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# **Evaluation of pelvic floor morphology in South African females**

By

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Submitted in fulfilment of the requirements for the degree of

**DOCTOR OF PHILOSOPHY**

in the Faculty of Health Sciences,

University of Pretoria

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2<sup>nd</sup> July 2017

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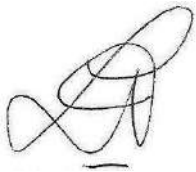
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## DECLARATION

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I, Dr Zeelha Abdool hereby declare that the dissertation I submit to the University of Pretoria for my PhD degree in Obstetrics and Gynaecology is my own work and has not been submitted to any other facility prior.



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**Dr Zeelha Abdool**

2nd day of July 2017

## **DEDICATION**

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**To my beloved parents, your words resonate with me forever,  
“Shoot for the moon and you will land among the stars”.**

# ETHICAL APPROVAL

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The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 13/04/2011 and Expires 13/04/2014.



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Faculty of Health Sciences Research Ethics Committee

27/02/2014

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## Approval Certificate New Application

**Ethics Reference No** 226/2011

**Title** Evaluation of pelvic floor morphology in South African females

Dear Dr Zeelha Abdool

The **New Application** as supported by documents specified in your cover letter for your research received on the 28/08/2013, was approved by the Faculty of Health Sciences Research Ethics Committee on the 26/02/2014.

Please note the following about your ethics approval:

- Ethics Approval is valid for 3 years
- Please remember to use your protocol number (226/2011) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

**Ethics approval is subject to the following:**

- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

---

**Dr R Sommers;** MBChB; MMed (Int); MPharMed.

**Deputy Chairperson** of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

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## SUMMARY

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Pelvic floor dysfunction in the form of pelvic organ prolapse (POP) is a common gynaecological condition, especially in the elderly. Although the aetiology is poorly understood, several risk factors such as vaginal childbirth, chronically raised intra-abdominal pressure (such as asthma and chronic constipation), ageing, previous hysterectomy and connective tissue disorders are thought to play a role in the pathophysiology of POP. Studies have shown that vaginal childbirth can result in both gross and micro-architectural distortion/alteration of the pelvic floor musculature and is thus considered to play a major role in the development of POP. Although ethnicity has been proposed as a risk factor, there are limited studies on this subject.

Recently, transperineal ultrasound (TPUS) has been used to study the structural integrity and the dynamic interaction between the pelvic organs and pelvic floor musculature. Using a specified methodology we intended to determine and compare pelvic floor morphology, namely pelvic organ descent and levator hiatus distensibility in a multi-ethnic South African population (Asian, Caucasian and Black) in both asymptomatic nulliparous and symptomatic multiparous women. Secondly we also intended to study the association between prolapse symptoms and functional anatomy of the pelvic floor, and finally to determine the impact of vaginal childbirth on the pelvic floor morphology 3-6 month postpartum. For all the studies women were recruited from the local nursing school, general gynaecology and tertiary urogynaecology clinic. Pregnant women were recruited from the district antenatal clinic. This cohort included only Black pregnant women.

After informed consent all ultrasound volumes were acquired at rest, maximal pelvic floor contraction and Valsalva maneuver. Volumes were deidentified and analysed 6-8 weeks later using GE Kretz 4D View (GE Kretztechnik GmbH, Zipf, Austria).

In the nulliparous cohort, we found that Black South African women had greater pelvic organ descent on ultrasound and clinically and greater distensibility compared to South Asian and Caucasian women. Multivariate modelling revealed that Black

ethnicity remained a significant factor for pelvic organ mobility on clinical examination, (P=0.024).

In women with symptomatic POP, there was significant variation in clinical prolapse stage, levator distensibility and pelvic organ descent in this racially diverse population presenting with pelvic organ prolapse, with South Asians having a lower avulsion rate than the other two ethnic groups (P= 0.014).

As regards the association between prolapse symptoms and functional anatomy of the pelvic floor we found a significant association between awareness, visualization and/or feeling of a vaginal lump and abnormal pelvic floor functional anatomy, that is, hiatal ballooning and levator avulsion (all P< 0.05).

The fourth part of the study included eighty four women who returned at a mean of 4.8 months postpartum. We found significant alteration in pelvic organ support and levator hiatal distensibility after vaginal delivery i.e. a significant increase in mean values from ante to postpartum measurements, more so for the vaginal delivery group. 15% of Black primiparous women sustained levator trauma after their first vaginal delivery.

In conclusion, to the author's knowledge this is the first study on pelvic floor morphology in South African women. Contrary to previous publications inferring that Black women rarely develop PFD, we have shown that this particular ethnic group had significantly different pelvic floor dynamics than Caucasian and South Asian women for both nulliparous and multiparous symptomatic women. Levator trauma occurs in 15% of Black women after vaginal childbirth.

**Keywords:** pelvic organ prolapse, ethnicity, transperineal ultrasound, pelvic organ descent, levator avulsion

## ACKNOWLEDGEMENTS

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I extend my deep appreciation and gratitude to Professor Hans Peter Dietz and Professor Barend Gerhardus Lindeque for their unwavering support, expert mentoring and encouragement. Your leadership and wealth of knowledge were invaluable for the completion of this dissertation.

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In addition I am indebted to my 4 wonderful children, my three fantastic siblings and patient husband, Shahed who blessed me with a life of academic joy!



## LIST OF ABBREVIATIONS

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ATLA	Arcus tendineus levator ani
ARA	Anorectal angle
BMI	Body mass index
BND	Bladder neck descent
D	Dimensional
Et al	Et alia ('and others')
EAS	External anal sphincter
IUGA	International urogynaecology association
UI	Urinary incontinence
ICS	International continence society
ICIQ-VS	International consultation on incontinence-vaginal symptom
LAMC	Levator ani muscle complex
LUG	Levator urethral gap
MOS	Modified oxford score
MRI	Magnetic resonance imaging
PFD	Pelvic floor dysfunction
POP-Q	Pelvic organ prolapse quantification
PFMC	Pelvic floor muscle contraction
ROC	Receiving operator characteristics
TPUS	Transperineal ultrasound
TUI	Tomographic ultrasound imaging
T	Transducer

US	Ultrasound
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## LIST OF PAPERS

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This dissertation is based on the following papers, referred to in the text by arabic numerals.

1. Abdool Z, Dietz H.P, Lindeque B.G. Are there ethnic differences in the levator hiatus and pelvic organ descent? A Prospective observational study. *Ultrasound Obstet Gynecol*, DOI 10.1002/uog.17297.

2. Abdool Z, Dietz H.P, Lindeque B.G. Prolapse symptoms are associated with abnormal functional anatomy of the pelvic floor. *Int Urogynecol J* (2017). doi:10.1007/s00192-017-3280-0

3. Abdool Z, Dietz H.P, Lindeque B.G. Interethnic variation in pelvic floor morphology in women with symptomatic pelvic organ prolapse. Accepted by *Int Urogynecol J* as at 31 May 2017. Ref IUJO-D-17-00059R2.

4. Abdool Z, Lindeque B.G, Dietz H.P. The impact of childbirth on pelvic floor morphology in primiparous Black South African females: A prospective longitudinal observational study. Submitted to *Ultrasound in Obstetrics and Gynecology*- awaiting response as at 2<sup>nd</sup> July 2017.

## INTRODUCTION

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Pelvic floor disorders (PFD) include pelvic organ prolapse (POP), urinary incontinence (UI), fecal incontinence (FI), bladder storage symptoms, sexual and anorectal dysfunction<sup>1</sup>. A national US population based study found that one quarter of all women reported at least one pelvic floor disorder, and the prevalence increases with age<sup>2</sup>. With the projected increase in older population it is expected that an increase in PFD will substantially impact negatively on health care costs and quality of life. The focus of this dissertation is on POP specifically.

Although population based epidemiological studies of POP are rare, POP is a common reason for benign gynaecological consultation and surgery<sup>3, 4</sup>. The condition has been described as early as 2000 years before the birth of Christ, at which time the insertion of foreign substances was common practice. Interestingly Hippocrates recommended succussion therapy which involved tying the women upside down by her legs and rapidly moving her up and down to reposition the pelvic organ<sup>5</sup>. Currently both surgical management and the use of vaginal pessaries remain the mainstay of treatment. POP is a multifactorial condition with several risk factors which include vaginal childbirth, chronically raised intra-abdominal pressure (e.g. chronic obstructive airway disease, asthma), raised body mass index (BMI), ageing, previous hysterectomy and connective tissue disorders. Specific obstetric factors include prolonged second stage and forceps delivery<sup>6, 7</sup>. Although ethnicity has been proposed as a risk factor, there are limited studies on this subject.

**Table 1: Risk factors for pelvic organ prolapse**

- Vaginal delivery
- Advancing age
- Obesity
- Pregnancy (Irrespective of mode delivery)
- Forceps delivery
- Young age at first delivery
- Prolonged second stage delivery
- Infant birth weight >4500g

**Other proposed risk factors:**

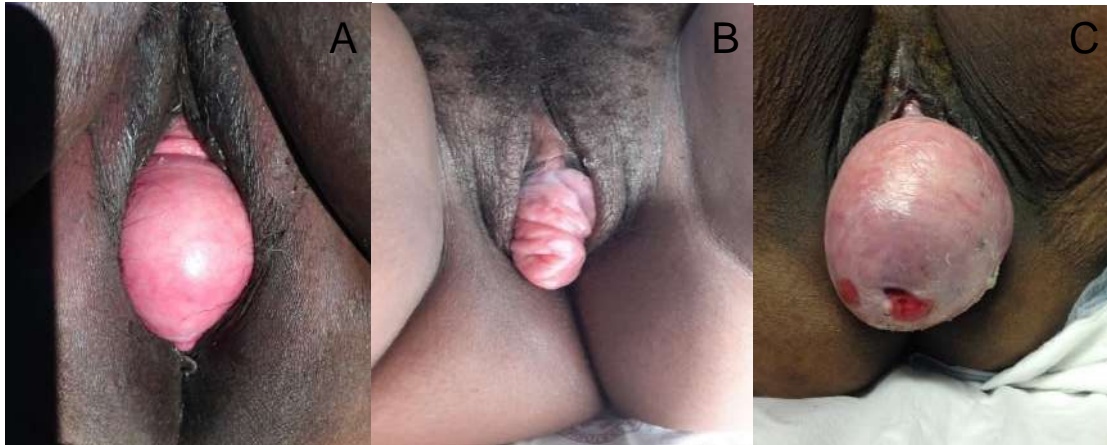
- Shape or orientation of bony pelvis
- Family history of pelvic organ prolapse
- Race or ethnic origin
- Chronically raised intra-abdominal pressure e.g. asthma
- Connective –tissue disorder
- Previous hysterectomy

**Pelvic organ prolapse:**

**Definition and Staging:**

According to the International Urogynecological Association/ International Continence Society (IUGA/ICS) joint report on the terminology for female pelvic floor dysfunction POP is defined as: descent of the one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix), or apex of the vagina (vaginal vault or cuff scar after hysterectomy). The presence of any such sign should be correlated with relevant POP symptoms. More commonly the correlation would occur at the level of the hymen or beyond <sup>1</sup>. Herniation of the pelvic organs includes the bladder (anterior vaginal wall), and/or rectum (posterior vaginal wall), and/or the uterus/apex of the vagina (vault) and/or bowel (enterocele). Figure 1 shows the different types of clinical POP. Bladder prolapse is most common and is referred to as a cystocele.





**Figure 1:** Different types of pelvic organ prolapse. A, Bladder prolapse (cystocele); B, prolapse of apex of vagina (vault prolapse); C, uterine and bladder prolapse.

Currently the Pelvic Organ Prolapse Quantification (POP- Q) system is used to stage POP <sup>8</sup>. This was introduced in 1996 and it provides a standardized tool enabling clinicians to document, compare and communicate clinical findings (see Table 2). Using the hymen as fixed reference point, six defined points are measured in centimetres above or below the hymen.

<b>Table 2: Five stages of pelvic organ support as defined by the pelvic organ prolapse Quantitation System</b>	
<b>Stage</b>	<b>Definition</b>
0	No prolapse
I	The most distal portion of the prolapse is >1 cm above the level of the hymen
II	The most distal portion of the prolapse is ≤ 1cm proximal or distal to the hymen
III	The most distal portion of the prolapse is >1cm below the hymen but protrudes no further than 2cm less than the total vaginal length
IV	Complete eversion of the total length of the vagina The distal portion protrudes at least the total vaginal length minus 2cm beyond the Hymen

## Symptoms of POP:

POP symptoms are described as, a departure from normal sensation, structure, or function, experienced by the woman in reference to the position of her pelvic organs. Symptoms are generally worse at times when gravity might make the prolapse worse (e.g. after long periods of standing or exercise) and better when gravity is not a factor, for example, lying supine <sup>1</sup>. Common symptoms include the complaint of vaginal lump/bulge which can be either felt or seen on the inside /outside of the vagina, feeling of pelvic pressure, need to digitate to empty bladder or rectum and reduce the prolapse and also lower backache. In the presence of urethral kinking obstructive voiding may also occur <sup>9</sup>. Many of these symptoms have not been validated against objective prolapse assessment. Although a standard definition for vaginal laxity/ looseness is lacking it is also a bothersome condition with a prevalence of 24%, and has been shown to be associated with younger age, vaginal parity, symptoms of POP and objective prolapse on POP-Q staging and ultrasound <sup>10</sup>.

Recently Chatel et al investigated the predictive value of two common symptoms i.e. 'vaginal lump/bulge' and /or 'dragging sensation' for POP (clinically and on ultrasound) and found that 'vaginal lump/bulge was a stronger predictor of objective POP than 'dragging sensation' <sup>11</sup>.

POP has been shown to be associated with significant bother including financial burden and thus clinicians have begun to focus on the impact of POP by using several validated self-completed questionnaires such as the International Consultation on Incontinence Questionnaire (ICIQ-VS) <sup>12,13,14</sup>. It is important to note that the use of questionnaires has been criticized for their cumbersomeness and lack of specificity <sup>11</sup>.

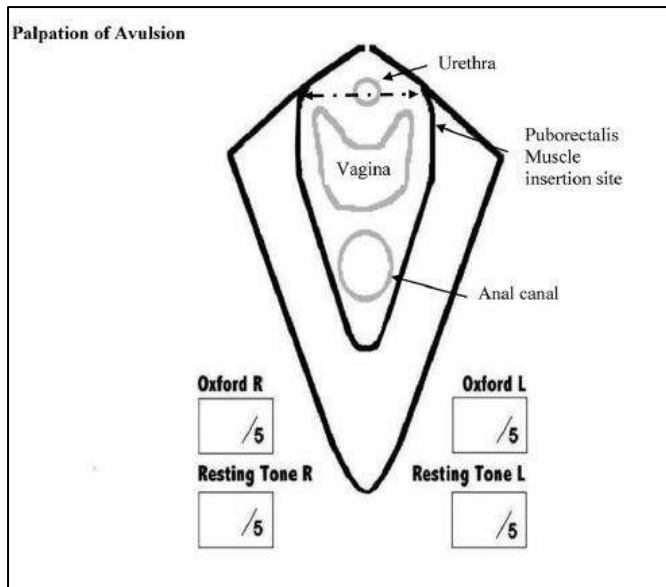
Currently there is no conclusive data on the prevalence and/or burden of POP in South Africa, although common <sup>15</sup>. Data on incidence and prevalence is currently limited to Western populations (mainly of Caucasian ethnicity) with scant information in developing countries. It has been suggested that risk factors in developing countries are unique i.e. early childbirth; home deliveries, poor nutrition and heavy lifting are thought to play a role <sup>16, 17</sup>. It has also been generally accepted that PFD is rare in Black South African and African American women, due to genetic endowment

of superior connective tissue quality<sup>18, 19</sup>. Thus, for several decades now, ethnicity has been proposed to play a role in the pathophysiology of both UI and POP.

### **Assessment of POP:**

After a detailed history a POP-Q examination is performed to stage the prolapse. This is performed with the patient in the supine position and usually after bladder emptying. The prolapse is staged on Valsalva maneuver to fully define the full extent of POP, using a Sims speculum. The aim of the Valsalva maneuver is to replicate the anatomical prolapse defect responsible for the symptom. Mulder et al evaluated the abdominal pressures required to achieve near maximal pelvic organ descent in women referred for pelvic floor dysfunction, and found that almost all patients are able to generate sufficient pressures allowing maximal pelvic organ descent and thus the need to standardize Valsalva pressures is not necessary<sup>20</sup>.

The modified Oxford scoring (MOS) system is used to determine the strength of the levator ani muscle during a voluntary pelvic floor contraction and is graded on a six point scale i.e. 0, no contraction ; 1, minor contraction; 2, flicker; 3, moderate muscle contraction; 4, good contraction ; 5 , strong contraction against resistance by the examining<sup>21</sup>. During this examination the insertion/ attachment of the levator ani muscle to the inferior pubic ramus can be palpated, although this has been shown to require substantial training<sup>22</sup>. Dietz et al has also shown that detachment of the puborectalis part of the LAMC (referred to as an avulsion injury) is associated with a significant reduction in the mean overall Oxford grading<sup>23</sup>. To obtain the MOS score we have used the template given in Fig. 2.



**Figure 2:** Template used for recording of both resting tone and Oxford score as well as digital assessment for levator avulsion. (Courtesy HP Dietz, Sydney)

Apart from clinical examination, the addition of imaging such as magnetic resonance imaging (MRI) and ultrasound (US) has greatly improved our ability to further study the dynamics/function and morphology (form and structure) of the pelvic floor and is thus performed in many research units.

## LITERATURE REVIEW

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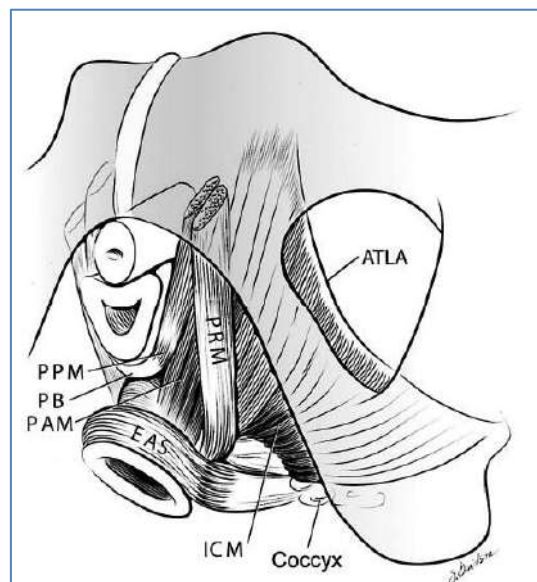
In the following literature review the relevant gross anatomy and factors associated with the development of POP are considered with specific emphasis on the clinical implications of the impact vaginal childbirth on the pelvic floor. Ethnic differences of the pelvic floor, as well as the role of ultrasound in the study of the LAMC are also discussed.

### **2.1 Gross anatomy and impact of vaginal childbirth:**

The levator ani muscle complex (LAMC) is responsible for maintaining adequate pelvic floor support <sup>24, 25</sup>. Its structure and function is complex and unlike other striated muscles, is composed of both smooth and skeletal muscle bundles responsible for its myoelectric activity <sup>26</sup>.

According to Terminologia Anatomica the pelvic floor consists of three muscle groups, namely, the iliococcygeus, puborectalis and pubococcygeus/ pubovisceral (which may be subdivided into puboperinealis, pubovaginalis and puboanalis) <sup>27</sup>. See Table 3 for a detailed description of origin/insertion and function. Figure 3 illustrates the composition of the LAMC with a view from below. An accurate understanding of the structure and function of the LAMC is important as damage during vaginal childbirth (apart from other factors discussed) plays a significant role in the development of POP <sup>28, 29</sup>.

