size. However, petroleum jelly did produce imaging that was superior in 12 participants (28.57%) and similar in quality in four participants (9.52%) (Table 5). Patient factors such as obesity may affect ultrasound image quality irrespective of which coupling medium is used.

Petroleum jelly was cheaper to use (42c vs 60c) per patient. This equated to a 30% (18c) saving per renal ultrasound. The tongue depressor was the biggest expense when using petroleum jelly (30c). If an alternative dispensing method could be used for example: warming the petroleum jelly, or using single sachets of petroleum jelly a further reduction in cost per patient could have been achieved. Buying larger quantities of petroleum jelly would also reduce the cost.

Bias:

Adequacy of imaging for clinical use was the subjective opinion of the sonographer. However, the fact that one sonographer was used for the study was a way of standardizing the observations. Ultrasound is a dynamic investigation, but known to be user-dependant.

Conclusion:

Although ultrasound gel remains the gold standard coupling medium for renal ultrasound, in a setting where ultrasound gel is not available, petroleum jelly is a good affordable alternative to obtain renal ultrasound imaging.

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APPENDIX 1: Approved research protocol and review of the literature

Dr Reuben C. Ras

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Head of Department of Urology

University of the Witwatersrand

Dr Marietha Nel

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Ultrasonographer:

Busisiwe Mapoko

Thelle Mogoerane Regional Hospital

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Table of Contents:

1. INTRODUCTION p.4

1.1 Cost comparison p.6

1.2 Research question p.7

2. STUDY AIM AND OBJECTIVES

2.1 Study aim p.7

2.2 Study objectives

2.2.1 Primary objectives p.7

2.2.2 Secondary objectives p.7

3. METHODS

3.1 Setting p.8

3.2 Study population p.8

3.3 Study design p.8

3.4 Patient selection criteria

3.4.1 Patient inclusion criteria p.8

3.4.2 Patient exclusion criteria p.8

3.5 Patient sample size p.9

3.6 Data collection and evaluation p.9

4. DATA ANALYSIS p.10

5. ETHICS p.10

6. STUDY LIMITATIONS p.11

7. FUNDING p.11

8. TIMING p.13

9. References p.14

APPENDIX A: Participant information sheet p.17

APPENDIX B: Patient consent form p.20

APPENDIX C: Data collection sheet/image evaluation form p.21

APPENDIX D: The Thelle Mogoerane Regional Hospital CEO permission p.22

APPENDIX E: Dr Kasapato - HOD Urology TMRH permission p.23

1. INTRODUCTION:

Ultrasound was first used for medical diagnosis in 1937 by Dr Karl Dussik to perform a cranial ultrasound (Lane *et al.,* 2015), (Hill 1973). He was a neurologist who aimed to visualize the cerebral ventricles (Lane *et al.,* 2015). Dr Dussik placed ultrasound transducers on either side of the patient's head which was partially submerged in water. Water was thus the coupling medium. Ultrasound has developed since then and is now used in various medical fields such as obstetrics, cardiology and urology (Lane *et al.,* 2015).

A coupling medium is used when performing an ultrasound to improve the sound wave conduction between the probe of the machine and the patient's tissue (Riguzzi *et al*., 2017). Today ultrasound gel is commonly used as a coupling agent. Conventional ultrasound gel is water based and typically contains an agent that retains water, a preservative and colouring agent (Mueller *et al*., 2013)

Renal ultrasound plays an important role in the management of urology patients Ultrasound gel is often out of stock in rural hospitals, as it is frequently used; suppliers may have difficulty distributing to remote locations and hospital funds are limited. Thus, cheaper, more readily available alternatives warrant consideration.

Although there is a paucity on possible ultrasound alternatives in the literature, a few alternative ultrasound media have been investigated. Riguzzi *et al*., (2017) used a home-made cornstarch-based gel to obtain ultrasound imaging with similar image quality compared to conventional ultrasound gel. However, this cornstarch medium should be used within 2 days of preparation as the starch and water can separate (Riguzzi *et al*., 2017). Sterility is also uncertain as it is home-made (Riguzzi *et al*., 2017). Mueller and Theoharis (2013) reported the successful use of mineral oil, 0.9% saline and water as alternative coupling agents when performing a venous duplex

ultrasound. Alternatives were sought as a patient who needed a duplex doppler ultrasound for a suspected deep vein thrombosis, reported an allergic reaction after a previous ultrasound was performed. Possible allergens in ultrasound gel are polypropylene glycol, propylene glycol and parabens (Mueller *et al.,* 2013). The alternatives they considered did not contain any of these substances (Mueller *et al*., 2013). Luewan *et al.,* (2007) found that olive oil can be used to obtain ultrasound images that are of similar quality compared to conventional ultrasound gel (Mueller *et al*., 2013).

I propose using petroleum jelly as an alternative to conventional ultrasound gel when performing a renal ultrasound, as it is cheaper and more readily available than ultrasound gel.

According to the International Programme on Chemical Safety and the Commission of the European Communities petroleum jelly consists of hydrocarbons with carbon numbers greater than 25 (2002).

Conventional ultrasound gel is made up of a gelling agent (i.e.etherified hydroxyethylcellulose), a solvent (i.e.1,3-propanediol), water and an antimicrobial agent (i.e. benzalkonium chloride) (Google patents 2019).

A PubMed database search was done, which was restricted to the human species and the English language. The following search strategies were used with the keywords: “ultrasound” and “petroleum jelly”; “sonar” and “petroleum jelly”; “ultrasound” and “Vaseline”; “sonar” and “Vaseline”. No literature was found with regards to the use of petroleum jelly to perform ultrasound in general, or in renal ultrasound specifically. However, petroleum jelly has reportedly been used for ocular ultrasound in an Emergency Department setting by Engelbert and Palma in 2015. Engelbert and Palma (2015) only reported that petroleum jelly did not damage the ultrasound probe, but did

not report on the quality of such images on its own or in comparison to ultrasound gel images (Engelbert and Palma, 2015).

1.1 Cost comparison:

An initial Internet search was done on 21 April 2018 on the cheapest petroleum jelly, ultrasound gel and wooden spatulas (to apply petroleum jelly to the ultrasound probe) available in South Africa. The results were updated on the 9th of August 2018 with results as shown in the table below.

MERCHANT:	**PRODUCT:**	**PRICE PER CONTAINER**	**AMOUNT USED PER PATIENT**	**PATIENTS PER CONTAINER**	**PRICE PER PATIENT**
Clicks	**Vaseline blue seal original** (Price Check (a))	R49.95 for 450ml	5ml	90	56c+25c (spatula) = 81c
Clicks	**Vaseline blue seal original** (Price Check (b))	R32.99 for 250ml	5ml	50	66c+25c (spatula) = 91c
Afrimedics	**Ultrasound gel** (Afrimedics)	R25 for 250ml	15ml	16	R1,67
Afrimedics	**Wooden spatula** (Price Check (c))	100 spatulas for R25	1	100	25c

A saving of 86 cents per patient, equating to a saving of almost 50% (48.5%) per patient could possibly be achieved by using petroleum jelly instead of ultrasound gel.

1.2 Research question:

The research question is whether petroleum jelly, instead of ultrasound gel, could possibly be used in remote locations and as a cost saving option for renal ultrasound imaging.

2 STUDY AIM AND OBJECTIVES

2.1 Study aim:

The aim of the study is to demonstrate whether petroleum jelly may be used to produce renal ultrasound images of similar quality to those obtained with conventional ultrasound gel.

2.2 Study objectives:

2.2.1 Primary objectives

1. To compare renal ultrasound imaging obtained by using petroleum jelly (test) *versus* conventional ultrasound gel (control).
2. To determine if petroleum jelly ultrasound imaging is adequate for clinical use.

2.2.2 Secondary objective

1. To stimulate interest in further research of petroleum jelly as a cost-effective alternative ultrasound medium.

3. METHODS

3.1 Setting:

This study will be done at Thelle Mogoerane Regional Hospital (TMRH) in Vosloorus. It is one of four academic hospitals of the University of the Witwatersrand. It has 821 beds and delivers level 1 and level 2 health care to the East Rand of Johannesburg.

3.2 Study population:

A minimum of forty patients aged 18 to 70 years presenting to the Out Patient Department of TMRH, Department of Urology will be consented for this study. Recruitment of patients will be done in the 3 month period following ethics clearance. A minimum of 40 patients will each have two renal ultrasounds done of the left kidney with conventional ultrasound gel (control) and with petroleum jelly (test) respectively.

3.3 Study design:

This will be a prospective pilot study.