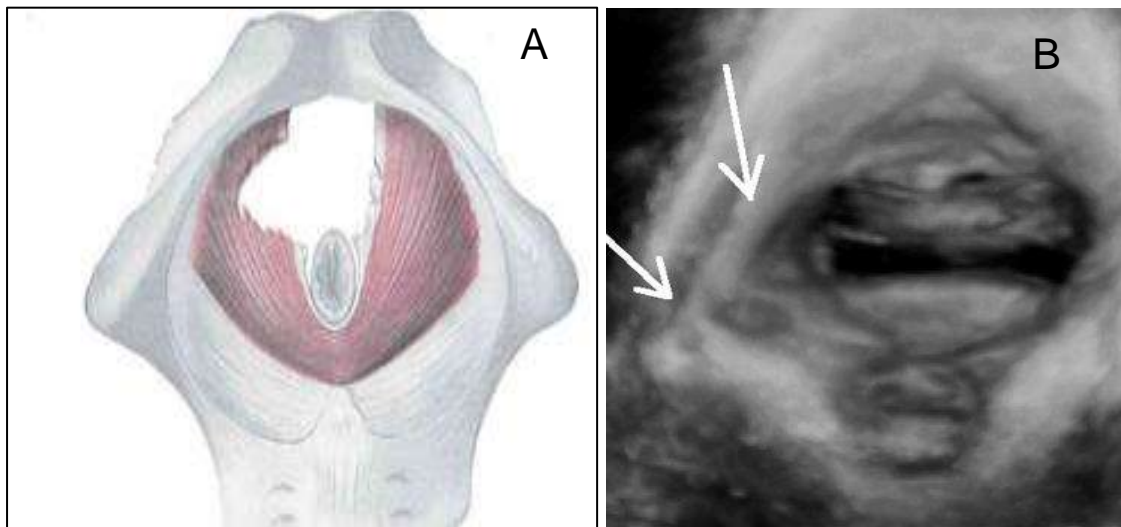
Table 3 Terms and descriptions Used in Terminologia Anatomica		
Terminologia Anatomica	Origin/Insertion	Function
<b>“Pubococcygeus” (recommend pubovisceral)</b>	Pubis/perineal body	Tonic activity pulls perineal body ventrally toward pubis
<b>Pubovaginalis</b>	Pubis/vaginal wall at the level of the mid-urethra	Elevates vagina in region of the mid-urethra
<b>Puboanalis</b>	Pubis/ intersphincteric groove between internal and external anal sphincter to end in the anal skin	Inserts into the inter-sphincteric groove to elevate the anus and its attached anorectum
<b>Puborectalis</b>	Pubis/form sling behind the rectum	Forms a sling behind the rectum forming the anorectal angle and closing the pelvic floor
<b>Iliococcygeus</b>	Tendinous arch of the levator ani /the 2 sides fuse in the iliococcygeal raphe	The 2 sides form a supportive diaphragm that spans the pelvic canal.



**Figure 3:** Schematic view of the levator ani muscles from below after the vulvar structures and perineal membrane have been removed showing the arcus tendineus levator ani (ATLA); external anal sphincter (EAS); puboanal muscle (PAM); perineal

body (PB) uniting the two ends of the puboperineal muscle (PPM); iliococcygeal muscle; puborectalis; muscle (PRM). Note that the urethra and vagina have been transected just above the hymenal ring. Copyright ©DeLancey 2003.

During vaginal childbirth the most medial part of the LAMC has to stretch substantially to allow passage of fetal head i.e. the area of the levator hiatus ranges from 6-36cm<sup>2</sup> (on Valsalva) in young nulliparous women and the average area required by the fetal head is 70-90 cm<sup>2</sup> (equating to a head circumference of 30-35 cm), thus straining and possibly tearing the puborectalis muscle off its normal insertion on the inferior pubic ramus<sup>30, 31</sup>. This trauma is referred to as an avulsion injury and is clearly visualized with modern imaging techniques, see Figure 4.

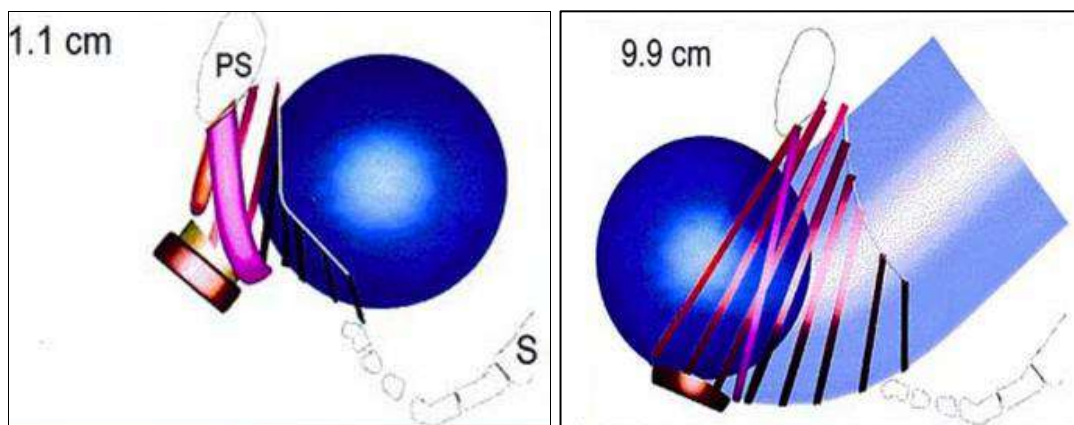


**Figure 4:** Gross appearance (A) of an avulsion the ultrasound equivalent thereof in B as seen on ultrasound. White arrows in B indicate the defect.(Figure A De Lee J. *The Principles and Practice of Obstetrics (7th Edition)*. WB Saunders Company, PA, USA (1938)). Figure B reproduced with permission from John Wiley and sons from Dietz HP. *Ultrasound Obstet Gynecol* 2006; 28:80-92.

In 1907, Josef von Halban (Obstetrician and Gynaecologist) and Julius Tandler (anatomist) from Vienna Medical School described findings compatible with this injury<sup>32</sup>. Using physical examination, Howard Gainey, an Obstetrician from Kansas City, subsequently reported an incidence of 14-21% for this injury in both

primiparous and multiparous women <sup>33, 34</sup>. It has been stated and I quote 'levator trauma is likely to be the 'missing link' explaining the epidemiological association between childbirth and female pelvic organ prolapse', and hence the clinical relevance of further studies on this topic are essential <sup>35</sup>.

Svabik et al performed a retrospective observational study on 227 nulliparous women between 36-38 weeks gestation to determine by how much does the levator hiatus (in particular the puborectalis muscle) has to stretch during vaginal delivery. Using 4D TPUS the stretch ratio of the levator hiatus was calculated and it was found that the some women will have to distend by up to 245% beyond muscle length at maximal Valsalva. All the more remarkable that most women will not develop gross trauma in the form of an avulsion <sup>31</sup>. Lien et al developed a 3D computer model to predict levator ani muscle stretch during second stage of labor. Using serial MRI images of one nulliparous patient and engineering software they determined that the total stretch ratio required is 3.26 to deliver a fetal head <sup>36</sup>. Both studies were performed in Caucasian women.



**Figure 5:** Simulation of fetal head (blue) descent during the second stage of labor, at 1.1 and 9.9 cm below the ischial spine, demonstrating that the most medial fibres of the puborectalis muscle undergo most stretch/strain. Reproduced with permission from Wolters Kluwer Health, Inc from Lien KC, Mooney B, DeLancey J et al. *Obstet Gynecol* 2004;103:31-40.

Apart from gross trauma i.e. avulsion injury, the biomechanical properties of the LAMC may alter in the form of 'ballooning' (also referred to as distensibility) which can be visualized on ultrasound. Distensibility of the levator ani muscle has been shown to affect pelvic organ mobility <sup>35</sup>. Dietz et al conducted a retrospective study



involving 544 datasets of women seen at a tertiary urogynaecology clinic, in order to define normality for levator hiatus area on Valsalva by assessing its relationship with clinical signs and symptoms of POP. Based on receiving-operator characteristics (ROC) curves it was suggested that a levator hiatus area  $> 25\text{cm}^2$  on Valsalva be used to define abnormal distensibility.

In summary the pelvic floor might sustain both gross and microscopic trauma after childbirth and to the authors knowledge this has never been studied in South African women using 3/ 4 dimensional (3/ 4D) transperineal ultrasound (TPUS) as the investigation of choice.

## **2.2: Ethnicity and pelvic floor morphology:**

Early studies on ethnicity and the pelvic floor dates back to 1963 when Skinner et al studied the subjective degree of stress UI, urethral length and contractile strength of the pelvic floor (using a Kegel perinoemeter) in nulliparous Caucasian, Asian and Black nurses<sup>37</sup>. Contrary to popular belief of the rarity of UI in Black women, 40.9% of Black women and 46.9 and 42.4% of Caucasian and Asian women respectively demonstrated overt primary stress UI. This was noted as an unexpected finding. Graham et al assessed the effect of race on UI and POP in 183 African –Americans and 132 Caucasians with symptoms of UI and POP. Using stepwise logistic regression to compare the risk factors of UI, Caucasian race was the most significant predictor of stress UI, and African-American race was a predictor of detrusor instability, and there were no significant ethnic differences in the presence and severity of POP<sup>38</sup>.

More recently using ultrasound Howard et al demonstrated that there are functional and structural differences in the pelvic floor as African-American women had greater mobility of the bladder neck than when compared to Caucasians<sup>39</sup>. Dietz conducted a prospective observational study to test for differences in pelvic organ support in one hundred and seventy seven nulliparous pregnant women which included Asians (n=16) and Caucasians (n=161). Using transperineal pelvic floor ultrasound (TPUS) urethral rotation, bladder neck descent (BND) and maximal descent of the posterior bladder wall (anterior compartment), leading edge of cervix and (middle compartment) and rectal ampulla (posterior compartment) was measured relative to the inferior margin of the symphysis pubis. Asians had statistically significantly lower

pelvic organ mobility for all parameters ( $p < 0.05$ ), with no difference noted for cervical mobility than compared to Caucasian counterparts<sup>40</sup>.

To determine what actually constitutes normal pelvic organ mobility, using the same methodology, Dietz et al studied the same parameters in one hundred and eighteen nulligravid Caucasian women prospectively, and quantified descent for all parameters i.e urethral rotation varied from 0-90 degrees (mean 32 degrees), BND from 1.2 - 40.2mm (mean 17.4mm), the cervix descended to between 59 and 0mm (mean 30.8mm) above the symphysis pubis and rectal ampulla descended to between 54mm above and 22 mm below the symphysis pubis (mean 7.8mm)<sup>41</sup>.

More recently ethnic differences in the structure and function of the pelvic floor between primiparous and nulliparous African-American and Caucasian women using MRI have also been investigated<sup>42, 43</sup>. These include greater pelvic floor muscle bulk, closer attachment of the puborectalis muscle insertion, narrower pelvic inlet and greater pelvic organ mobility among African American. Shek et al has recently shown that compared to Caucasians, Black Ugandan nulliparous women had greater pelvic organ descent and levator hiatal distensibility and no difference between puborectalis muscle thickness and area<sup>44</sup>.

A recent South African study by van der Walt et al found that Black nulliparous (n=44) women had greater pelvic floor muscle strength ( $p=0.02$ ) (using a perineometer and vaginal balloon sensor) than Caucasian (n=44) and mixed race (n=34) women<sup>45</sup>. There is currently no data on the ultrasound morphology in nulliparous and symptomatic women with POP in South African women.

### **2.3: Ethnicity and Levator avulsion:**

Although anatomical alterations compatible with avulsion was described in 1907 by Halban and Tandler and later palpated by Howard Gainey in 1943, the subject has remained dormant for several decades<sup>32, 33, 34</sup>. This morphological abnormality has now been described in symptomatic women as well as post vaginal birth<sup>46, 47, 48</sup>. Dietz et al studied the clinical significance and prevalence of such defects in three hundred and thirty three consecutive (majority Caucasian) women referred for urodynamic tests at a tertiary urogynaecology unit. All women had a 2D and 3D TPUS after bladder emptying. The average age was 52.8 ( $\pm 13.3$ ) years and median

parity was 3 (0-8). Avulsion defects were found in 15.4 % of vaginally parous women and there was statistically significant relationship with anterior (bladder) and central (uterine/vault) compartment prolapse (all  $p < 0.001$ )<sup>46</sup>. The findings of this study are regarded as seminal as this was the first published data on the prevalence of such defects using 3D TPUS.

The same author studied the incidence of levator trauma after vaginal delivery in a group of sixty one nulliparous pregnant women. All had a 3D TPUS between 36-40 weeks and this was repeated between 2-6 months postpartum. Fifty women returned for their postpartum visit, of which thirty seven (74%) were of Caucasian ethnicity. Of the thirty nine women who delivered vaginally levator avulsion was diagnosed in 36% (n=14) and there was a statistically significant increase in both anterior and posterior compartment mobility ( $p < 0.001$ )<sup>48</sup>. This was the first perinatal study to demonstrate a direct association between levator ani trauma and vaginal childbirth, and the same author published a case documenting and illustrating intrapartum diagnosis of levator avulsion in a patient who sustained a large vaginal tear after a normal vaginal delivery<sup>28</sup>.

In a prospective observational study performed at two tertiary Urogynaecology clinics which included two hundred and sixty two women referred for complaints of lower urinary tract dysfunction and POP, avulsion injury was diagnosed in 19% (n=50), and were mainly located on the right side of the pelvic floor (n=17). The mean age was 54 (range, 26-82) years and average parity was 2.7 (range, 1-6). Seventeen women (34%) had a previous forceps delivery. All patients had a structured interview, clinical assessment and 3D TPUS<sup>47</sup>. Although ethnicity was not mentioned in the paper, we confirmed with the author that the vast majority (> 90%) were indeed Caucasian.

In a longitudinal observational cohort study, van Delft et al sought to determine the relationship between postpartum levator avulsion and signs/symptoms of PFD. Two hundred and sixty nine primigravidae participated and were scanned at a median of 36 weeks gestation. One hundred and forty three women delivered vaginally. At a median of 13 weeks postpartum and 71% (n = 191) returned. Levator avulsion was found in 21% of vaginal deliveries (n = 30). In those who sustained levator avulsion, vaginal looseness and reduced vaginal sensation were major complaints, and fewer

women in this group resumed sexual intercourse within three months postpartum . The mean age of 30.7 years ( $\pm$  5.5), the mean BMI was 25.3 ( $\pm$  5.5), the majority (55%) were of Caucasian ethnicity <sup>49</sup>.

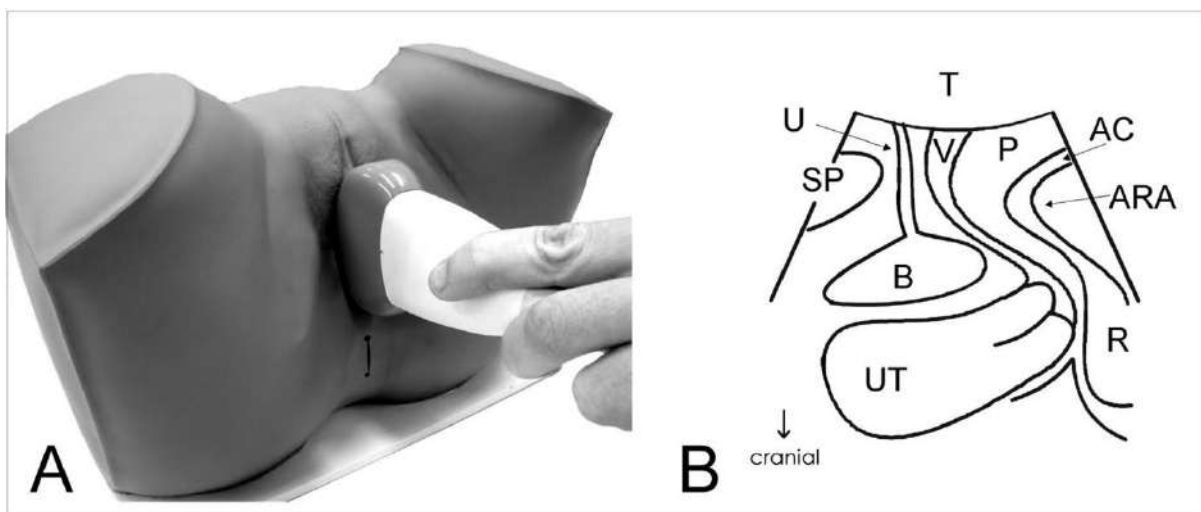
Currently there is no data on the prevalence of levator avulsion as well as its association with pelvic floor symptoms in our local South African population.

#### **2.4 Ultrasound anatomy in the study of pelvic floor morphology:**

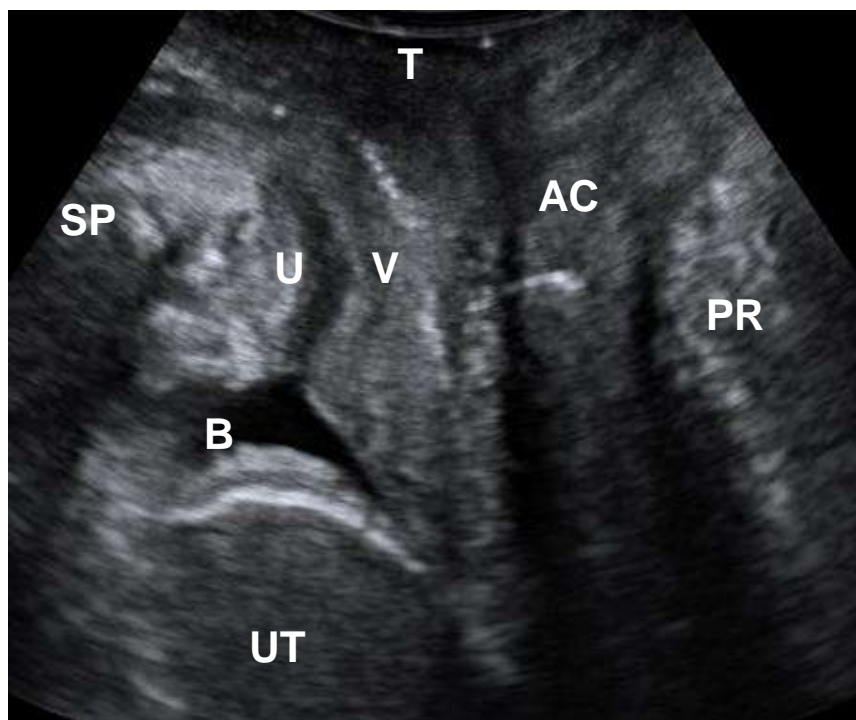
Transperineal ultrasound imaging of the pelvic floor has recently emerged as the investigation of choice for women with PFD. Compared to MRI it is readily available, non-invasive, cost effective and allows dynamic evaluation of the pelvic floor <sup>50,51</sup>. The use of MRI is limited by cost and the difficulty of assessing functional/dynamic maneuvers on the pelvic floor.

##### **2.4.1. Ultrasound methodology:**

The basic methodology involves the placement of a transducer (covered with a powder free glove (after the placement of ultrasound gel) onto the perineum with the patient in the dorsal lithotomy position, as shown in Figure 6. This is performed after bladder emptying with the ankles close to buttocks. A mid-sagittal ultrasound view is then obtained and the urethra, bladder neck, vagina, cervix, rectum and anal canal can be visualized as seen in the Figure 6. Figure 7 shows the corresponding 2 dimensional (2D) ultrasound image.



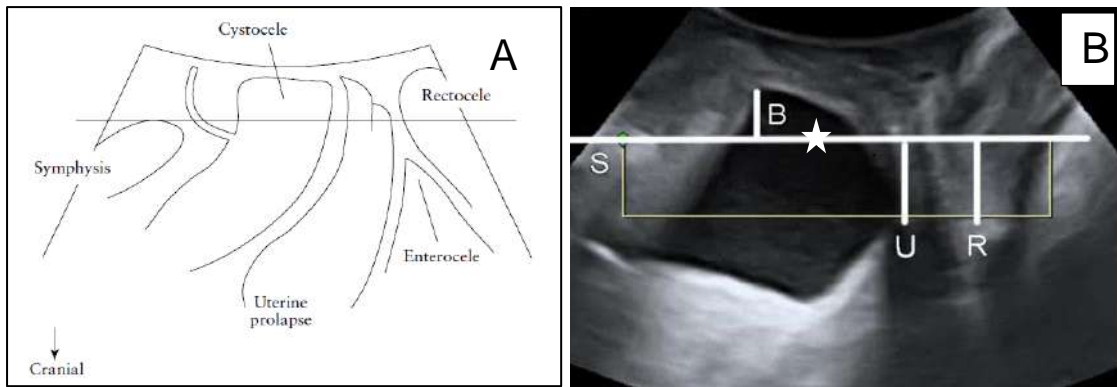
**Figure 6:** Transperineal ultrasound of the pelvic floor and the corresponding mid-sagittal annotated image. SP, symphysis pubis; U, urethra; V, vagina; B, bladder; P, perineum; AC, anal canal; ARA, anorectal angle; UT, uterus; R, rectum, T, transducer. Reproduced with permission from Elsevier from Dietz HP. *J Minim Invasive Gynecol* 2010; 17: 282-294.



**Figure 7:** Mid-sagittal view of the pelvic floor using two dimensional transperineal pelvic floor ultrasound. SP, symphysis pubis; U, urethra; V, vagina; B, bladder; AC, anal canal; UT, uterus; T, transducer surface; PR= puborectalis muscle.

#### **2.4.2. Measurement of pelvic organ descent:**

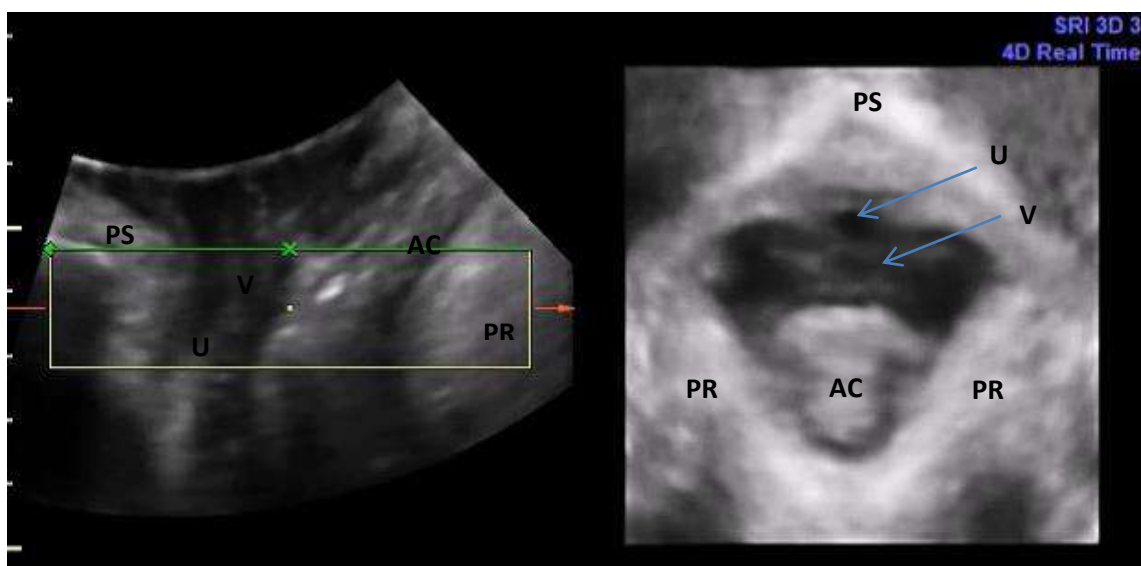
Maximal pelvic organ descent is measured (in mm) on Valsalva relative to a reference line i.e. a horizontal line from the inferior margin of the pubic symphysis. Figure 8 is an ultrasound illustration of the pelvic organ descent on maximal Valsalva. To optimise pelvic organ descent women are coached and the best of usually 3 volume datasets are then used during offline analysis using proprietary software. For an adequate assessment of pelvic organ descent and levator hiatal distensibility the Valsalva maneuver should last for at least 6 seconds<sup>52</sup>.



**Figure 8:** Ultrasound quantification of pelvic organ descent relative to the inferior margin of the pubic symphysis on maximal Valsalva (A). Ultrasound measurement (B) of descent of the pelvic organs, B, bladder; U, uterus; R, rectal ampulla is measured in millimetres relative to this reference line drawn from inferior margin of the pubic symphysis (S). Figure A reproduced from Dietz HP. *Ultrasound Obstet Gynecol* 2004; 23:80-92, with permission.

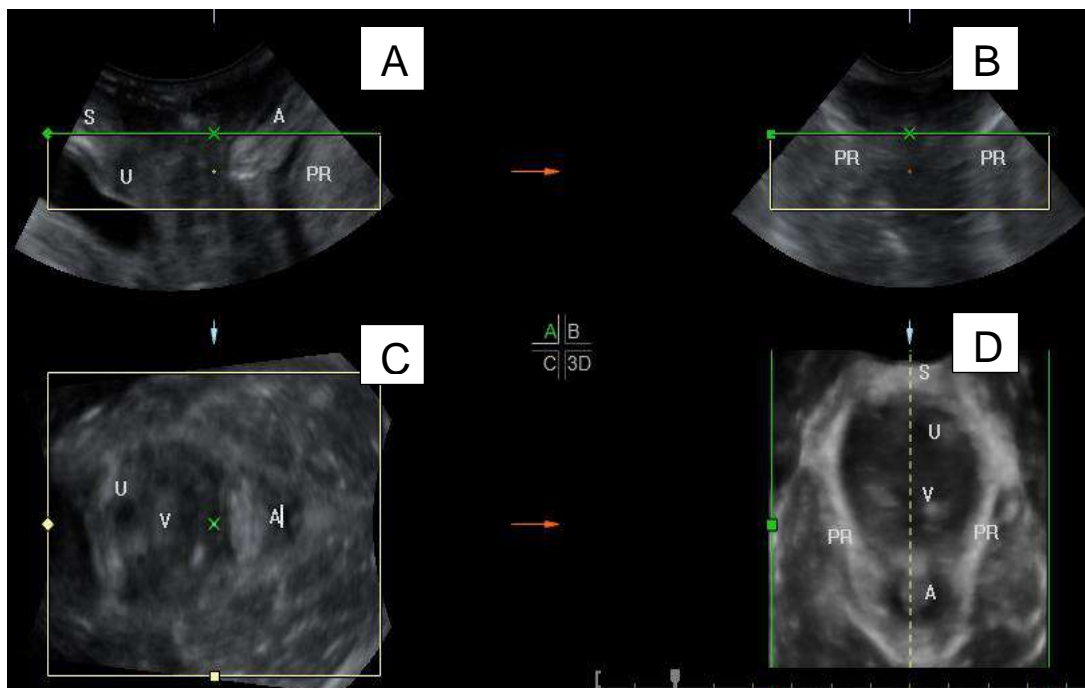
### 2.4.3. Diagnosis of levator avulsion:

Due to recent ultrasound technological advancement such as motorised acquisition, 2D sectional images can be integrated into 3D volume data. The oblique axial plane is used for imaging of the pubovisceral muscle which can be optimised by adjusting slice thickness and slice tilt/ orientation. The puborectalis muscle and its insertion on the inferior pubic ramus can be visualized as indicated in Figure 9.



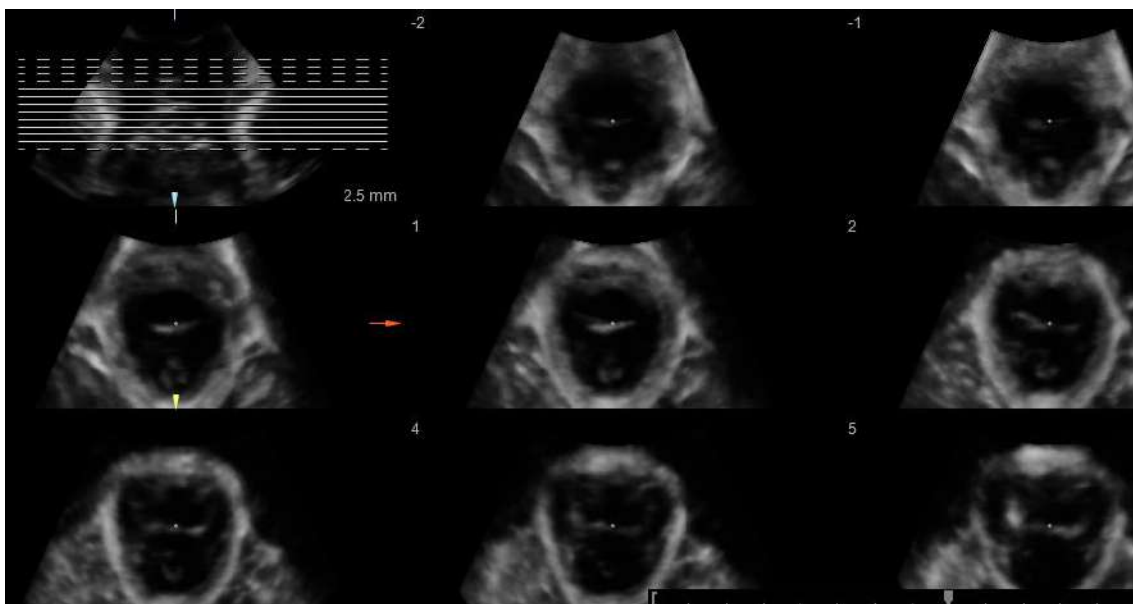
**Figure 9:** Transperineal pelvic floor ultrasound of the pelvic floor at rest in the midsagittal (A) and oblique axial (B) planes illustrating intact insertion of the puborectalis muscle (PR). PS, pubic symphysis; U, urethra; V, vagina; AC, anal canal. The axial plane image in the right panel is a rendered volume which is a semi-transparent representation of all pixels in the 'box' or 'region of interest' visible in the left panel.

Multiplanar / orthogonal display modes show the cross-sectional planes of the volume i.e. the mid-sagittal, axial and coronal plane as shown in Figure 10 below. 4D imaging refers to real-time acquisition of volume data which can be represented in orthogonal planes or rendered volumes. The ability to save cineloop volumes has allowed pelvic floor specialist to study the interaction between the LAMC and the pelvic organs in real-time. Lastly postprocessing software such as GE Kretz 4D View (GE Kretztechnik GmbH, Zipf, Austria) enables manipulation of the images and volumes at the convenience of the clinician.



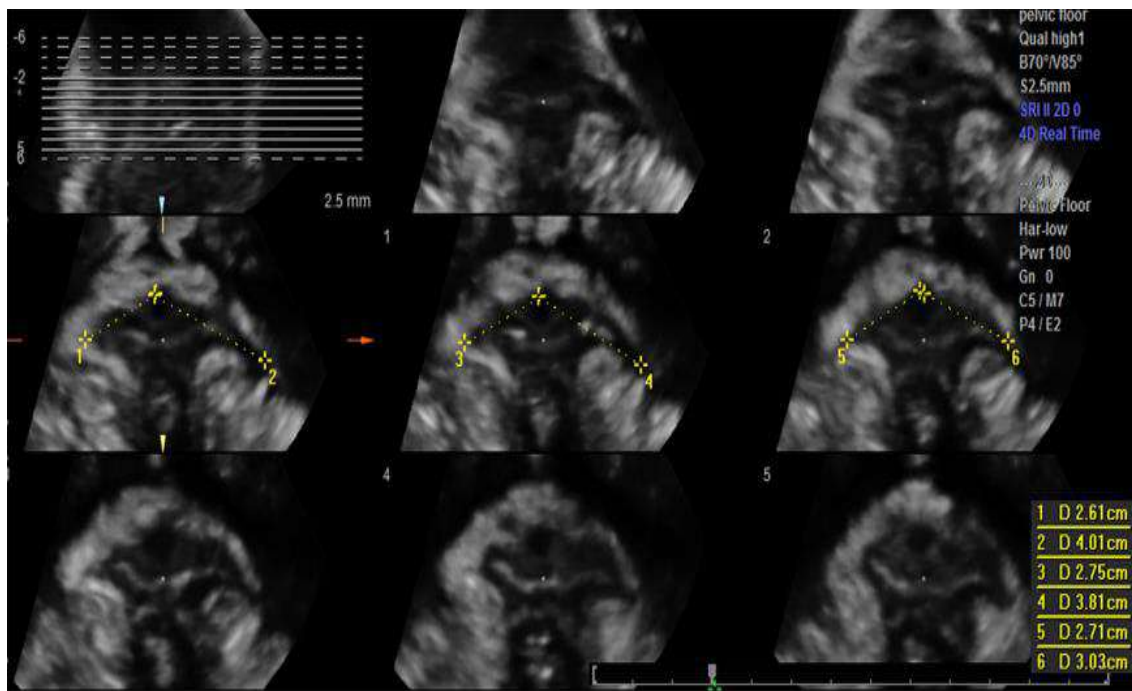
**Figure 10:** 3 Dimensional transperineal ultrasound illustrating the three orthogonal planes: (A) sagittal, (B) coronal, (C) axial, and in (D) a rendered volume which is the semi-transparent representation of all pixels in the region of interest. S, symphysis pubis; U, urethra; A, anal canal; PR, puborectalis; V, vagina.

To diagnose levator avulsion as described earlier, multi-slice imaging (TUI™, tomographic ultrasound imaging) at 2.5mm intervals produces a set of eight tomographic slices in the axial plane, 5mm below and 12.5mm above the plane of minimum dimension as shown in Figure 11<sup>47,53</sup>. Obvious detachment of the puborectalis insertion from its insertion on the pelvic sidewall can then be visualised and is quantified as either unilateral and/or bilateral. Figure 12 illustrates bilateral avulsion using TUI imaging. A levator urethral gap (LUG) measuring > 25mm has been proposed as a cut-off for the diagnosis of levator avulsion<sup>54</sup>. This cutoff value was obtained in a large Caucasian population.



**Figure 11:** Tomographic ultrasound imaging illustrating normal insertion of the puborectalis muscle in middle three slices.



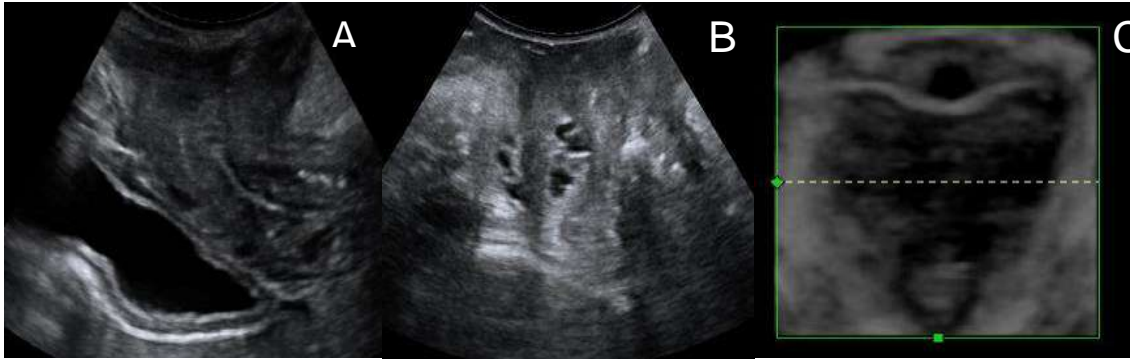


**Figure 12:** Bilateral levator avulsion with levator urethral gap measuring between 2.61 and 4.01cm.

#### 2.4.3: Other 2D/ 3D applications:

Apart from measuring POP descent a more detailed analysis of the pelvic floor can be obtained from 2/ 3D imaging. This includes:

- measuring of the bladder wall thickness, (see figure 13)
- position and mobility of the bladder neck,
- visualization of a pelvic floor contraction thus providing biofeedback to the patient,
- presence of levator coactivation<sup>55</sup>,
- assessment of obstructed defecation: true rectocele, enterocele, rectal intussusception/ prolapse, anismus;
- examination of urethral and bladder anatomy to exclude other incidental or unexpected findings, (urethral diverticulum in figure 13)
- diagnosis of levator avulsion
- Imaging of implants/mesh (Obturator sling in figure 13)



**Figure 13:** Bladder wall thickness (A) measured on 2 dimensional transperineal imaging ; B) urethral diverticulum; and (C) Obturator sling on 3 dimensional imaging.

## AIMS

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1. To determine and compare normal pelvic floor morphology, namely pelvic organ descent and levator hiatal distensibility in a multi-ethnic (Asians, Caucasians and Blacks) asymptomatic nulliparous population.

Hypothesis 1 was: ***There is no difference in pelvic floor morphology across different ethnicities in nulliparous women.***

2. To determine and compare the pelvic floor morphology, namely pelvic organ descent and levator hiatal distensibility and levator avulsion in a multi-ethnic population (Asians, Caucasians and Blacks) with symptomatic pelvic organ prolapse.

Hypothesis 2 was: ***There is no difference in pelvic floor morphology across different ethnicities in women presenting with symptoms of pelvic organ prolapse.***

3. To determine the association between prolapse symptoms and functional anatomy of the pelvic floor.

Hypothesis 3 was: ***There is no association between symptoms of prolapse and pelvic floor functional anatomy.***

4. To determine the impact of vaginal childbirth on pelvic floor morphology 3-6 months post-partum.

Hypothesis 4 was: ***There is no postpartum alteration in pelvic floor morphology in vaginally parous women.***

## METHODOLOGY

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For those four studies, women were recruited from the local nursing school and general gynaecology clinic (Study 1), and the local tertiary Urogynaecology clinic (Study 2 and 3). Pregnant women were recruited from a district antenatal clinic (Study 4). A more detailed description of the methodology is discussed in each publication.

After informed consent, a detailed medical history, and completion of the relevant symptom questionnaire, a 3/ 4D TPUS using GE Voluson i ultrasound system with 8-4MHz curved array volume transducer (GE Kretz Ultrasound, Zipf, Austria) was performed. TPUS was performed after bladder emptying, in the supine position with the ankles close to the buttocks.

Ultrasound volumes were acquired at rest, on maximal pelvic floor muscle contraction (PFMC) and maximal Valsalva maneuver. The volume demonstrating maximal pelvic organ descent was used for analysis of parameters on Valsalva. Women were coached verbally and via visual feedback to avoid coactivation of the pelvic floor.

All volumes were de-identified and analysed 6-8 weeks later with GE Kretz 4D View (GE Kretztechnik GmbH, Zipf, Austria).

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## MAIN RESULTS

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### **Paper 1: Are there ethnic differences in the levator hiatus and pelvic organ descent? A Prospective observational study**

Forty one South Asians (19.8%), sixty nine Caucasians (33.3%) and ninety seven Black women (46.9%) were recruited in total (n=207). The mean age was 25.1 (range, 18-39) years and mean body mass index was 24.3kg/m<sup>2</sup> (range, 13-39). Of the 207 sets of 3D ultrasound volumes, 10 were excluded from formal analysis due to poor image quality (mostly acquired during study initiation), leaving 197 datasets for measurements at rest. One patient could not perform a PFMC and 8 patients could not perform a Valsalva maneuver, leaving 196 PFMC datasets and 189 Valsalva datasets for analysis.

One way ANOVA revealed that Caucasian women were younger ( $P < 0.001$ ) and Black patients had a higher BMI ( $P = 0.004$ ). Pelvic organ descent and mean hiatal areas at rest, PFMC and Valsalva were all higher in Black nulliparae ( $P < 0.000$ ) even after controlling for age and BMI as potential confounders. South Asian women had the least organ mobility as compared to Caucasian and Black women ( $P = 0.000$ ).

**In conclusion** we found that Black South African women had greater pelvic organ descent on ultrasound and clinically and greater distensibility compared to South Asian and Caucasian women. Multivariate modelling revealed that Black ethnicity remained a significant factor for pelvic organ mobility on clinical examination, ( $P = 0.024$ ).

## **Paper 2: Prolapse symptoms are associated with abnormal functional anatomy of the pelvic floor**

This prospective observational study included 258 patients with symptoms of POP (as defined by pertinent ICIQ questions) seen at a tertiary urogynaecological unit. Mean age was 60.6 (25-91) years and mean BMI 29.8 (18-53). Levator defects were found in 32.4% (n=78) of patients and almost half of those were bilateral (n=36).

There were significant associations between awareness and visualization of a vaginal lump on the one hand and hiatal area measurements as well as diagnosis of avulsion on the other hand. The interference with everyday life was significantly associated with hiatal area and prolapse stage, but not with avulsion.

**In conclusion** there is a significant association between awareness, visualization and/or feeling of a vaginal lump and abnormal pelvic floor functional anatomy, that is, hiatal ballooning and levator avulsion.

## **Paper 3: Interethnic variation in women with symptomatic pelvic organ prolapse**

This prospective observational study included two hundred and fifty eight consecutive women referred for pelvic organ prolapse assessment and management at a tertiary urogynaecological clinic.

Mean age was 60.6 (range, 25-91) years, mean BMI 29.83 (range, 18-53).

Points Ba and C were lower and the genital hiatus more distensible in Black women (all  $p < 0.05$ ). Black women were significantly more vaginally parous ( $p = 0.000$ ); previous prolapse procedures were more often reported by Caucasian women ( $p = 0.001$ ). Black women were found to have greater hiatal area ( $p = 0.017$  at rest,  $p = 0.006$  on Valsalva) compared to South Asians and Caucasians and showed greater pelvic organ mobility (all  $P < 0.05$ ) than Caucasians on ultrasound. Levator defects were diagnosed in 32.2% (n=83) of patients and the majority were bilateral (48.2%, n=40), with significant interethnic differences ( $P = 0.014$ ).

**In conclusion** there was significant variation in clinical prolapse stage, levator distensibility and pelvic organ descent in this racially diverse population presenting with pelvic organ prolapse, with South Asians having a lower avulsion rate than the other two ethnic groups ( $P= 0.014$ ).

**Paper 4: The impact of childbirth on pelvic floor morphology in primiparous Black South African females: A prospective longitudinal observational study**

A total of one hundred and fifty three nulliparous women were recruited from a district antenatal clinic between 35-39 weeks gestation.

Eighty four (54.9%) women returned at a mean of 4.8 months postpartum. 60 (71.4%) women had a vaginal delivery and the rest caesarean section (20 emergency versus 4 elective). Of the 84 women, 60 delivered vaginally (5 forceps and 4 vacuum) and the rest ( $n=20$ ) had an emergency caesarean section (CS) for cephalopelvic disproportion ( $n=19$ ) or antepartum haemorrhage ( $n=1$ ). 4 women had a elective caesarean section for hypertension, failed induction (2) and breech presentation respectively.

Overall there were statistically significant increases in bladder neck descent ( $P = 0.003$ ), pelvic organ descent and levator hiatal distensibility (all  $P < 0001$ ), in the postpartum period. Levator avulsion was diagnosed in 15% ( $n=9$ ) amongst those delivered vaginally. Mean birth weight was higher in the caesarean group (3.04 versus 3.34 kg,  $P =0.001$ ). Postpartum vaginal laxity was the commonest bothersome vaginal symptom reported.