3.4 Patient selection criteria:

3.4.1 Patient inclusion criteria:

- All adult patients aged between 18 and 70 years presenting to TMRH Urology Out Patient Department. The ultrasound performed for this study will not be used for diagnosis or treatment and it will not replace any formal imaging that is required for patient care.

3.4.2 Patient exclusion criteria:

- Patients who have wounds or skin conditions affecting their abdominal or flank area, will be excluded from the study.

3.5 Patient sample size:

The assistance of a biostatistician was used to determine the minimum patient sample size needed in each group for this study. A minimum of 40 patients will need to be recruited for the study to be able to analyse the data collected effectively.

3.6 Data collection procedure:

All the selected patients will have consented for the ultrasound procedure. The patients selected for the study will however be asked to consent for the anonymous use of their kidney scan data. Participation is voluntary and any patient may withdraw from the study at any point without jeopardizing any treatment at the hospital at any stage.

All the selected patients will have two ultrasounds done of the left kidney using conventional ultrasound gel and petroleum jelly respectively. One ultrasonographer will perform all the ultrasounds and score each image from 1 to 3 (1-worst, 3- best) with regards to the following criteria (Shapiro *et al*., 1998):

1. Penetration: Demonstration of the kidney at increasing depth.
2. Detail: Sharpness of the outline of the solid and fluid filled areas.
3. Total image quality: Contrast between solid and fluid areas and absence of artifact or noise.

The ultrasonographer will also comment on whether the imaging is adequate for clinical use and which image's quality is better?

Each patient will have a file containing the following documents:

1. Written consent.
2. Image evaluation sheet.
3. Printed ultrasound image.

The data will be entered on an Excel spreadsheet and statistically analyzed using R software.

4 DATA ANALYSIS:

A codebook will be used to record the following variables to facilitate importation into the software: Penetration, detail, total image quality on a scale of 1 (worst) to 3 (best) and adequacy for clinical use. The distribution of the data will be analysed using descriptive statistics. Numerical variables will be described using measures such as

mean, standard deviations, minimum and maximum. Categorical variables will be reported with frequencies and graphs. The two images obtained for each patient using the control- and test medium respectively will be compared by the sonographer. She will decide which one is of better quality overall.

The Pearson's correlation, independent sample T-test and Bland Altman test will be used for inferential statistical analysis. The Pearson's correlation will be used to evaluate the categorical variables of the control and study group. The independent T-test will be used to compare the means of the control and study groups. The level of agreement between the control and study groups will be analysed using the Bland-Altman plot.

If data is not normally distributed the Fischer's exact test will be used instead of the Pearson's correlation to evaluate categorical variables.

If data is not normally distributed the Mann-Whitney test will be used instead of the independent T-test to compare the medians of the control and study groups.

These statistical methods will be used to draw conclusions from the collected data.

5 ETHICS:

Ultrasound gel and petroleum jelly pose no risk to patients. For infection control, a clean tongue depressor will be used for each patient to apply petroleum jelly on the ultrasound probe. The probe will be cleaned after each use, according to the specifications of the manufacturer of the ultrasound machine.

All patient's personal details will be kept confidential and a specific study number will be allocated to each individual patient's data collection sheet. This study number will appear on the data collection sheet and the patient consent form. Although the patient consent form will display the patient name and hospital number too, the consent forms

will be kept separate from the data collection sheets in a safe locked drawer to which only the principal investigator has access.

The Human Research Ethics Committee (HREC) (medical) of the University of the Witwatersrand have been approached for ethical approval of this study. The data will only be accessed by the principal investigator and will remain anonymous from the start of data collection since no patient names, hospital numbers or ID numbers will be recorded, to ensure patient confidentiality. Permission to conduct the research has already been granted by The Thelle Mogoerane Regional Hospital management team (CEO) and by Dr TM Kasapato (Head of Department of Urology at Thelle Mogoerane Regional Hospital) respectively, subject to ethical approval by the HREC (medical) of the University of the Witwatersrand.

6 STUDY LIMITATIONS:

- Subjective image evaluation is done by one experienced senior ultrasonographer.
- The person evaluating the images is not blinded as to which ultrasound medium is used.
- Ultrasound is a dynamic, operator dependent investigation.

7 FUNDING:

- The costs of ultrasound gel, petroleum jelly, wood spatulas and all stationary will be covered by the principal investigator.
- Printing will be done at the Department of Surgery, Division of Urology of the University of the Witwatersrand.
- The ultrasound machine of the Department of Urology at TMRH will be used with permission (please see appendices D and E attached).

ITEM	ESTIMATED COST

Ultrasound gel	R 300
Petroleum jelly	R 200
Wood spatulas	R 100
Stationary	R 400
Total Cost to PI	**R 1000**

8 TIMING:

	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May	June	July	Aug	Sep	Oct
Literature review	X	X	X										
Preparing Protocol		X	X	X	X								
Protocol Assessment						X							
Ethics Application		X											
Collecting Data							X	X	X				
Data Analysis									X	X	X		
Writing up MMed											X	X	X
Writing up Paper											X	X	X

9 References:

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APPENDIX A: Participant information sheet

STUDY INFORMATION DOCUMENT
Dr. R.C. Ras

Study title:

CAN PETROLEUM JELLY BE USED TO OBTAIN SATISFACTORY RENAL ULTRASOUND IMAGING?

Introduction: Good day, my name is Dr Reuben Ras and I am a registrar in the Department of Surgery in the Division of Urology at the University of the Witwatersrand. I am currently conducting a compulsory research study for my MMed degree in order to complete my specialization as an urologist. I have permission from the Human Research Ethics Committee (HREC) (medical) of the University of the Witwatersrand with clearance number **M181131** to do this study. I also have written permission from the CEO of the Thelle Mogoerane Regional Hospital and the Head of the Department of Urology to do this study.

We are doing this study to see if petroleum jelly (Vaseline) can be used to do an ultrasound of a kidney. Vaseline is being considered as it is less expensive and more readily available than conventional ultrasound gel.

What does the study involve? An ultrasound scan of your left kidney will be done using petroleum jelly and conventional ultrasound gel respectively. The images will be evaluated individually and compared to each other.

1. Ultrasound gel is used to do ultrasound imaging. We are testing the use of petroleum jelly to obtain ultrasound images.
2. The procedure will be done at the Thelle Mogoerane Regional Hospital Department of Urology. The procedure time is more or less 10 minutes. If you agree to participate in this study you will be asked to sign a consent form giving us permission to use your kidney scan as part of our study.

Risks of being involved in the study: This study poses no risk to your health.

Benefits of being in the study: There is no benefit or remuneration for participating in this study.

Invitation to Participate: We are inviting all adults over the age of 18 already booked for a kidney ultrasound to take part in this research study after reading this information sheet and after the study is verbally explained to you.

Participation is voluntary: Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty, or loss of benefits to which you are otherwise entitled. You will not be required to provide a reason for withdrawing from the study. In case of withdrawal, any data collected on you will in default be destroyed, unless you specifically consent to its retention.

Reimbursements: No reimbursement will be given.

Confidentiality: Your personal information will be treated in the strictest confidence as it will only be available to the Principal Investigator (Dr RC Ras). All patient's personal details will be kept confidential and a specific study number will be allocated to each individual patient's data collection sheet. This study number will appear on the data collection sheet and the patient consent form. Although the patient consent form will display the patient name and hospital number, the consent forms will be kept separate from the data collection sheets in a safe locked drawer to which only the principal investigator (Dr RC Ras) has access.

Anonymity: Your data will be used anonymously as no name, hospital number or ID number will be recorded.

Contact details of researcher/s:
Principal Investigator: Dr R.C. Ras: Tel: 011 481 2000. E-mail address: rasreu01@gmail.com
Supervisor: Prof M. Haffejee: Tel: 011 482 3663 E-mail address: mohamedhaffejee@mweb.co.za

Outputs: This study is done with the aim to improve ultrasound availability, to complete a MMed degree, to possibly present the results at academic and/or clinical meetings and to possibly publish the results. The results of the study can be sent to you if you would like to receive it.

Contact details of HREC administrator and chair (for more information and/or for reporting complaints/problems).

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.
If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

Date: / / 2019

You are welcome to keep this information sheet for your own records.

APPENDIX B: Patient consent form

Study title:

CAN PETROLEUM JELLY BE USED TO OBTAIN SATISFACTORY RENAL ULTRASOUND IMAGING?

Principal Investigator: Dr Reuben Charles Ras

I ……..
agree to voluntarily participate in this research study. The research has been explained to me, I have read the study information sheet and I understand what my participation will involve.