**In conclusion** there is significant alteration in pelvic organ support and levator hiatal distensibility after vaginal delivery. 15% of Black primiparous women sustained levator trauma after their first vaginal delivery.

## **PUBLICATIONS:**

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### **Paper 1:**

#### **Are there ethnic differences in the levator hiatus and pelvic organ descent? A Prospective observational study**

Short title: Ethnic differences in pelvic organ support

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**Keywords:** Ethnicity, Pelvic floor, Imaging, Levator hiatus, Pelvic organ descent

**Abstract:**

**Objective:** To date most studies on the functional anatomy of the pelvic floor have focussed on Caucasian women. There is scant information on this topic involving other ethnic groups. This study investigates levator hiatal area and pelvic organ descent in three racially diverse ethnic groups of healthy nulliparous South Asian, Caucasian and Black South African females, using three dimensional (3D) transperineal ultrasound (TPUS).

**Methods:** A total of two hundred and seven nulliparous women from three different ethnic groups aged 18 to 40 years were recruited for this prospective observational study between June 2012 and April 2015. After informed consent and clinical examination of the pelvic floor all patients underwent a 3/4D transperineal ultrasound examination. Ultrasound volumes were captured at rest, maximum pelvic floor contraction and on maximum Valsalva maneuver. Analysis of variance and covariance test was performed to compare the three ethnic groups, including a Bonferroni pairwise test.

**Results** After controlling for age and body mass index (BMI), mean levator hiatal measurements at rest, maximum pelvic floor contraction and Valsalva were all higher in Black nulliparae ( all  $P < 0.001$ ). Post-hoc Bonferroni pairwise comparison revealed that Black nulliparae demonstrated greater pelvic organ descent and levator hiatal areas compared to the South Asian and Caucasian women (  $P < 0.001$ ).

**Conclusion** This comparative study indicates that there are significant differences in levator hiatal areas and pelvic organ mobility between the studied ethnicities.

**Keywords** Ethnicity, nulliparous, pelvic floor morphology, 3/ 4D pelvic floor ultrasound

## **Introduction:**

Recently several studies have reported that the prevalence and risk factors for pelvic organ prolapse (POP) and urinary incontinence (UI) differs between ethnic groups.<sup>1,2,3,4</sup> In a large population-based cohort study (n=1136) which included Caucasians (n=569) , African-American (n=209), Asian (n=209) and Latina women (n=200) Whitcomb et al reported that Caucasian and Latina women had a four to five times higher risk of symptomatic prolapse when compared to African-American women.<sup>3</sup> Graham et al retrospectively assessed the effect of race on UI and POP in 183 African-American and 132 Caucasian women and reported that Caucasian race (compared to African-American) was the most significant predictor of genuine stress incontinence (odds ratio 2.21)<sup>1</sup>. To further investigate the claimed rarity of stress urinary incontinence in black women, both Knobel and Skinner et al studied pelvic floor contractility and urethral lengths in Black South African women and found greater pelvic floor contractile strength (using a Kegel perineometer) and urethral lengths (measured with a calibrated Foley catheter) in Black women when compared to Caucasian and Indian women.<sup>5,6</sup> While these differences have been shown via clinical examination, recently ultrasound has emerged as a simple, dynamic and potentially more objective diagnostic tool for the evaluation of the pelvic floor and organ support.<sup>7</sup> Using 3 dimensional transperineal ultrasound (3 D TPUS) Shek et al compared pelvic organ mobility and levator biometry between nulliparous Ugandan and Caucasian women, showing substantial differences with regards to pelvic organ mobility and levator hiatal biometry; i.e. all measurements were greater in Ugandan women (all  $p \leq 0.01$ ).<sup>8</sup> The aim of this study was to compare levator hiatal areas at rest, maximal pelvic floor muscle contraction (PFMC) and Valsalva maneuver and pelvic organ mobility in healthy nulliparous women in a racially diverse South African population, comprising Black Africans, South Asian and Caucasians.



## **Material and Methods:**

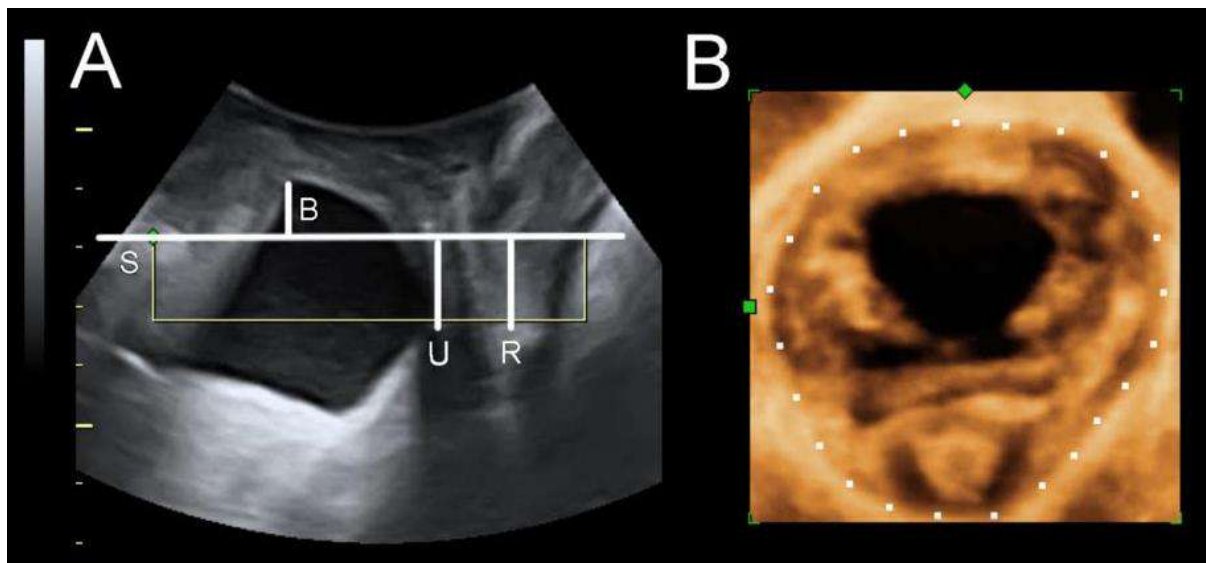
In this prospective observational study 207 healthy nulliparous women between 18 and 40 years were recruited from the general gynaecology clinic as well as from the local nursing college between June 2012 and April 2015. Individuals were assigned to an ethnic category by researcher ZA, and ethnicity was also self-reported. There were no discrepancies between self-reporting and assignment by the researcher. Women with mixed ethnicity were excluded. After informed consent the women were requested to void and thereafter a clinical examination for prolapse was performed using the ICS POP-Q grading system in those who had been previously sexually active, with the patient in the supine position.<sup>9</sup> A vaginal examination was not performed in those with an intact hymen. This was followed by a 3/4D transperineal ultrasound as previously described, using a GE Voluson i ultrasound system (GE Kretztechnik, Zipf, Austria) with RAB 8-4 MHz transducer (acquisition angle 85°).<sup>7</sup>

The ultrasound was performed with the probe covered with a powder free glove and applied in the mid-sagittal plane on the introitus, using moderate pressure. Volumes were acquired at rest, maximum pelvic floor muscle contraction (PFMC) and during maximal Valsalva maneuver. Patients were coached to Valsalva for at least 5 seconds, and the best of 3 volumes was used for analysis.<sup>10</sup> Using visual biofeedback an attempt was made to correct for levator co-activation by requesting the women to observe narrowing and widening of the levator hiatus during performance of maneuvers.<sup>11</sup>

3D volumes were measured offline using GE Kretz 4D View as previously described (see Figure 1).<sup>7</sup> Using the best Valsalva maneuver, pelvic organ descent measurements were obtained relative to a horizontal line drawn from the inferior margin of the pubic symphysis. We measured the position of the bladder neck and the most dependent/leading parts of the bladder, cervix and rectal ampulla as previously described.<sup>12</sup> Levator hiatal area was assessed in the plane of minimal hiatal dimensions.<sup>13</sup> Measurements were performed after de-identification (blinded to ethnicity and patient identification) 6 to 8 weeks after acquisition by the first author (ZA) using measurements that have been shown to be highly repeatable.<sup>14,15,16,17</sup>

All patients gave written informed consent. Ethics approval had been obtained from the Human Research Ethics Committee, University of Pretoria (226/2011). Statistical analysis was performed after normality testing (Kolmogorov Smirnov testing), using

Stata version 13.1 (StataCorp, College Station, TX) in consultation with a biostatistician. To compare ethnic differences between the 3 groups a one way analysis of variance (ANOVA) was performed and necessary adjustments for age and BMI were controlled for in the analysis of covariance (ANCOVA) considering age and BMI as covariates. Pair wise comparison for ethnicity was performed using Bonferroni statistics. A *P* value < 0.05 was considered statistically significant.



**Figure 1:** Mid-sagittal transperineal pelvic floor ultrasound (A) indicating pelvic organ descent on maximum Valsalva: (B) rendered volume in the axial view for determination of hiatal area (B). Vertical lines in (A) signify measurements of organ descent. S=pubic symphysis, B=bladder, U=uterus; R=rectal ampulla

### Results:

Forty one South Asians (19.8%), sixty nine Caucasians (33.3%) and ninety seven Black women (46.9%) were recruited in total (n=207). The mean age was 25.1 (range, 18-39) years and mean body mass index was 24.3kg/m<sup>2</sup> (range, 13-39). Of the 207 sets of 3D ultrasound volumes, 10 were excluded from formal analysis due to poor image quality (mostly acquired during the study initiation), leaving 197 datasets for measurements at rest. One patient could not perform a PFMC and 8 patients could not perform a Valsalva maneuver, leaving 196 PFMC datasets and

189 Valsalva datasets for analysis. Pelvic organ mobility was measured in 165 patients due to a clerical error in data acquisition and storage upon initiation of the study (Asian, n=33; White, n=61; Black, n=71).

One way ANOVA revealed that Caucasian women were younger ( $P < 0.001$ ) and Black patients had a higher BMI ( $P = 0.004$ ). To determine if age and BMI were

statistically significant confounders on pelvic organ mobility and levator hiatal areas, analysis of covariance was performed. Bonferroni post hoc statistics was used to determine where the differences are between the groups. Pelvic organ descent and mean hiatal areas at rest, PFMC and Valsalva were all higher in Black nulliparae ( $P < 0.000$ ) (see table 1) even after controlling for age and BMI as potential confounders. Multivariate modelling revealed that Black ethnicity remained a significant factor for pelvic organ mobility on clinical examination, ( $P = 0.024$ ).

Parameter	South Asians (n=41)	Caucasians (n=69)	Blacks (n=97)	P value
Age (years)	26.34 (4.58)	23.60(4.05)	25.67(4.50)	<0.001
Body Mass Index (kg/m <sup>2</sup> )	22.66 (5.02)	23.88 (4.42)	25.58 (4.96)	0.004
Hiatal area at rest (cm <sup>2</sup> )	10.94 (3.14)	11.58(2.65)	13.60(3.25)	0.000
Hiatal area on PFMC (cm <sup>2</sup> )	9.13 (2.60)	9.54(2.34)	10.75(2.27)	0.000
Hiatal area on Valsalva (cm <sup>2</sup> )	14.59 (4.74)	15.24(5.03)	18.10(4.97)	0.000
Bladder neck descent (mm)*	9.20 (5.18)	10.68(7.13)	12.60(6.92)	0.02
Bladder position on Valsalva (mm)*	15.44 (3.90)	15.91(6.45)	11.82(6.38)	0.000
Uterine position on Valsalva (mm)*	23.31 (6.29)	26.42(6.75)	20.09(7.23)	0.000
Rectal ampulla position on Valsalva (mm)*	7.70(6.16)	9.39(6.16)	2.91(8.0)	0.000

**Table 1** Demographic data, pelvic organ mobility and hiatal distensibility on ultrasound examination in South Asian, Caucasian and Black South African nulliparous women. n=165 for pelvic organ descent\* The data presented are mean (SD).

POP-Q data was only available in 142 women (the hymen was intact in 23 women with no vaginal examination performed). The mean findings for POP-Q coordinates are presented in table 2 and highlight that South Asian women had the least organ mobility as compared to Caucasian and Black women (P=0.000). There were no differences noted for genital hiatus (Gh) and perineal body (Pb) measurements. In short we found that Black South African women had greater pelvic organ descent on ultrasound and clinically and greater distensibility compared to South Asian and Caucasian women.

<b>POP-Q coordinates</b>	<b>South Asians (n=31)</b>	<b>Caucasians (n=49)</b>	<b>Blacks (n=62)</b>	<b>P value</b>
Ba	-2.6 (-3 to -1)	-1.9 (-3 to 2)	-1.6 (-3 to 1)	0.000
C	-5.7 (-6 to -4)	-5 (-6 to -2)	-3.4 (-5 to 0)	0.000
Bp	-2.6 (-3 to -1)	-2 (-3 to 1)	-1.6 (-3 to 1)	0.000
Gh (cm)	3.5 (2.5 to 5)	3.5 (2.5 to 4.5)	3.5 (2.5 to 5)	0.813
Pb (cm)	4 (3 to 5)	4 (3 to 5)	4 (3 to 5)	0.998

**Table 2** Comparison of POP-Q coordinates and hiatal distensibility between three ethnic groups. Data presented as mean (range).n=142

### **Discussion:**

In this multi-ethnic South African nulliparous population, we found significant differences between ethnic groups as regards levator hiatal areas and pelvic organ mobility, both on ultrasound and on clinical examination. To date studies on ethnic differences in the pelvic floor have focussed largely on Caucasian women using clinical examination.<sup>2-4</sup> Although it is widely accepted that pelvic floor trauma as a consequence of vaginal childbirth is a significant factor for pelvic floor dysfunction, it is likely that congenital/hereditary factors need further exploration.<sup>18,19</sup>

Our findings of increased levator hiatal areas and pelvic organ mobility among individuals identified as Black women (n=71) are similar to the recently published findings of Shek et al.<sup>8</sup> Bladder neck descent (BND), bladder, uterine and rectal

descent were all statistically significantly higher in Black women as compared to Asian (n=33) and Caucasian women (n= 61) (p= 0.02 for BND and p<0.001 for bladder, uterine and rectal descent). Using the same methodology and ultrasound equipment Shek et al explored pelvic organ support in 76 healthy nulliparous Ugandan volunteers. The hiatal area at rest was 13.60cm<sup>2</sup> and 18.10cm<sup>2</sup> on Valsalva in our study which compares to 15.66cm<sup>2</sup> at rest and 22.76cm<sup>2</sup> on Valsalva in the Ugandan volunteers. Analysis of levator hiatal areas and pelvic organ descent measurements was significantly greater in Ugandan women as compared to Caucasians, which is fully consistent with the findings presented here. Asian women demonstrated the smallest levator hiatal areas (at rest, contraction and Valsalva) and the less pelvic organ mobility as compared to Black women, supporting findings obtained on 2D ultrasound, although Asian ethnicity in that study is likely to have included more East Asians rather than South Asians.<sup>20</sup>

The strengths of our study include the three- way comparison of ethnic groups which to our knowledge makes this the first such study in the literature. Another strength is the identical methodology to the only other African study by Shek et al., and inclusion of a POP-Q examination in those nulliparae who were sexually active. While the three ethnic groups examined by us are not fully representative of the South African population, they do come close. The 2014 South African demographic profile revealed that Black African comprised 79.2% of the total population, with White, Asian and coloured constituting ethnic minority groups (20.8%).

Limitations include the fact that ultrasound acquisition and clinical examination were performed by ZA and thus not blinded to ethnicity. To overcome this potential bias, volumes were de-identified during acquisition and only analysed 6-8 weeks later. Hence, the ultrasound data presented here should not be confounded by assessment bias. However, we did not enquire about education and type of work which could be a potential confounder. We did not perform power calculations due to absence of such data in the literature at the time of study planning in 2011. Lastly, although we excluded mixed race women, we acknowledge that their inclusion might have added further information.

Regardless of those potential shortcomings, it seems highly likely that Black nulliparae show increased hiatal dimensions and pelvic organ mobility compared to other ethnic groups. A plausible explanation could be that both muscle and connective tissue support structures may be more elastic and/or distensible in Blacks than in Caucasian or Asians. Such differences in biomechanical properties of pelvic organ support tissues may be due to differences in lifestyle, nutritional factors, and/or genetic/congenital factors, and further studies are needed to separate these factors. It is also possible that such differences may be attributable to morphological variations in dimensions of the bony pelvis in different ethnicities.<sup>21</sup>

Both pelvic organ mobility as well as levator hiatal dimensions have been shown to be predictors of delivery outcome in antenatal women.<sup>22,23,24</sup> Regardless of causation, one could speculate that the increased pelvic floor distensibility of Black women might be protective of childbirth trauma i.e. levator avulsion, and may result in a shorter second stage duration which makes our findings of potential obstetric interest.<sup>24</sup> We are currently undertaking a study to evaluate changes in pelvic floor morphology pre and post-delivery in Black South African primigravidae and will test this hypothesis once recruitment is complete. Long-term follow up of these nulliparous women using the same methodology will be useful to identify other potential risk factors of pelvic floor dysfunction over time.

In conclusion, the results of this study support our primary research hypothesis that there are significant ethnic differences in pelvic floor functional anatomy, differences that may well affect both connective tissue and muscle.<sup>25</sup> This is evident both on pelvic floor ultrasound and on clinical examination. The combination of greater distensibility and higher pelvic organ mobility in Black South African women compared to White Caucasians and South Asians is fascinating and deserves further study.

### **Acknowledgment**

The authors would like to thank Prof P Becker for statistical assistance.

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## **Paper 2:**

### **Prolapse symptoms are associated with abnormal functional anatomy of the pelvic floor**

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Word count 1739

#### **Conflict of interest:**

Z Abdool: None

HP Dietz: unrestricted educational grants from GE Medical

BG Lindeque: None

**Previous presentation:** IUGA , Cape Town, 2-6 August 2016

**Author's contribution:**

Z Abdool: protocol development, data collection, manuscript writing

H.P Dietz: protocol development, manuscript editing

B.G Lindeque: protocol development, manuscript editing

**Abstract:****Introduction and hypothesis:**

The aetiology of pelvic organ prolapse (POP) likely includes overdistension or tears (avulsion) of the levator ani muscle. However, there is a lack of studies evaluating the association between symptoms of POP and these factors. This study was designed to determine the association between POP symptoms and clinical prolapse stage on the one hand, and pelvic floor functional anatomy on the other hand.

**Methods:**

This prospective observational study included 263 patients with symptoms of POP as defined by pertinent ICIQ questions seen at a tertiary Urogynecological unit. After informed consent and a detailed history including the ICIQ, a 3D transperineal ultrasound was performed using a GE Voluson i ultrasound system. Offline analysis was performed on de-identified datasets.

**Results:**

Mean age was 60.6 (25-91) years and mean BMI 28.8 (18-53). Levator defects were found in 32.4% (n=78) of patients and almost half of those were bilateral (n=36). There were significant associations between awareness and visualization of a vaginal lump on the one hand and hiatal area measurements as well as diagnosis of avulsion on the other hand. The interference with everyday life was significantly associated with hiatal area and prolapse stage, but not with avulsion.

**Conclusions:**

There is a significant association between awareness, visualization and/or feeling of a vaginal lump and abnormal pelvic floor functional anatomy, that is, hiatal ballooning and levator avulsion.

**Keywords:** Levator avulsion, Pelvic organ descent; Prolapse symptoms

**Brief summary:** There is a significant association between prolapse symptoms and functional pelvic floor anatomy

## **Introduction:**

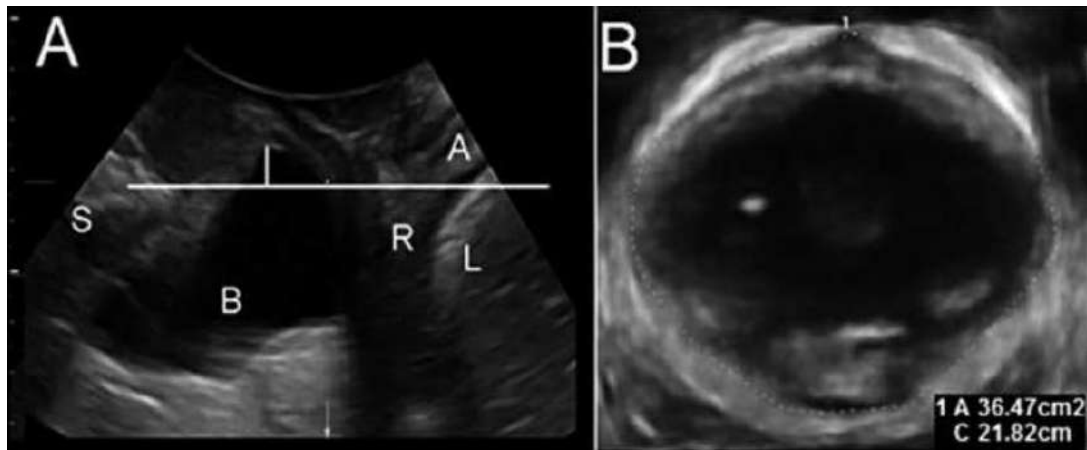
Symptomatic female pelvic organ prolapse is a common gynaecological problem that impacts negatively on various quality of life domains [1]. Although the pathophysiology is still poorly understood, both macroscopic ('avulsion') and microtrauma (irreversible overdistension) to the levator ani muscle are regarded as causative factors for at least some forms of symptomatic female pelvic organ prolapse (POP) [2]. The first prospective study to demonstrate a direct association between levator trauma and vaginal childbirth was published in 2005. Levator avulsion was diagnosed (using 3 dimensional transperineal ultrasound) in 36% (n=14) of women between 2-6 months postpartum [3].

Subsequent prospective observational studies found that levator avulsion occurs in 13-36% of vaginally parous women and is also prevalent in patients presenting for urogynaecological evaluation [4, 5, 6]. Levator avulsion is more common in patients with major prolapse and a risk factor for prolapse recurrence [7, 8, 9, 10]. In an observational longitudinal cohort study of two hundred and sixty nine primigravidae, levator avulsion was diagnosed in 21% of vaginal deliveries, and these women reported more troublesome vaginal symptoms as per the validated International Consultation on Incontinence Vaginal Symptoms (ICIQ-VS) questionnaire [5,11].

While early studies on pelvic floor symptoms primarily focused on determining a relationship with prolapse stage, there are limited studies evaluating the association with functional pelvic floor anatomy on ultrasound [12,13]. In addition, most of the data in the literature has been obtained in Caucasians. We sought to determine the relationship between most commonly reported vaginal symptoms for POP (awareness of lump/bulge; visualization of lump/bulge and need for digitation to empty bowels) and clinical prolapse stage, levator hiatal area (at rest, maximum pelvic floor muscle contraction (PFMC) and on Valsalva) and levator avulsion, in a multi-ethnic population.

## Materials and Methods:

Between June 2013 and March 2015, women who attended a tertiary urogynaecology clinic with symptomatic POP were invited to participate in a prospective observational study on pelvic floor morphology in South African women as part of an ongoing PHD thesis. After informed consent patients were requested to empty their bladders. Clinical examination was performed in the supine position with the hips and knees flexed at 90 degrees. Prolapse was staged according to the POP-Q method [14]. To assess levator muscle morphology 3D/4D transperineal pelvic floor ultrasound (TPUS) was performed with a GE Voluson i system using a 4-8 MHz RAB probe with an acquisition angle of  $85^{\circ}$ . Volumes datasets were de-identified and acquired at rest, maximum PFMC and maximum Valsalva maneuver by the first author. Levator hiatal areas were measured at rest, maximum PFMC and on maximum Valsalva maneuver 6-8 weeks after volume acquisition using the software 4D View version 10, following the rendered volume method described previously [15]. Measurements were obtained by the first author blinded against all clinical data. Tomographic ultrasound imaging (TUI) on maximum PFMC was used to diagnose levator avulsion as previously described [16]. Figure 1 illustrates marked distension (ballooning) of the levator hiatus on maximal Valsalva maneuver [17].



**Figure 1:** Transperineal three-dimensional ultrasound in the midsagittal plane (A) illustrating pelvic organ descent, with the vertical line showing measurement of cystocele descent. (B) Demonstrates a corresponding rendered volume in the axial view, illustrating marked distension (ballooning) of the levator hiatus on maximal

Valsalva maneuver. S=pubic symphysis, B=bladder, R=rectal ampulla, L=levator ani, A=anal canal.

Patients completed the ICIQ-VS questionnaire which is routinely used at our urogynaecology clinic. This study was approved by the National Research Ethics committee (University of Pretoria 226/2011). Statistical analysis was performed after normality testing which included histogram analysis and/ or Kolmogorov-Smirnov testing using SPSS version 23. Our null hypothesis was defined as “prolapse symptoms/ clinical prolapse stage are NOT associated with levator hiatal area and avulsion of the levator ani muscle as diagnosed by TPUS.”

To determine the relationship between commonly reported vaginal symptoms / POPQ stage and levator avulsion, chi squared statistics were used since avulsion is a binary variable'. The ICIQ produces a 4- or 5- point Likert response; we used analysis of variance (ANOVA) tests to determine the relationship between vaginal symptoms and levator hiatal area (at rest, on maximum pelvic floor contraction and maximum Valsalva maneuver). A  $P < 0.05$  was considered statistically significant.

### **Results:**

The datasets from 5 of 263 women recruited had missing information. Thus, 258 women were included in the study. The mean age was 60.6 years (range, 25-91 years), median parity was 3 (range, 0-9) and the mean BMI was 29.8 (range, 18-53). Of the 258 women, 254 (98.5%) were vaginally parous. Previous assisted delivery was recalled in 14.7% (n=38), and 21.3% had undergone a previous prolapse operation (n=55). This study cohort consisted of a racially diverse cohort i.e. 12% Asian (n=31), 41.5% Black (n=107) and 46.5% Caucasian (n=120); ethnicity was self-reported. POP-Q stage 2 was detected in 124 patients (48.1%) and POP-Q stage 3 and 4 in 115 (44.5%). The demographic characteristics of the 258 women are shown in Table 1. Only 236 datasets were analyzed for levator avulsion as 22 patients could not perform a pelvic floor muscle contraction, and 4 women could not perform a Valsalva maneuver despite repetitive coaching, leaving 254 datasets for hiatal area assessment.

Parameter (n=258)	Mean	(%)
Age*	60.64 ± 12.1	
BMI*	29.83 ± 6.3	
Parity†	3	
Recall of assisted delivery	38	14.7
Previous prolapse surgery	55	21.3
Stage of POP		
Stage I	19	7.4
Stage II	124	48.1
Stage III	96	37.2
Stage IV	19	7.3
Avulsion	78	32.4

**Table 1:** Demographic data. \*Age and BMI expressed as mean ± SD;† Parity expressed as median.

Table 2 shows the associations between questionnaire answers, POPQ staging and ultrasound measurements of functional pelvic floor anatomy. Statistically significant associations were found between awareness of lump or bulge in the vagina (question 5a on ICIQ-VS questionnaire), feeling and visualization of the lump or bulge (question 6a) and levator avulsion ( $p=0.003$ , and  $p=0.000$  respectively) and for all measurements of hiatal area and POP-Q stage. Interference with everyday life was statistically significantly associated with POP-Q stage ( $p=0.009$ ) and hiatal area on Valsalva ( $p=0.028$ ) but not with levator avulsion. The correlation between visualization of bulge and interference with everyday life with hiatal area at rest did not reach statistical significance ( $p=0.052$  and  $p=0.065$  respectively). Exclusion of women with previous prolapse surgery did not materially change these results.

Symptom (n=258)	POP-Q Stage	HA Rest	HA PFMC	HA Val	Avulsion*
1. Are you aware of a lump or bulge coming down in your vagina?	0.001	0.001	0.025	0.001	0.003
2. Do you feel a lump or bulge come out of your vagina, so that you can feel it on the outside or see it on the outside?	0.001	0.016	0.021	0.001	0.001
3. Do you have to insert a finger into your vagina to help empty your bowels?	0.320	0.264	0.163	0.384	0.275
4. Overall, how much do vaginal symptoms interfere with your everyday life?	0.009	0.065	0.050	0.028	0.124

**Table 2:** P values for the associations between pelvic floor symptoms and POP-Q stage, hiatal area measurements and levator avulsion. \*Chi-squared test for levator avulsion; and ANOVA tests for POP-Q stage and hiatal area measurements. N= 254 for hiatal area analysis and N= 236 for avulsion analysis.

### Discussion:

This prospective observational study in a multiethnic population has demonstrated strong correlations between abnormal functional pelvic floor anatomy and core symptoms of POP as defined by ICIQ-VS. This correlation was strongest for core symptoms such as awareness of lump/bulge and visualization or feeling of lump/bulge on the outside. Associations were weaker for the question of digitation to defecate. This is not surprising as need for digitation has been shown to be positively associated with true rectoceles which there is no strong link with abnormal levator ani anatomy [9, 18].

Of note, we chose to test the relationship between core symptoms of POP as the other questions i.e. 'are you aware of pain in your lower abdomen', 'are you aware of



soreness in your vagina', do you feel that you have a reduced sensation in or around your vagina', are non-specific for POP, and statistical analysis did not reveal significant correlations with levator avulsion, levator hiatal area and POP-Q stage. The 4th ICIQ question investigated by us is much less specific (Overall, how much do vaginal symptoms interfere with your everyday life?) as it would also be answered in the positive by e.g. women suffering from vaginal atrophy and/or dyspareunia.

The aetiology of POP is thought to be multifactorial, however it is increasingly evident that in many instances prolapse is mediated by alterations in pelvic floor functional anatomy. There seems to be little doubt that major levator trauma is a factor in the pathogenesis of POP [9]. While a cause and effect relationship seems highly plausible for avulsion, the role of excessive hiatal distensibility i.e. ballooning is complex [19]. Since there is some evidence that ballooning often persists after successful prolapse procedures it may be regarded as a 'cause', but this is debatable [20]. The findings of our study support this contention.

Considering that levator avulsion has a significant effect on both pelvic floor anatomy and function, it is not surprising that such trauma is associated with awareness and visualization of bulge [21–24]. Interestingly, this is not the case for other symptoms of pelvic floor dysfunction such as stress urinary incontinence, urge incontinence and anal incontinence [17, 25]. Dietz et al. [25] studied the relationship between levator avulsion and bladder function in 420 women presenting with pelvic floor dysfunction and lower urinary tract symptoms and found that women with avulsion were less likely to report stress urinary incontinence ( $p < 0.001$ ) and urodynamic stress incontinence ( $p = 0.065$ ) and were more likely to present with POP symptoms. The lack of association between levator avulsion and stress urinary incontinence/urodynamic stress incontinence and anal incontinence is most likely explained by the complex nature of the pathophysiology of urinary and fecal incontinence.

To our knowledge this is the first study conducted at a tertiary urogynaecology clinic to present data demonstrating an association between prolapse questionnaire components and abnormal functional anatomy of the pelvic floor. The multiethnic composition of our population could be considered a major strength and we plan to report the findings of interethnic variation on pelvic organ descent and distensibility in a separate publication. Limitations include the fact that ultrasound acquisition and clinical examination were both performed by the first author. To overcome this

potential bias, volumes were de-identified during acquisition and only analysed 6-8 weeks later. Hence, the ultrasound data presented here should not be confounded by assessment bias. Also, we are aware that levator avulsion may be diagnosed at rest [26] , but at the time of recruitment we decided to only allow diagnosis of levator avulsion on TUI during maximum PFMC, as originally published [16]. Finally it would also be of interest to investigate the association between other symptoms of pelvic floor dysfunction (symptoms of bladder and sexual dysfunction) and pelvic floor functional anatomy. We are in the process of performing such as study in this cohort.

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**Paper 3:**

**Interethnic variation in pelvic floor morphology in women with symptomatic pelvic organ prolapse**

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**Authors contribution:**

Z Abdool: protocol development, data collection, manuscript writing

HP Dietz: protocol development, manuscript editing, critical review

BG Lindeque: protocol development, manuscript editing, critical review

**Abstract:****Introduction and Hypothesis:**

There is a lack of epidemiological studies evaluating female pelvic organ prolapse in developing countries. Current studies have largely focused on women of Caucasian ethnicity. This study was designed to determine interethnic variation in pelvic floor functional anatomy, namely, levator hiatal distensibility and pelvic organ descent, in women with symptomatic pelvic organ prolapse in a multi-ethnic South African population.

**Methods:**

This prospective observational study included two hundred and fifty eight consecutive women referred for pelvic organ prolapse assessment and management at a tertiary urogynaecological clinic. After a detailed history and clinical examination including POPQ assessment, patients had a 4D transperineal ultrasound. Offline analysis was performed with 4D View software (GE Kretztechnik, Austria). Main outcome measures included levator muscle distensibility, pelvic organ descent and levator ani defects (avulsion).

**Results:**

Mean age was 60.6 (range, 25-91) years, mean BMI 29.83 (range, 18-53). Points Ba and C were lower and the genital hiatus more distensible in Black women (all  $P < 0.05$ ). They were found to have greater hiatal area ( $p = 0.017$  at rest,  $p = 0.006$  on Valsalva) compared to South Asians and Caucasians and showed greater pelvic organ mobility (all  $P < 0.05$ ) than Caucasians on ultrasound. Levator defects were found in 32.2% ( $n = 83$ ) of patients and the majority were bilateral (48.2%,  $n = 40$ ), with significant interethnic differences ( $P = 0.014$ ).

**Conclusion:**

There was significant variation in clinical prolapse stage, levator distensibility and pelvic organ descent in this racially diverse population presenting with pelvic organ prolapse, with South Asians having a lower avulsion rate than the other two ethnic groups ( $p = 0.014$ ).



**Keywords:** Pelvic organ prolapse; ethnicity; pelvic organ descent; levator avulsion

**Brief summary:** There is significant interethnic variation in clinical and functional anatomy in women presenting with pelvic organ prolapse.

## **Introduction :**

Interethnic differences are well documented for the bony anatomy of *homo sapiens*. The bony skull and more recently the pelvis are most commonly used to determine biological affinity i.e. gender and ethnicity in forensic anthropology and archaeology. Measurements of bony pelvic dimensions suggest that ethnicity can be determined with high accuracy (88 percent) [1-3]. Patriquin *et al* studied consistent bony landmarks in os coxae of 100 white and black South African females of known age, and ethnicity and found statistically significant differences in 12 out of 13 measurements i.e. white females had greater pelvic dimensions than black women suggesting that ethnic differences in the bony pelvis are highly significant [4].

Recently there has been interest in studying the potential impact of ethnicity on the development of pelvic floor dysfunction (PFD) and variations in obstetrics outcomes. Magnetic resonance imaging (MRI) and 4 dimensional transperineal ultrasound (4D TPUS) studies have shown that there are significant ethnic differences in the female pelvic architecture as regards bony and soft tissue pelvic dimensions and pelvic floor function [5-7].

Handa *et al* compared soft tissue dimensions between 178 white and 56 African-American primiparous women using MRI imaging at 6-12 month postpartum. Apart from finding significant differences in both the pelvic inlet and outlet measurements (greater in white women), African-American women had statistically significantly greater pelvic floor descent measured by calculating the difference in descent of the posterior rectal wall from the pubococcygeal line on straining [8].

In a group of two hundred and seven asymptomatic nulliparous women, we have recently shown that compared to Caucasian and South Asian women, Black nulliparous women had statistically significantly greater levator distensibility and pelvic organ descent of the anterior, middle and posterior compartment as measured on 4D TPUS [9]. Similarly Shek *et al* have shown that there are significant differences in pelvic organ support and levator hiatal distensibility between Black Ugandan and Caucasian nulliparous women using 4D TPUS [10]. This has not been tested for in women with symptomatic pelvic organ prolapse (POP). The clinical significance of observed differences may well suggest that different

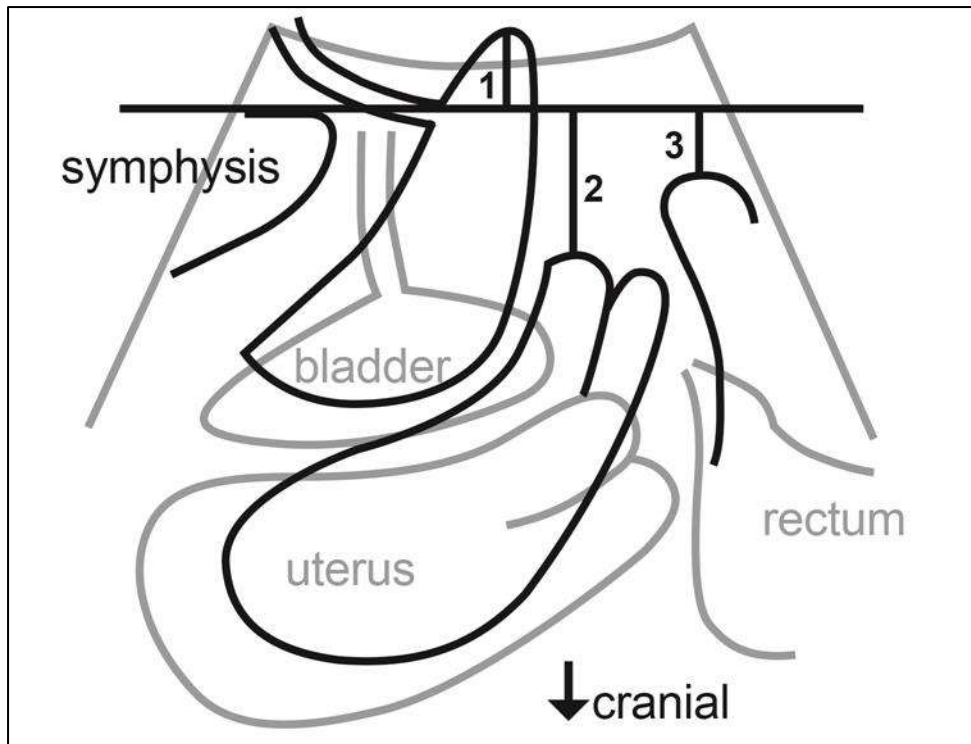
pathophysiological mechanisms exist in women with POP of different ethnicities which need further exploration.

The primary objective of this study was to prospectively analyse biometric indices of pelvic floor functional anatomy on clinical examination and pelvic floor ultrasound (hiatal distensibility and pelvic organ descent) in a multi-ethnic South African population presenting with symptomatic POP.

### **Materials and methods:**

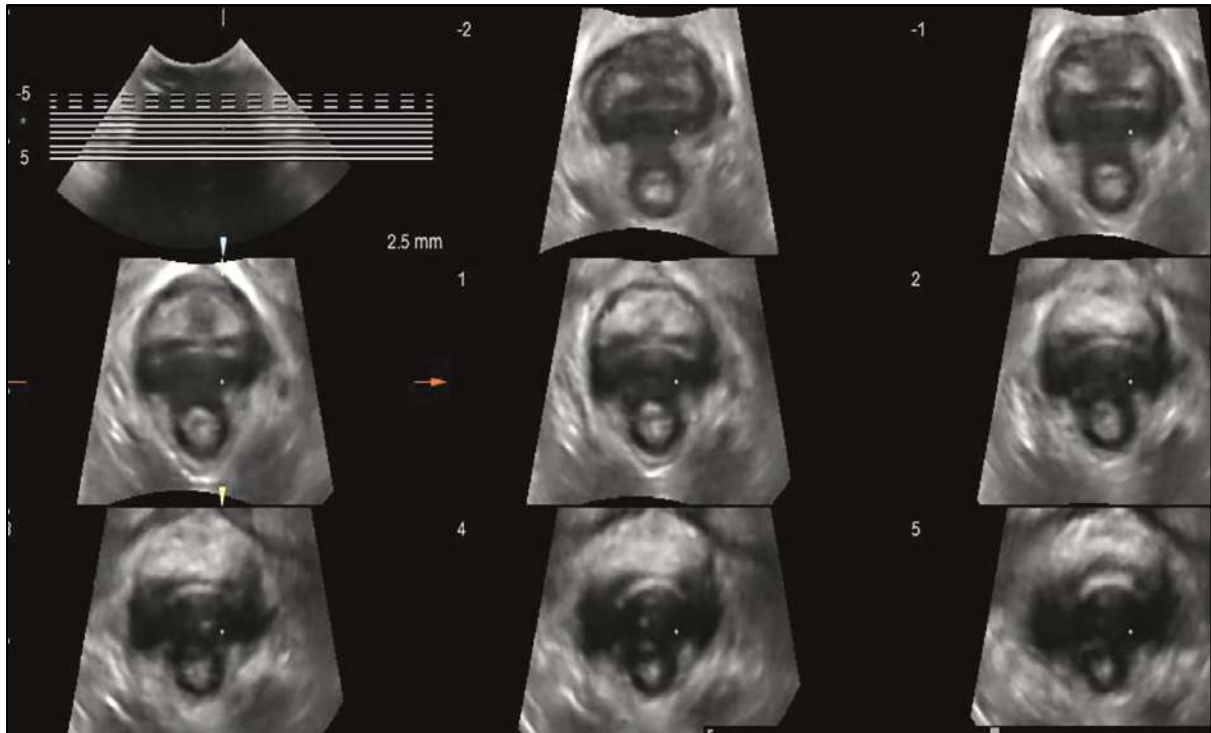
This study was conducted at Steve Biko Academic Hospital tertiary urogynaecology clinic and included 263 women presenting with symptomatic female pelvic organ prolapse (POP) from June 2013 to March 2015. The hospital is located in an urbanized city and is the major referral center for the province. After informed consent, clinical examination using the pelvic organ prolapse quantification system of the International Continence Society (ICS POP-Q) and completion of the ICIQ Vaginal Symptoms (ICIQ-VS) questionnaire, all women had a pelvic floor assessment by 4D transperineal ultrasound using a GE Voluson i ultrasound system with 8-4 MHz curved array volume transducer (GE Kretz Ultrasound, Zipf, Austria) as previously described [11,12]. The acquisition angle was set at 85° to include the entire levator hiatus. For analysis of the central compartment we excluded women after hysterectomy as imaging of the vault has yet to be validated. Data on ethnicity was self-reported. Oxford grading to assess the levator ani muscle was also performed.