- I understand that my participation is voluntary
- I understand that I can withdraw from this study at any time without any consequences to my hospital treatment
- I understand that my participation will remain anonymous
- I understand that the researcher may print and use my renal ultrasound images in his research
- I understand that the information I provide may be used anonymously by researchers following this study

…… (Patient Signature) …… (Date)

…… (Principal Investigator Signature) …… (Date)

…… …… (Name of participant)
…… (Hospital number)
…… …… (Study ID)

APPENDIX C: Data collection sheet: Ultrasound image evaluation form:

CAN PETROLEUM JELLY BE USED TO OBTAIN SATISFACTORY RENAL ULTRASOUND IMAGING?

Dr Reuben C. Ras

Student Number: 0704663F

Date:

Study ID:

Medium used:

Criteria:	**Score out of 3 (1-worst, 3-best) (Please circle)**
➢ **Penetration**	1 2 3
➢ **Detail**	1 2 3
➢ **Total image quality**	1 2 3

Is the image adequate for clinical use? YES NO (Please circle)

APPENDIX D: The Thelle Mogoerane Regional Hospital management team (CEO) permission

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Enquiries: P/N Sigasa/P/N Mabizela
Directorate: Staff Development
Telephone number: (011) 590 0109
Email: Moipone.Sigasa@gauteng.gov.za

Date: 26 June 2018

Dr RC Ras

Thelle Mogoerane Regional Hospital Management Team is pleased to grant you provisional permission to conduct your study to conduct research on **In settings where resources are limited and conventional ultrasound gel is not always readily available, can petroleum jelly be used to obtain satisfactory renal ultrasound imaging.** Your data will be conducted through obtaining information through **"Prospective data collection"** in your protocol for which you will obtain the ethics clearance certificate from the University of Witwatersrand for Full permission to be granted.

The following condition must be adhered to otherwise permission will be withdrawn:

- Only the research and/or research methods outlined in the protocol presented to the Research Committee should be conducted and/or followed otherwise the research will be cancelled.

Please note that you can only get full clearance once you provide the hospital with the Ethics Clearance Certificate

Dr C N Mqhayi-Mbambo
Chief Executive Officer
Thelle Mogoerane Regional Hospital
Date: 27/6/18

"To be the best provider of quality health care services to the people of Gauteng"

APPENDIX E: Dr Kasapato- HOD Urology TMRH permission

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Permission for Dr RC Ras to do a MMed study at Thelle Mogoerane hospital:

MMed topic: In settings where resources are limited and conventional ultrasound gel is not always readily available, can petroleum jelly be used to obtain satisfactory renal ultrasound imaging?

Method: 40 patients that present to Urology OPD will have a renal ultrasound done. 20 will be done using petroleum jelly and 20 will be done using conventional ultrasound gel. The ultrasound machine of the department of Urology will be used.

Participation is voluntary. The patients will be asked to consent for the ultrasound and the anonymous use of their data.

I, Dr TM Kasapato (HOD Urology- Thelle Mogoerane Hospital)

give permission for this study to be done at Thelle Mogoerane Hospital Urology OPD.

Signature:

Date: 11/06/2018

APPENDIX 2: Ethics clearance certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research & Post Graduate Affairs)

TO: Dr RC Ras and Ms B Mapoko
School of Clinical MedicineSchool of Clinical Medicine
Department of Urology
Medical School
University

E-mail: rasreu01@gmail.com

CC: Supervisor: Professor M Haffejee <mohamedhaffejee@mweb.co.za>
and <HREC-Medical.ResearchOffice@wits.ac.za>

FROM: Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 10/05/2019

REF: *R14/49*

PROTOCOL NO: **M181131** *(This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)*

PROJECT TITLE: Can petroleum jelly be used to obtain satisfactory renal *ultrasound imaging?*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr RC Ras and Ms B Mapoko

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M181131

NAME: (Principal Investigator)	Dr RC Ras and Ms B Mapoko
DEPARTMENT:	School of Clinical Medicine Department of Urology Medical School University
PROJECT TITLE:	Can petroleum jelly be used to obtain satisfactory renal ultrasound imaging?
DATE CONSIDERED:	30/11/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professor M Haffejee
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	10/05/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. I **agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore reports and re-certification will be due early in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE CLEARANCE CERTIFICATE NUMBER IN ALL ENQUIRIES

APPENDIX 3:

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by Marietha Nel

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