The ultrasound methodology as well as offline volume analysis has been described in detail for the same cohort in a previous study evaluating the association between pelvic floor symptoms and functional pelvic floor anatomy [13]. Ultrasound volumes were de-identified and analysed 6-8 weeks later using proprietary software 4D View version 10. Figure 1 is a schematic representation illustrating descent of the pelvic organs on Valsalva relative to the inferior margin of the pubic symphysis.



**Figure 1:** Schematic representation of transperineal ultrasound at rest (light grey) and on Valsalva (black) illustrating measurements of maximal descent of bladder (1), cervix (2) and rectal ampulla (3) against the reference of the inferior margin of the pubic symphysis

Multi-slice or tomographic imaging was obtained in the axial plane, with the interslice interval set at 2.5mm intervals from 5mm below to 12.5mm above the plane of minimal hiatal dimensions as described previously. Levator avulsion was diagnosed by visualizing detachment of the pubovisceral muscle from the pelvic sidewall in the rendered axial volumes obtained at maximal PFMC, or in volumes obtained at rest in those unable to contract (n=22) [14,15]. Figure 2 demonstrates a bilateral levator avulsion on tomographic ultrasound.



**Figure 2:** Tomographic ultrasound image illustrating bilateral levator avulsion on maximum pelvic floor contraction. The stars indicate detachment of the pubovisceral muscle from its insertion on the inferior pubic ramus.

This study was approved by the local Human Research Ethics Committee, University of Pretoria (226/2011). Statistical analysis was performed after normality testing (Kolmogorov Smirnov testing) using IBM SPSS statistics v23 (IBM Corporation). To compare ethnic differences between the 3 groups, one way analysis of variance (ANOVA) was performed and necessary adjustments for age, BMI, parity and previous prolapse surgery were controlled for in the analysis of covariance (ANCOVA). Pairwise comparison for ethnicity was performed using Bonferroni statistics. Fisher’s exact test was used for comparing the prevalence of avulsion between ethnicities. A  $p$  value  $< 0.05$  was considered statistically significant. Our null hypothesis was defined as “there is no ethnic variation in levator muscle distensibility, levator avulsion and pelvic organ descent in women presenting for symptoms of prolapse.”

**Results:**

Two hundred and fifty eight women were included in the analysis after excluding 5 cases due to missing data. The mean age was 60.6 (range, 25-91) years, mean vaginal parity was 3.6 (range, 0-9) and mean BMI 29.8 (range, 18-53). This study consisted of a racially diverse cohort i.e. 12% Asian (n=31), 41.5% black (n=107) and 46.5% Caucasian (n=120). Table 1 shows demographic characteristics for the entire population and for the three ethnic groups.

<b>Demographic characteristics</b>	<b>Entire population</b>	<b>South Asians (n=31)</b>	<b>Caucasians (n=120)</b>	<b>Blacks (n=107)</b>	<b>P value</b>
Age	60.64 (12.19)	61.32 (12.35)	61.73 (11.87)	59.23 (12.47)	0.290
BMI	29.83 (6.37)	27.84 (4.21)	29.79 (6.54)	30.30 (6.64)	0.402
Vaginal parity	3.6 (1.82)	3.5 (1.47)	3.1 (1.42)	4.2 (2.12)	0.000
Assisted delivery	38 (14.7)	3 (9.7)	24 (20)	11 (10.3)	0.429
Previous prolapse procedure	55 (21.3)	8 (25.8)	36 (30)	11 (10.3)	0.001

**Table 1:** Demographic characteristics of entire group. Age, BMI and vaginal parity presented as a mean (SD); and assisted delivery and previous prolapse procedure as a number (%).

Black women were significantly more vaginally parous ( $p=0.001$ ); previous prolapse procedures were more often reported by Caucasian women ( $p=0.001$ ).

Table 2 shows the results of POP-Q coordinates on clinical examination. There were significant differences between the studied ethnicities specifically for the anterior (Ba) ( $p=0.048$ ) and central compartment (C) ( $p=0.001$ ) as well as genital hiatus and perineal body measurements ( $p=0.001$ ). Post hoc test confirmed that the observed differences for the anterior compartment, point C and genital hiatus (Gh) + perineal body (Pb) were statistically significant between Blacks and Caucasians.

<b>POP-Q Coordinat es</b>	<b>Entire population</b>	<b>South Asians (n=31)</b>	<b>Caucasians (n=120)</b>	<b>Blacks (n=107)</b>	<b>P value</b>
Ba	+1.97 (1.05)	+ 1.91 (0.76)	+ 1.78 (1.16)	+2.13 (0.97)	0.048
C	+1.10 (1.31)	+ 0.76 (1.09)	+0.68 (1.17)	+1.66 (1.32)	0.000
Bp	+ 0.82 (1.16)	+0.50 (1.00)	+0.96 (1.12)	+0.64 (1.26)	0.202
Gh (cm)	5.95 (1.06)	5.50 (0.97)	5.76 (0.81)	6.52 (0.97)	0.000
Pb (cm)	3.36 (0.48)	3.32 (0.47)	3.30 (0.43)	3.43 (0.52)	0.100
Gh +Pb (cm)	9.31 (1.23)	9.09 (0.97)	8.80 (1.09)	9.95 (1.14)	0.000

**Table 2:** Pelvic organ prolapse coordinates (Ba, C and Bp, Gh, Pb ,Gh +Pb) are reported in centimetres either below (-) or above (+) the hymen as per ICS POPQ system. Positive values signify descent below the hymen. Gh, genital hiatus; Pb, perineal body.

On 4D ultrasound volume data acquisition, four women were unable to produce a proper Valsalva maneuver despite coaching, leaving 254 datasets for levator distensibility/ area assessment. Black women were found to have statistically significantly greater hiatal areas at rest ( $p=0.017$ ) and on Valsalva ( $p=0.006$ ) compared to Asians and Caucasians. Bonferroni posthoc test revealed that this

difference was mainly between Black and South Asians for both rest ( $p=0.01$ ) and Valsalva volumes ( $p=0.006$ ). Black women showed greater pelvic organ descent on Valsalva in all three compartments (all  $p<0.05$ ) and these differences in descent seen on imaging were mainly between Black and Caucasian women. Exclusion of women with previous prolapse surgery did not materially change these results.

Levator defects were found in 32.3 % ( $n=83$ ) of patients and the majority were bilateral (48.2%,  $n=40$ ). Table 3 shows ethnic variations in levator distensibility, pelvic organ descent and avulsion as examined by translabial ultrasound. South Asians showed a lower avulsion rate than the other two ethnic groups ( $P= 0.014$  on Fisher's exact test). The mean Oxford scores were significantly lower in those women with an avulsion (mean, 1.62 (right), 1.71 (left) compared to those without i.e. 2.58 (right) and 2.57 (left); ( $p=0.001$ ).



Parameter	Entire population	South Asians (n=31)	Caucasians (n=120)	Blacks (n=107)	P value
<b>Levator distensibility:</b>					
Hiatal area at rest (cm <sup>2</sup> )	26.04 (7.18)	22.60 (7.08)	26.23 (7.35)	26.77 (6.79)	0.017
Hiatal area on PFMC (cm <sup>2</sup> )	21.12 (6.41)	19.17 (5.51)	21.18 (6.70)	21.73 (5.85)	0.182
Hiatal area on Valsalva (cm <sup>2</sup> )	38.28 (9.69)	34.15 (8.28)	37.64 (9.76)	40.15 (9.59)	0.006
<b>Compartmental descent:</b>					
Bladder position on Valsalva (mm)	-26.03 (11.22)	-25.86 (8.68)	-20.67 (6.11)	-26.31 (15.24)	0.022
Uterine position on Valsalva (mm)	-25.95 (11.60)	-17.70 (8.50)	-22.68 (11.08)	-29.09 (11.25)	0.048
RA position on Valsalva (mm)	-20.47 (8.41)	-15.17 (6.95)	-19.26 (7.61)	-26.01 (9.18)	0.029
Avulsion	83	4/31 (13%)	41/120 (34.2%)	38/107 (35.5%)	0.014*

**Table 3:** Pelvic floor biometry in South Asian, Caucasian and Black patients with symptomatic POP. One way analysis of variance (ANOVA) was performed to determine mean differences between ethnicities, and pair wise comparison for ethnicity was performed using Bonferroni statistics. Values are mean (SD) and negative values for descent signifies position below the pubic symphysis. PFMC, pelvic floor muscle contraction; RA, rectal ampulla. \*Fisher's exact test for South Asians vs. all others.

For the analysis of symptoms we tested positive responses to 'most of the time' and 'all of the time' of the ICIQ-VS questionnaire. The major core symptoms reported were for questions 4a (do you feel that your vagina is too loose or lax?); 5a (are you aware of a lump or bulge coming down in your vagina?); 6a (do you feel a lump or bulge come out of your vagina, so that you can feel it on the outside or see it on the outside?); and 8a (do you have to insert a finger into your vagina to help empty your bowels?), and the results are as follows: 70.5% (*n*=182), 79.8% (*n*=206), 71.3% (*n*=184), 21.3% (*n*=55) respectively. There were no statistically significant interethnic differences in the prevalence of symptoms.

### **Discussion:**

Pelvic organ prolapse (POP) is a significant health problem in developing countries with an estimated mean prevalence of 19.7% (range 3.4–56.4%) [16-18]. However, most clinical and imaging studies on morphological changes of the pelvic floor musculature focus on nulliparous and multiparous Caucasian women presenting with pelvic floor dysfunction [7, 19-21].

Current studies on ethnicity emphasize epidemiological findings (i.e. prevalence and risk factors) as opposed to functional anatomical assessment. To our knowledge this is the first study evaluating clinical and pelvic floor functional anatomy in a racially diverse South African population presenting with symptomatic POP. Furthermore it includes a large cohort of black women (41.5%, *n*=107) thus illustrating that FPOP is common in this ethnic group. Although it has been shown that age, parity, menopause, assisted delivery and levator trauma are significantly associated with

pelvic floor dysfunction it is likely that women in developing countries are exposed to other potential risk factors for pelvic floor dysfunction such as heavy lifting, younger age at first delivery, early resumption of household duties postpartum, poor nutrition and lower annual household income. Proper identification and description of these potentially modifiable risk factors may require further study.

The epidemiological evidence for the role of ethnicity as a potential risk factor for POP has long been debated and is conflicting. Hendrix and Whitcomb *et al* reported that African American women demonstrated the lowest risk for POP as compared to Caucasian and other ethnic minorities (Hispanic, Asian and American Indian) [22,23]. In contrast Bump *et al* found a similar prevalence of POP for Black and white women referred for a Urogynecologic evaluation (24 versus 23% respectively) [24]. Graham *et al* evaluated the effect of ethnicity on POP and UI in 183 symptomatic African Americans and 132 Caucasians, and found no significant ethnic difference in the presence and severity of POP [25]. While this scientific debate on ethnic distribution of POP continues we have noted higher POP-Q stage than compared to developed countries with more than a third of symptomatic patients (36.4%) presenting with POP-Q stage 3 prolapse [26]. In a Caucasian exclusive cohort (n=270) 25.2% had the leading edge of the prolapse at or below the hymen, in contrast to our mixed population with the leading edge of the prolapse at almost +2cm for the anterior compartment and +1cm for the middle and posterior compartment [27]. This implies that patients present to our clinic with higher stages of prolapse than in developed countries which is likely due to the nature of healthcare services in South Africa and/or other factors mentioned earlier.

With regards to avulsion, most studies in this field have reported on Caucasians [28, 29]. The similar avulsion rates for Caucasian (34.2%) and Blacks (35.5%) is an interesting finding. The lower prevalence in South Asians is intriguing and may be due to a surprisingly low number of vaginal assisted deliveries in this group. We intend to study this issue in more detail in future. As regards the reported symptoms we have recently shown that there is a significant association between core prolapse symptoms i.e. awareness, visualization and/or feeling of a vaginal lump and levator hiatal distensibility and levator avulsion [13].

Limitations of the study include the fact that ultrasound acquisition and clinical examination were both performed by the first author (ZA). To overcome this potential bias for the analysis of imaging data, volumes were de-identified during acquisition and only analysed 6-8 weeks later, blinded against all clinical data including ethnicity. Hence, the ultrasound data presented here should not be confounded by assessment bias as the evaluation of imaging data was blinded against ethnicity. The congruence of imaging and clinical findings, incidentally, argues against any such bias. The impact of higher socio-economic class, educational level, employment status, and differential access to primary care are various forms of selection bias that need to be further explored.

In conclusion we have found significant ethnic differences in clinical prolapse stage, levator distensibility and pelvic organ descent. Possible reasons include differences in bony pelvis, genetic inheritance of collagen endowment, lifestyle, nutritional factors and labour. POP is common in Black African women and to date this topic has been inadequately studied. The role of levator avulsion in the pathogenesis of prolapse is unlikely to vary greatly between the examined ethnicities, although interethnic differences deserve further study.

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**Paper 4:**

**The impact of childbirth on pelvic floor morphology in primiparous Black South African females: A prospective longitudinal observational study**

**Short title:** Pelvic floor morphology in Black primiparae after childbirth

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**Keywords:** pelvic floor morphology, levator avulsion, childbirth, pelvic floor ultrasound



**Abstract:****Objective:**

There is a lack of prospective studies evaluating the impact of childbirth on the pelvic floor. We intended to study delivery related changes in pelvic floor morphology i.e. pelvic organ mobility, levator hiatal distensibility and levator avulsion in Black South African primiparae. We also intended to determine the impact on vaginal symptoms in the postpartum period.

**Methods:**

A total of one hundred and fifty three nulliparous women were recruited from a district antenatal clinic between 35-39 weeks gestation. All women had a standardised interview, completed the International consultation on incontinence vaginal symptom questionnaire followed by 3/ 4 dimensional transperineal ultrasound. This was repeated 3 -6 months postpartum.

**Results:**

Eighty four (54.9%) women returned at a mean of 4.8 months postpartum. 60 (71.4%) women had a vaginal delivery and the rest caesarean section (20 emergency versus 4 elective). Overall there were statistically significant increase in measurements of bladder neck descent ( $P = 0.003$ ), pelvic organ descent and levator hiatal distensibility (all  $P < 0.001$ ), in the postpartum period. Levator avulsion was diagnosed in 15% ( $n=9$ ) amongst those delivered vaginally. The mean birth weights were greater in the caesarean group (3.04 versus 3.34 kg,  $P = 0.001$ ). Postpartum vaginal laxity was the commonest bothersome vaginal symptom reported.

**Conclusion:**

There is significant alteration in pelvic organ support and levator hiatal distensibility after both vaginal delivery and emergency caesarean section. 15% of Black primiparous women sustain levator trauma after their first vaginal delivery.

**Introduction:**

An intact levator ani muscle complex (LAMC) is key to maintaining normal pelvic organ support.<sup>1, 2</sup> Although gross trauma to this muscle in the form of an avulsion injury has been described several decades ago, it is only recently that biomechanical derangements in the form of altered pelvic organ mobility, levator hiatal distensibility and levator avulsion has been described and studied.<sup>3, 4, 5, 6</sup>

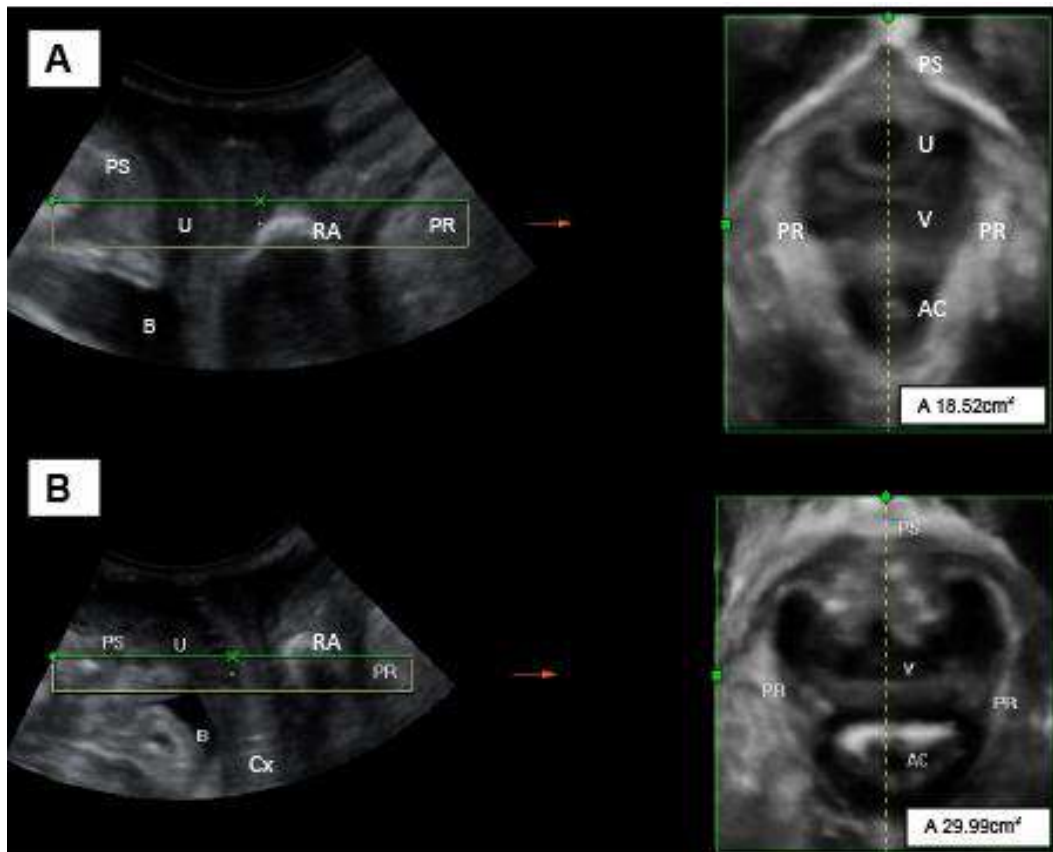
Using 3/ 4 dimensional transperineal ultrasound (TPUS) levator avulsion occurs in 10-30% of women after delivery and most studies include women of Caucasian ethnicity.<sup>4, 7, 8</sup> It has recently been shown that compared to Caucasians and Asians, Black Ugandan and Black South African nulliparous women have greater pelvic organ mobility and levator hiatal distensibility and as such might be less susceptible to delivery related trauma.<sup>9, 10</sup>

We conducted a prospective longitudinal cohort study on Black South African primiparous women to firstly establish the impact of childbirth on levator ani morphology (pelvic organ mobility; levator distensibility and levator avulsion) by 3/ 4 dimensional TPUS and secondly, determine the effect on vaginal symptoms using the validated International Consultation on Incontinence Vaginal Symptoms (ICIQ-VS) questionnaire.<sup>11</sup> Our hypothesis was that Black primiparous women are less likely to sustain delivery related trauma to the pelvic floor.

**Materials and Methods:**

Between November 2015 and 2016 consecutive primigravid women between 35 and 39 weeks gestation were invited from a district antenatal clinic to participate in this study. Inclusion criteria were an uncomplicated singleton pregnancy, maternal age > 18 years, and no previous pregnancy > 20 weeks gestation. Patients were excluded when an elective caesarean section was planned by the attending clinician. After a standardised interview which included demographic details, medical history, body mass index (BMI) measurement, all women completed the validated ICIQ-VS questionnaire. A clinical examination for pelvic organ prolapse (POP) using the International Continence Society pelvic organ prolapse quantification system (ICS POP-Q) was then performed followed by 3/ 4 D TPUS in the supine position and after bladder emptying using a GE Voluson i with a 8-4MHz volume transducer.<sup>12</sup> Volumes were acquired at rest, maximum pelvic floor muscle contraction (PFMC) and maximum Valsalva. All patients were coached to optimise these maneuvers (at

least 3 attempts for PFMC and Valsalva) and limit levator coactivation.<sup>13</sup> The volume data of the best PFMC and Valsava maneuver was used for analysis. We used the ultrasound methodology as previously described by the third author.<sup>14,15</sup> Figure 1 compares pelvic organ descent and levator hiatal distensibility in the antenatal vs postpartum period illustrating significant change.

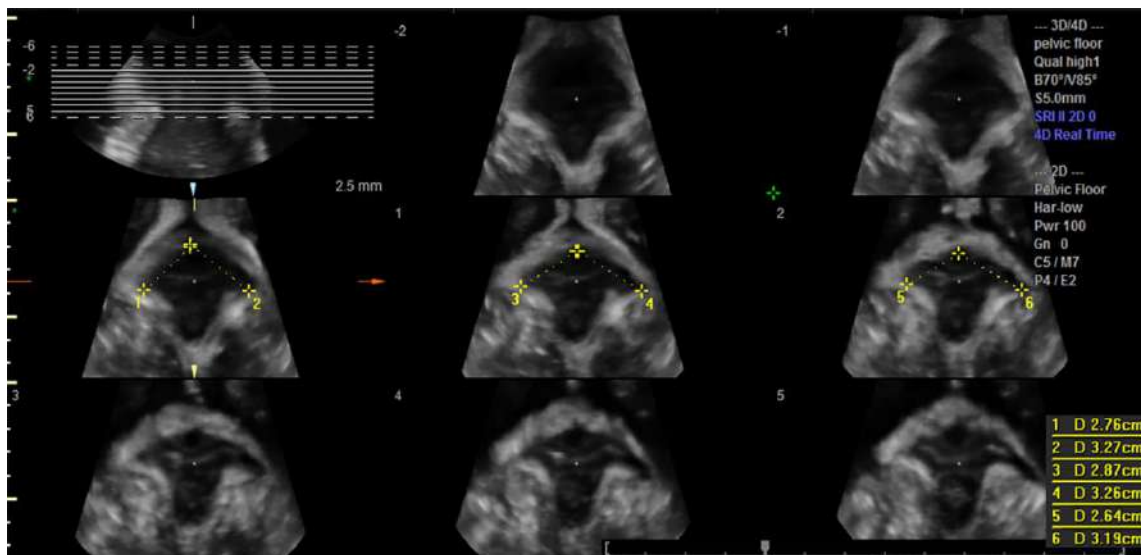


**Figure 1:** Comparison of the levator hiatus seen in rendered volumes antenatally (A) and postnatally (B) and larger levator hiatal area on Valsalva maneuver. PS, pubic symphysis, B, bladder, U, urethra, Cx, cervix, RA, rectal ampulla, PR, puborectalis, V, vagina, AC , anal canal.

The clinical and ultrasound examination and the ICIQ-VS questionnaire were then repeated 3-6 months postpartum. The ultrasound examination was performed first (patient was requested to drape the abdomen up to the pubic symphysis) in order to blind the clinician to all delivery data. Discussion of their delivery and clinical examination for POP was only allowed after the ultrasound. Postpartum data was

retrieved from the patient maternity book at the time postpartum visit and/or hospital maternity register.

All ultrasound parameters were measured at the plane of minimal hiatal dimension as defined in the midsagittal plane using GE Voluson i system with an 8-4MHz volume transducer and acquisition angle set to 85 degrees.<sup>16</sup> Tomographic ultrasound imaging at an interslice interval of 2.5mm was used to diagnose levator avulsion. Discontinuity of the puborectalis muscle from its insertion on the inferior pubic ramus and a levator-urethral gap greater than 25mm in the central three slices was the diagnostic criteria used, see Figure 2<sup>17</sup>. This method has been shown to be highly reproducible.<sup>18</sup>



**Figure 2:** Tomographic ultrasound imaging illustrating bilateral levator avulsion as evidenced by levator urethral gap of greater than 25mm.

All imaging data was de-identified and analysed 8-12 weeks after the second ultrasound to minimise bias, and blinded to all clinical data. Analysis of data was performed offline using the 4D View software (GE Medical Systems Kretztechnik, Zipf, Austria).

This study was approved by the local Human Research Ethics committee, University of Pretoria (226/2011) and is the final part of a PhD study on pelvic floor morphology

in South African women. We did not perform power calculations as this was considered a pilot study. Statistical analysis was performed using SPSS v. 24 (IBM Corporation). Paired t test was used to assess for differences in mean values and the independent sample t test was used to determine association between mode of delivery and birth weight. A  $P < 0.05$  was considered statistically significant.

### **Results:**

One hundred and fifty three women were recruited at a mean gestation of 36.6 weeks (range, 35-39.4). Eighty four (54.9%) returned for their postpartum visit at a mean of 4.8 months, hence the analysis is presented for this group. The mean age of the study population was 25.35 years (range, 18-38) and mean BMI was 30.09 (range 20-60). There were no statistically significant differences in age ( $P = 0.431$ ) and BMI ( $p = 0.945$ ) between the attenders and non-attenders. One patient died antenatally due to respiratory morbidity. Of the 84 women, 60 delivered vaginally (5 forceps and 4 vacuum) and the rest ( $n=20$ ) had an emergency caesarean section (CS) (19 for cephalopelvic disproportion (CPD), 1 for antepartum haemorrhage). The remainder ( $n=4$ ) had an elective CS for hypertension, failed induction ( $n=2$ ) and breech presentation respectively). Demographic, delivery data and pelvic floor parameters are compared in Table 1. Paired  $t$ -tests to compare difference in means ( $\pm$  standard deviation) at baseline and after delivery are shown in Table 2.

Parameter	Vaginal delivery (n=60)	Caesarean section (n=24)	<i>P</i>
Age	24.64 (± 3.96 )	27.43 (±3.99 )	0.007
Body mass index (kg/m <sup>2</sup> )	29.50 (± 6.31 )	31.87 (± 8.28 )	0.166
Gestation (weeks)	36.55 (± 9.09 )	36.57 (± 7.96 )	0.687
Birth weight (kg)	3.083 (± 0.51 )	3.378 (± 0.47 )	0.012
Head circumference (cm)	34.41 (± 1.53 )	33.83 (± 1.80 )	0.293
Length (cm)	51.02 (± 2.73 )	51.30 (± 2.81 )	0.673
Assisted delivery*	9 (15)		
Episiotomy*	43 (71.6)		

**Table 1:** Demographic and delivery data at 4.8 months postpartum (n=84). Data are a mean ± standard deviation, or n (%)\*.

Parameter (n=84)	Antepartum, 35-39 wk	Postpartum, 4.8 mo	P value
<b>Pelvic organ descent (mm)</b>			
Bladder neck descent	7.22 (± 3.68)	9.69 (± 6.44)	0.003
Cystocele descent	12.06 (± 4.77)	8.93 (± 5.34)	0.000
Uterine descent	23.33 (± 5.63)	18.66 (± 5.69)	0.000
Rectal ampulla descent	7.80 (± 7.13)	5.3 (± 7.26)	0.000
<b>Levator hiatal distensibility</b>			
Midsagittal hiatal diameter (rest) (mm)	46.55 (± 5.02)	51.42 (± 4.65)	0.000
Midsagittal hiatal diameter (PFMC)(mm)	35.58 (± 5.06)	42.47 (± 6.36)	0.000
Midsagittal hiatal diameter (Valsalva)(mm)	53.98 (± 6.18)	58.48 (± 7.82)	0.000
Hiatal area (rest) (cm <sup>2</sup> )	18.15 (± 4.26)	22.56 (± 4.54)	0.000
Hiatal area (PFMC) (cm <sup>2</sup> )	14.30 (± 3.03)	18.64 (± 4.3)	0.000
Hiatal area (Valsalva) (cm <sup>2</sup> )	24.23 (± 6.48)	31.39 (± 6.06)	0.000

**Table 2:** Paired *t*-tests to compare difference in means (± standard deviation) at baseline and after delivery. The increase in mean bladder neck value and lower mean values for cystocele, uterus and rectal ampulla imply greater pelvic organ descent. PFMC, pelvic floor muscle contraction; wk, weeks; mo, months.

Statistical analysis revealed a significant increase in mean values from ante- to postnatal measurements in pelvic organ mobility and levator hiatal distensibility after vaginal birth and CS (all  $p \leq 0.008$ ) see Table 3.

Parameter	Vaginal delivery (n=60)	Caesarean section (n=24)	<i>P</i> value
<b>Avulsion</b>	9 (15%)	0	
<b>Pelvic organ descent</b>			
Bladder neck descent	2.37 ( ±6.26)	- 0.84 (± 7.66)	0.008
Cystocele descent	- 2.91 ( ± 4.73)	- 3.7 ( ± 3.70)	0.008
Uterine descent	- 4.10 ( ± 5.55)	- 6.34 ( ± 4.29)	0.000
Rectal ampulla descent	- 1.49 ( ±6.30)	- 2.50 ( ±3.09)	0.000
<b>Levator hiatal distensibility</b>			
Midsagittal hiatal diameter (rest)	+5.26 (± 3.3)	+3.95 (± 2.79)	0.000
Midsagittal hiatal diameter (PFMC)	+5.13 (± 7.14)	+5.87 ( ± 4.29)	0.001
Midsagittal hiatal diameter (Valsalva)	+7.17 (± 7.37)	+3.27 (± 4.02)	0.000
Hiatal area (rest)	+4.76 ( ± 2.83)	+3.53 ( ± 2.27)	0.000
Hiatal area (PFMC))	+4.60 ( ± 2.79)	+3.67 ( ± 2.75)	0.000
Hiatal area (Valsalva)	+7.67 ( ± 5.18)	+5.75 ( ± 2.69)	0.000

**Table 3:** Changes in pelvic organ descent after vaginal birth and CS. Values represent changes in mean values from ante- to postnatal measurements. In all instances changes were towards more organ mobility and hiatal distensibility, and such changes were always more marked in women who delivered vaginally.



Amongst the vaginal delivery group levator avulsion was diagnosed in 15% (n=9; 2 forceps, 1 vacuum and 6 spontaneous deliveries). No avulsions were diagnosed in the CS group. Independent sample t test revealed a significant association between levator avulsion and anterior compartment descent ( $P=0.039$ ), and  $\chi^2$  statistics showed a significant association between avulsion and assisted delivery ( $P=0.013$ ). Neither age nor BMI was associated with levator avulsion. There was a statistically significant association between assisted deliveries and episiotomy and all measurements of levator distensibility at rest, PFMC and Valsalva (all  $P<0.05$ ). The average birth weight in those delivered by caesarean section was greater than the vaginal delivery group i.e. 3.34 vs 3.04kg ( $P=0.012$ ).

On POPQ exam: the anterior compartment 33% (28/84) showed improved and 58% (49/84) showed poorer support, with 27% (23/84) one stage worse and 13% (11/ 84) two stages worse than antenatally. Due to small numbers we combined the middle and posterior compartments, and 10% (8/84) were one stage worse. Overall, 15% (n=13/84) remained unchanged. Table 4 shows the mean POP-Q coordinates before and after childbirth, and illustrates that the anterior compartment (Ba) was more susceptible to change ( $P= 0.001$ ). There were no significant changes in the POP-Q coordinates in the CS group.

<b>POP-Q Coordinates (n=84)</b>	<b>Antenatal</b>	<b>Postpartum</b>	<b>P value</b>
Ba	- 2.13 ( $\pm 1.06$ )	- 0.87 ( $\pm 1.30$ )	0.002
C	- 4.38 ( $\pm 1.5$ )	- 4.0 ( $\pm 0.92$ )	0.567
Bp	- 3.0 ( $\pm 0.00$ )	- 2.83 ( $\pm 0.40$ )	0.363
Gh	2.2 ( $\pm 4.60$ )	5.40 ( $\pm 0.54$ )	0.219
Pb	3.33 ( $\pm 0.51$ )	2.83 ( $\pm 0.40$ )	0.076

**Table 4:** Comparison of mean change in POP-Q coordinates before and after childbirth. Values represent mean ( $\pm$  standard deviation)

Table 5 details the mean ICIQ-VS scores before and after delivery. 67% were sexually active antenatally (56/84), and 54% (45/84) in the postpartum period.

<b>ICIQ-VS question (n=84)</b>	<b>Antenatal</b>	<b>Postnatal</b>	<b>P value</b>
Q1 <i>Are you aware of dragging pain in your lower abdomen?</i>	0.54 (± 0.84)	0.43 (± 0.86)	0.401
Q2 <i>Are you aware of soreness in your vagina?</i>	0.28 (± 0.66)	0.64 (± 1.07)	0.006
Q3 <i>Do you feel that you have a reduced sensation or feeling in or around your vagina?</i>	0.04 (± 0.18)	0.15 (± 0.59)	0.118
Q4 <i>Do you feel that your vagina is too loose or lax?</i>	0.02 (± 0.15)	1.43 (± 1.24)	0.001
Q5 <i>Are you aware of a lump or bulge coming down in your vagina?</i>	0.02 (± 0.22)	0.06 (± 0.32)	0.409
Q6 <i>Do you feel a lump or bulge come out of your vagina, so that you can feel it on the outside or see it on the outside?</i>	0.00 (± 0.00)	0.02 (± 0.15)	0.159
Q7 <i>Do you feel that your vagina is too dry?</i>	0.05 (± 0.30)	0.65 (± 1.08)	0.001
Q8 <i>Do you have to insert a finger into your vaginal to help empty your bowels?</i>	0.02 (± 0.22)	0.05 (± 0.44)	0.657
Q9 <i>Do you feel that your vagina is too tight?</i>	0.00 (± 0.00)	0.00 (± 0.00)	NA
Q10 <i>Do you have a sex life?</i>	1.31 (± 0.64)	1.02 (± 0.68)	0.001
Q13 <i>How much do you feel that your sex life has been spoilt by vaginal symptoms?</i>	0.12 (± 0.77)	1.40 (± 1.96)	0.001
Q14 <i>Overall, how much do vaginal symptoms interfere with your everyday life?</i>	0.18 (± 0.78)	2.90 (± 2.17)	0.001

**Table 5:** Overall scores of the ICIQ-VS questionnaire antenatally and postpartum. Data represented as a mean ( $\pm$  SD). The correlation for question 9 could not be computed as the standard error of the difference is 0.

### **Discussion:**

To the authors knowledge there are no published studies on the impact of childbirth on the pelvic floor support mechanisms as measured on 3D TPUS in Black African women. Hence this is likely to be the first prospective study to report altered postpartum levator morphology in Black South African females. For all parameters on Table 2 there was a significant increase in pelvic organ mobility and levator hiatal dimensions in the postpartum period, more so for the vaginal delivery group. Other studies have shown similar alteration in pelvic floor morphology in other ethnicities.<sup>7, 8, 19, 20, 21</sup>

When one considers the vaginal delivery group our findings of increased pelvic organ mobility are similar to Dietz et al. In their prospective observational study 61 nulliparous women between 36-40 weeks were recruited to define the incidence of major levator trauma after vaginal delivery by 3D TPUS. 50 women (82%) returned between 2 and 6 months postpartum and levator avulsion was diagnosed in 14 women (36%), although a non-standardised early 3D ultrasound methodology was used which likely overestimated the incidence of major trauma. A comparison of antenatal and postnatal data showed an increase in pelvic organ mobility for the anterior, middle and central compartment (all  $p \leq 0.001$ ) as well as an increase in levator hiatal area on Valsalva ( $p=0.018$ ). There were no significant changes in women delivered by emergency caesarean section ( $n=10$ ). In all cases of emergency caesarean section fetal head descent was above the level of the ischial spines.<sup>4</sup> At a mean follow up of 5.3 months postpartum Shek et al showed that 19% ( $n=24/128$ ) of women sustained levator avulsion after vaginal delivery and levator hiatal area on PFMC and Valsalva maneuver were markedly increased in this group compared to those without avulsion and CS group ( $p<0.001$  and  $p=0.002$  respectively).<sup>7</sup>

It is widely accepted that since the levator ani muscle endures substantial stretch during the passage of the fetal head, it is this insult that results in levator

defects/tears and avulsion.<sup>4, 21</sup>. In those without macroscopic tears, increased pelvic organ mobility and levator hiatal areas may in some women be surrogate markers of microscopic trauma. The role and effect of emergency CS on pelvic floor morphology is currently unclear. In our cohort the vast majority of caesarean sections were performed for CPD i.e. 19 of the 24 (79.1%). A local i.e. South African retrospective review of 2553 hospital births using the Robson Ten Group classification system in determining appropriateness of CS's revealed that the main indications for emergency CS in nulliparous single cephalic term pregnancies was a combination of fetal distress with CPD followed by hypertensive disorders of pregnancy and abruptio placenta and the overall CS rate was 42.4% (1 082/2 553).<sup>22</sup>

There is emerging data that emergency CS is associated with labour also confers some risk of pelvic floor alteration. Novellas et al compared magnetic resonance imaging (MRI) features between 2 and 3 days postpartum between caesarean delivery without labour (n=10) and urgent caesarean delivery (n=20). In the caesarean group that had been in active labour, hypersignals of the puborectalis (n=11) and iliococcygeus muscle (n=7) as well as a defect in orientation of the iliococcygeus (n= 10) was the commonest abnormality described.<sup>23</sup> These 'hypersignals' may represent possible ischaemia and/or denervation as a result of the labour processes itself. Notably the mean fetal weight was significantly greater in the urgent caesarean group, 3.4kg vs 2.8kg ( $p=0.008$ ) and the mean cervical dilatation was 6.2cm (range, 3-10) and mean duration of labour was 5.65 h (range, 2-20). Albrich et al conducted a prospective cross-sectional observational study between 48-72 hours postpartum using 3D TPUS on a GE Voluson system, to evaluate levator morphology between vaginal delivery and caesarean section group, and also determine whether the first stage of labour had an effect on levator morphology in those who had emergency CS.<sup>19</sup> A total of 157 primiparous women were recruited and 81 delivered vaginally (70 spontaneous, 10 vacuum and 1 forceps) and 76 had CS (55 elective and 21 emergency). Similarly the measured levator biometric parameters (midsagittal antero-posterior and coronal hiatal diameter, hiatal area and circumference) were greater in the vaginal delivery group ( $p<0.001$ ) compared to the CS group. Overall levator defects were found in 39.5% (32/81) in the vaginal delivery group and in 5.2% (4/76) in the CS delivery group. All 4 women and complete cervical dilatation and required emergency CS for

intrauterine asphyxia (n=3) and arrest of the fetal head during the second stage of labour (n=1). The findings of both these studies are limited to the early postpartum period. Our data on CS is limited by the small number of patients in the CS group, hence no firm conclusions can be drawn in this regard.

With regards to vaginal symptoms, Van Delft et al reported that at mean of 13 weeks postpartum 21% (n=30) of primigravidae sustain levator avulsion after vaginal delivery, and this has a significant impact on signs and symptoms of PFD. Reduced vaginal sensation and loose vagina were commonly reported symptoms as per the ICIQ-QS especially in women with levator avulsion.<sup>8</sup> Postpartum we have found a statistically significant increase in the mean ICIQ-VS scores for vaginal laxity (question 4) and vaginal symptoms interfering with everyday quality of life (ICIQ-VS question 14, see Table 5). This is consistent with findings in Caucasian women.<sup>24</sup>

There was significant deterioration in pelvic organ support postpartum, which is consistent with the literature.<sup>4, 7, 8, 19, 25, 26</sup> Most mild prolapse in postpartum women is asymptomatic, as it was in this cohort. Only 4 women reported that they were sometimes aware of a lump/bulge.

Limitations of the study include a low follow-up rate. Work commitments and unavailability (visiting parents' home in another province) were the most common reason for non-attendance. Lack of intrapartum detail does not allow us to draw firm conclusions with regards to the impact of emergency CS for CPD on pelvic floor morphology. In addition, it is recognised that longer term follow-up may be necessary since slow improvement over time has been described in other ethnic groups.<sup>27</sup> It is plausible that over time, the measured parameters may revert to baseline measurements on nulliparous Black women a previously published.<sup>10</sup>

### **Conclusion:**

Vaginal childbirth results in a substantial alteration of the pelvic floor support mechanism as examined by 3D TPUS in Black South African primigravidae at a mean of 4.8 months postpartum. Our findings suggest that emergency caesarean delivery may not provide complete protection of the pelvic floor structures.

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## DISCUSSION

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POP is a common indication for gynaecological surgery and also a major public health priority <sup>1,2,3</sup>. Although innovative surgical procedures (e.g. mesh) have been introduced to address recurrence after surgery serious complications are not rare, underscoring the need to better understand the pathophysiology in order to prevent and appropriately treat this condition <sup>4,5,6</sup>. Imaging studies such as ultrasound are a useful tool for clinicians in order to study biomechanical properties and behaviour of the levator ani muscle and determine organ mobility. Parameters such as levator hiatal diameter and area, pelvic organ descent, distensibility ('ballooning') and levator avulsion have been studied and quantified. The aetiology of POP is multifactorial and among the implicated risk factors listed in literature review, there is scant data on the role of ethnicity in the development of PFD. We thus utilized TPUS as our imaging modality of choice to further elucidate the impact /role of ethnicity in PFD, specifically POP, and determine the incidence/prevalence of levator avulsion in South African women.

### **Pelvic organ descent and levator distensibility ("ballooning"): (Paper 1 and 3):**

POP is the downward displacement of the pelvic organs via the largest hernial portal in the human body i.e. the levator hiatus. The boundaries of this hiatus includes the pubic symphysis anteriorly and the puborectalis component of the levator ani muscle laterally and posteriorly as illustrated in Figure 9. It has been shown that there is significant variation in the measurements of levator hiatal dimensions in the general population <sup>7,8,9</sup>.

Cheung et al compared pelvic floor biometry between 200 East Asian and 168 nulliparous Caucasian women and found that East Asians had significantly less pelvic organ descent (bladder neck, bladder and rectal ampulla) and smaller levator hiatal areas, and after controlling for potential confounders using multivariate regression analysis ethnicity remained the only significant factor associated with these findings <sup>8</sup>. Similarly Dietz et al have previously shown that nulliparous East Asians have statistically significantly less pelvic organ descent for the same

parameters (all  $p < 0.05$ ) compared to Caucasians<sup>10</sup>. Our findings in South Asians are consistent with the mentioned studies.

There is a lack of data on evaluating pelvic floor morphology in African black women. To date (excluding the author's current publications) there has been only one other study on pelvic organ support in nulliparous Black Ugandan women<sup>9</sup>. Shek et al compared the same pelvic floor parameters and levator hiatal dimensions in a group of healthy Ugandan volunteers ( $n=76$ ) to Caucasians ( $n=49$ ). Using identical methodology to our study, substantial differences were found between the two groups. All measurements of pelvic organ descent and levator hiatal dimensions were significantly greater in Ugandan volunteers (all  $p < 0.01$ ). These findings strongly support our data which also showed that compared to South Asians and Caucasians, Black South African nulliparous women had greater pelvic organ descent and levator hiatal measurements (all  $p < 0.001$ )<sup>11</sup>.

Paper 3 has shown that there also are significant differences in pelvic organ descent and levator hiatal distensibility amongst women of different ethnicity presenting with symptomatic POP. Black women had significantly greater pelvic organ descent and levator hiatal distensibility than Caucasian and South Asian women. In addition, more than a third of symptomatic patients (36.4%) presented with a POP-Q stage 3 prolapse (points Ba and C were significantly lower in Black women). However, levator defects were found in similar proportions (34.2% of Caucasians and 35.5% of Blacks). To our knowledge this is the first study evaluating clinical and pelvic floor functional anatomy in a racially diverse population presenting with symptomatic POP; thus there are no other similar studies to compare our results to.

Possible explanations of increased pelvic organ descent include, and I quote: 'Such differences in biomechanical properties of pelvic organ support tissues may be due to differences in lifestyle, nutritional factors, and/or genetic/congenital factors, and further studies are needed to separate these factors. It is also possible that such differences may be attributable to morphological variations in dimensions of the bony pelvis in different ethnicities'<sup>11</sup>.

## **Pelvic organ prolapse symptoms (paper 2):**

The ICS POP-Q system was published in 1996 and clinicians are encouraged to quantify POP clinically using the nominal staging system i.e. stages 0 to 4<sup>12</sup>. While staging systems are useful for various reasons, it is important that it be validated against clinically relevant symptoms in order to accurately reflect the nature of the condition. Using the ICS POP-Q system Swift et al studied the distribution of pelvic organ support in women presenting for their annual gynaecological examination (n=1004)<sup>13</sup>. Almost 40% of women had POP-Q stage 2 pelvic organ support. Thus it is reasonable to propose a modification of staging to make it more predictive of symptoms. With this background Dietz et al investigated the relationship between ICS POP-Q measurements and symptoms of POP in 764 archived datasets of women presenting with PFD and lower urinary tract symptoms<sup>14</sup>. Using clinical examination, ROC statistics revealed optimal cutoffs for predicting prolapse symptoms for Ba at -0.5; for C at -5 and for Bp at -0.5, underscoring that for the same degree of descent the uterus is much more likely to cause prolapse symptoms than the bladder or rectum.

Bulge symptoms seem to be the dominant symptom reported in women with POP<sup>15</sup>. Barber et al reported a significant relationship between bulge symptoms and maximal extent of prolapse in 1cm increments relative to the hymen in 160 symptomatic women presenting to a tertiary Urogynaecology clinic. Other symptoms such as a dragging sensation, pelvic pressure, discomfort and heaviness show poorer correlations with prolapse. While most association studies on POP symptoms have focussed on clinical POP-Q stage, recent technological advancements in US imaging have allowed us to perform more detailed studies on the association with pelvic floor morphology.

Using 3/4D TPUS, bladder descent to  $\geq 10$ mm, rectal descent to  $\geq 15$ mm below the pubic symphysis, and descent of the cervix to  $\leq 15$ mm above the pubic symphysis have been shown to be strongly associated with prolapse symptoms, confirming again that current staging is suboptimal<sup>16,17</sup>.

In paper 2 we sought to determine the association between pertinent prolapse symptoms (awareness and feeling/visualization of lump/bulge and POP-Q stage, and functional anatomy of the pelvic floor i.e. levator hiatus areas (at rest, PFMC and on

Valsalva) and levator avulsion. There was a significant association between awareness and feeling of a lump with hiatal areas and levator avulsion (all  $p < 0.05$ ). Additionally we have shown a significant association between interference with everyday quality of life and abnormal levator hiatal distensibility<sup>18</sup>.

#### **Maternal birth trauma (paper 4):**

Several epidemiological studies have shown an increase in risk for POP and UI after vaginal birth compared to CS<sup>19, 20, 21, 22</sup>. Once again modern imaging has allowed Urogynaecologists to describe maternal vaginal birth trauma in the form of obstetric anal sphincter injury and levator avulsion and its relationship to PFD<sup>23, 24, 25, 26</sup>.

Levator avulsion is common, affecting 10-30% of vaginally delivered women<sup>27, 28</sup>. Prevalence figures are now available from over a dozen studies as highlighted in a review on 'Maternal birth trauma: why should it matter to urogynecologist?' by Dietz et al<sup>29</sup>. While most studies included women of Caucasian and East Asian ethnicity, we have documented an incidence of 15% in Black primiparous women at a mean of 4.8 months postpartum, consistent with results obtained in other ethnicities. Our findings of a significant association between assisted deliveries and levator avulsion is also consistent with the literature<sup>30,31,32,33</sup>.

Current evidence suggest that levator avulsion partially explains the link between vaginal birth and the development of POP and is thus clinically highly relevant<sup>25,34,35</sup>. However, we acknowledge the moderate return rate and relatively small cohort in our study and thus plan a larger study at a district/tertiary level hospital in the near future.

The complaint of vaginal laxity is gaining more attention as it is likely an early manifestation of abnormal levator distensibility and has been shown to be clinically relevant<sup>36, 37, 38</sup>. At a median of 13 weeks postpartum van Delft et al reported that reduced vaginal sensation and 'too loose vagina' were more commonly reported in women with levator avulsion<sup>39</sup>. We have found that at a mean of 4.8 months postpartum complaint of vaginal laxity was the commonest bothersome vaginal symptom reported.

## CONCLUSION

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Pelvic floor dysfunction in the form of Pelvic Organ Prolapse (POP) is a global health concern. This condition has been shown to impact negatively on general quality of life, bladder, bowel and sexual function domains. Amongst the listed risk factors (aging, menopause, chronically raised intra-abdominal pressure, connective tissue abnormalities etc.) parity/vaginal childbirth is likely to be most relevant for the development of POP. The combination of risk factors ultimately result in loss of the structural integrity of the pelvic floor between the endopelvic fascia, LAMC, and bony attachments. Recently imaging studies such as ultrasound has been used to study both the macroscopic and microscopic architectural distortion of the pelvic floor musculature. The clinical implication of these changes i.e levator avulsion and increased levator muscle distensibility has been discussed earlier.

Although various publications have cited race/ethnicity as a risk factor, this topic has received little scientific attention. Epidemiological studies have shown that ethnic differences exist as regards incidence/ prevalence, and thus might be a determinant of pelvic floor dysfunction (PFD). Most studies exploring this association have included women of Caucasian and East Asian ethnicity. Using TPUS we have:

- Studied pelvic organ support and distensibility of the LAMC in a diverse multi-cultural South African population i.e. South Asians, Caucasians and Black females. This included both asymptomatic nulliparous females and females with symptomatic POP. The results have shown significant interethnic variation in pelvic organ support and distensibility of the LAMC.
- Studied the association between prolapse symptoms and the functional anatomy of the pelvic floor. This study confirmed a significant association between awareness and visualization of a 'lump' or 'bulge' at the bottom and POP-Q stage, levator muscle distensibility and levator avulsion AND the interference of symptoms with 'everyday life' was significantly associated with POP-Q stage and levator distensibility on Valsalva. Studies exploring the association/correlation between specific symptoms and functional anatomy of

the pelvic floor will enable clinicians to better understand the clinical relevance of the symptom i.e. what does this symptom mean?

- Finally we studied the impact of vaginal childbirth on the pelvic floor in Black women. This is the first local study to report that 15% of Black South African women sustain levator avulsion. As we have shown that such trauma occurs in 32.2% of women attending a tertiary Urogynaecology clinic it has been suggested by numerous experts in the field that maternal birth trauma should be regarded as a key performance indicator of maternity services <sup>40</sup>. To further understand the natural history of maternal birth trauma in the form of avulsion a follow-up study of the 15% is planned in the near future.

The results of our study indicate significant ethnic diversity in pelvic floor morphology on TPUS. We believe that this data will contribute positively to further understanding of the role of ethnicity amongst other risk factors for the development of POP. This is clinically relevant as we might be able to recommend appropriate preventative and treatment strategies for the susceptible ethnic groups.

PFD, specifically POP and UI are major public health issues in South Africa. The last South African Demographic and Health survey did not prioritize these conditions in the questionnaire. This information is highly relevant as it can determine the distribution and availability of dedicated medical resources in the country. Using population projections from the United States Census Bureau from 2010 to 2050, Wu et al reported that there will be a significant increase in the prevalence of PFD which will ultimately have a significant negative impact on workforce productivity, quality of life and health care cost <sup>41</sup>.

To build on our findings we propose further studies which should include an epidemiological investigation of the burden of disease in our local population, followed by determining the impact on various quality of domains, an outcome analysis of various treatment strategies and finally a larger prospective study on maternal birth trauma. Since the methodology described is simple, easy, readily available (to every Obstetrician and Gynaecologist) and cost-effective further studies utilizing TPUS is a realistic goal.

## FUTURE RESEARCH

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PFD has a negative impact on various quality of life domains<sup>42, 43, 44, 45</sup>. Longterm consequences of maternal birth trauma (i.e. levator avulsion and obstetric anal sphincter injury) include POP, UI and fecal incontinence. In 1998 the South African Demographic and health survey documented that 10% of vaginally parous women reported urinary incontinence when they coughed, sneezed or lifted heavy weights<sup>46</sup>. To assess for fecal incontinence and bladder fistula women were asked if they were constantly wet or soiled. This information was disregarded as women considered vaginal discharge as 'wet'. The next survey should be accurately planned to fully assess the burden of PFD in South Africa.

Contrary to previous publications inferring that Black women rarely develop PFD, we have shown that it is common and that this ethnic group had significantly different pelvic floor dynamics than Caucasian and South Asian women for both nulliparous and multiparous symptomatic women<sup>47, 48</sup>. This should be further explored in prospective studies. Ethnicity is a difficult topic to study as various other factors such as genetics, life style, nutrition, social and educational background, access to medical facilities as well as cultural beliefs etc. play a role. This study has contributed to the urogynaecological literature in terms of ethnic variation of the pelvic floor musculature. In addition, customized cutoff values should be explored in view of the finding of ethnic variation.

Further studies should also focus on preventative strategies, and one potential focus would be the modification of obstetric practice in order to minimise maternal birth trauma. It is routine practice to inform women about complications of pregnancy at antenatal clinics, yet no information is shared as regards pelvic floor trauma which can have devastating emotional and psychological sequelae including posttraumatic stress disorder<sup>45</sup>.

Further technological development in imaging will allow pelvic floor research to better understand the dynamics of the pelvic floor and allow for widespread application of such knowledge in clinical practice. Both research and patient care are bound to

benefit from such developments, and the author of this thesis hopes to have made a small contribution to this goal.



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# Ethnic differences in the levator hiatus and pelvic organ descent: a prospective observational study

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**KEYWORDS:** 3D/4D pelvic floor ultrasound; ethnicity; nulliparous; pelvic floor morphology

## ABSTRACT

**Objective** To date, most studies on functional anatomy of the pelvic floor have focused on Caucasian women. There is scant information on this topic involving other ethnic groups. The aim of this study was to investigate levator hiatal area and pelvic organ descent in three racially diverse ethnic groups of healthy nulliparous South Asian, Caucasian and black South African women, using threefour-dimensional (3D/4D) transperineal ultrasound (TPS).

**Methods** Nulliparous women aged 18–40 years from three different ethnic groups were recruited for this prospective observational study between June 2012 and April 2015. After informed consent and clinical examination of the pelvic floor, all patients underwent a 3D/4D-TPS examination. Ultrasound volumes were captured at rest, on maximum pelvic floor muscle contraction (PFMC) and on maximal Valsalva maneuver. Analyses of variance and covariance were performed to compare the three ethnic groups, and a post-hoc Bonferroni pairwise test was applied.

**Results** A total of 207 nulliparous women were recruited, comprising 41 South Asian, 69 Caucasian and 97 black women. After controlling for age and body mass index, all measurements of mean levator hiatal area at rest, on PFMC and on Valsalva were higher in black women (all  $P < 0.0001$ ). Post-hoc Bonferroni pairwise comparison revealed that black women had greater pelvic organ descent and levator hiatal area compared with South Asian and Caucasian women ( $P < 0.0001$ ).

**Conclusion** This comparative study indicates that there are significant differences in levator hiatal area and pelvic organ mobility between Caucasian, South Asian and black ethnic groups. Copyright © 2016 ISUOG. Published by John Wiley & Sons Ltd.

## INTRODUCTION

Recently, several studies have reported that the prevalence and risk factors for pelvic organ prolapse (POP) and stress urinary incontinence (SUI) differ between ethnic groups<sup>1–4</sup>. In a large population-based cohort study ( $n = 1136$ ), which included Caucasian ( $n = 569$ ), African-American ( $n = 209$ ), Asian ( $n = 159$ ) and Latina ( $n = 199$ ) women, Whitcomb *et al.* reported that Caucasian and Latina women had four to five times higher risk of symptomatic prolapse compared with African-American women<sup>3</sup>. Graham *et al.* assessed retrospectively the effect of ethnicity on SUI and POP in 183 African-American and 132 Caucasian women and reported that Caucasian ethnicity was the most significant predictor of genuine SUI (odds ratio, 2.21) when compared with African-American ethnicity<sup>1</sup>. To further investigate the claimed rarity of SUI in black women, both Knobel *et al.* and Skinner *et al.* studied pelvic floor contractility and urethral length in black South African women and found them to have greater pelvic floor contractile strength (using a Kegel perineometer) and urethral length (measured with a calibrated Foley catheter) when compared with Caucasian and Indian women<sup>5,6</sup>.

While these differences have been shown by clinical examination, recently, ultrasound has emerged as a simple, dynamic and potentially more objective diagnostic tool for the evaluation of the pelvic floor and pelvic organ support<sup>7</sup>. Using four-dimensional (4D) translabial ultrasound, Shek *et al.* showed substantial differences with regards to pelvic organ mobility and levator hiatal biometry between nulliparous Ugandan and Caucasian women, with all measurements being higher in Ugandan women (all  $P \leq 0.01$ )<sup>8</sup>. The aim of the present study was to compare levator hiatal area at rest, on maximum pelvic floor muscle contraction (PFMC) and on maximal Valsalva maneuver, and pelvic organ mobility in healthy nulliparous women from a racially diverse South African

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population comprising black Africans, South Asians and Caucasians.

## SUBJECTS AND METHODS

In this prospective observational study, healthy nulliparous women aged between 18 and 40 years were recruited from the general gynecology clinic as well as from the local nursing college, in Pretoria, South Africa between June 2012 and April 2015. Ethnicity was both self-reported and assigned by a researcher (Z.A.) to one of three ethnic categories (South Asian, Caucasian or black) after recording the ethnicity of all four grandparents. There was no discrepancy between self-reported ethnicity and that assigned by the researcher. Women with mixed ethnicity were excluded. All patients gave written informed consent. Ethics approval was obtained from the Human Research Ethics Committee, University of Pretoria (226/2011).

After informed consent was obtained, women were requested to empty their bladder and thereafter a clinical examination for prolapse was performed in those who had previously been sexually active, using the POP quantification (POP-Q) grading system by the International Continence Society, with the patient in the supine position<sup>9</sup>. A vaginal examination was not performed in women with an intact hymen. Subsequently, three-dimensional (3D)/4D transperineal ultrasound (TPS) was performed using a GE Voluson i ultrasound system (GE Medical Systems, Zipf, Austria) with a RAB 8–4-MHz transducer at an acquisition angle of 85°, as described previously<sup>7</sup>.

TPS was performed with the probe covered with a powder-free glove and applied in the midsagittal plane to the introitus using moderate pressure. Volumes were acquired at rest, on maximum PFMC and during maximal Valsalva maneuver. Patients performed Valsalva for at least 5 s, and the best of three volumes was used for analysis<sup>10</sup>. Using visual biofeedback, an attempt was made to correct for levator co-activation by requesting the women observe the narrowing and widening of the levator hiatus during the maneuvers<sup>11</sup>.

3D volumes were measured offline using GE 4DView (GE Medical Systems), as described previously<sup>7</sup>. Using the best Valsalva maneuver, pelvic organ descent measurements were obtained relative to a horizontal line from the inferior margin of the pubic symphysis (Figure 1). Positions of the bladder neck and of the most dependent/leading parts of the bladder, cervix and rectal ampulla were measured, as described previously<sup>12</sup>. Levator hiatal area was assessed in the plane of minimal hiatal dimensions<sup>13</sup> by one author (Z.A.), 6–8 weeks after acquisition and with de-identification (blinded to ethnicity and patient identification). Levator hiatal area was measured using highly repeatable methods<sup>14–17</sup>.

### Statistical analysis

Statistical analysis was performed after testing for normality with the Kolmogorov–Smirnov test, using

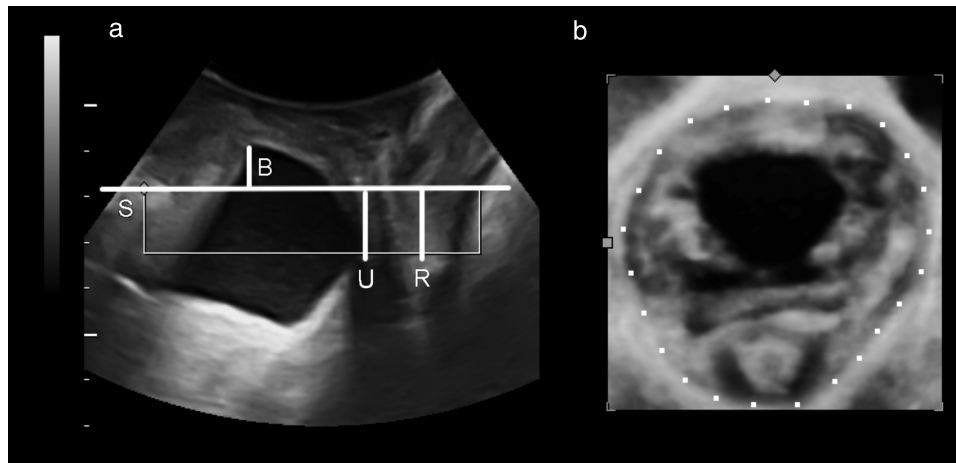
Stata version 13.1 (StataCorp, College Station, TX, USA) in consultation with a biostatistician. To compare differences between the three ethnic groups, a one-way analysis of variance (ANOVA) was performed and necessary adjustments for age and body mass index (BMI) were controlled for in an analysis of covariance (ANCOVA), considering age and BMI as covariates. Pairwise comparison for ethnicity was performed using the Bonferroni analysis. A  $P$ -value  $< 0.05$  was considered statistically significant.

## RESULTS

A total of 207 nulliparous women were recruited, comprising 41 South Asian (19.8%), 69 Caucasian (33.3%) and 97 black (46.9%) women. Mean age was 25.1 (range, 18–39) years and mean BMI was 24.3 (range, 13–39) kg/m<sup>2</sup>. Ten 3D-TPS volume datasets were excluded from formal analysis due to poor image quality (most acquired at study initiation), leaving 197 ultrasound datasets for measurement at rest. In addition, one woman could not perform PFMC and eight women could not perform a Valsalva maneuver, leaving 196 PFMC datasets and 189 Valsalva datasets for analysis. Pelvic organ mobility was measured in only 165 women (South Asian,  $n = 33$ ; Caucasian,  $n = 61$ ; black,  $n = 71$ ) due to a clerical error in data acquisition and storage upon initiation of the study.

Table 1 shows the demographic characteristics and 3D-TPS findings in each ethnic group. One-way ANOVA revealed that Caucasian women were younger ( $P < 0.001$ ) and black women had a higher BMI ( $P = 0.004$ ) (Table 1). ANCOVA was performed to determine if age and BMI were statistically significant confounders of pelvic organ mobility and levator hiatal area. *Post-hoc* Bonferroni analysis was used to determine the differences between groups. Pelvic organ descent and mean levator hiatal area at rest, on PFMC and on maximal Valsalva were all greater in black women than in the other ethnic groups ( $P < 0.0001$ ), even after controlling for age and BMI as potential confounders.

Of the 165 women with pelvic organ mobility results, POP-Q data were available for 142 (South Asian,  $n = 31$ ; Caucasian,  $n = 49$ ; black,  $n = 62$ ) as vaginal examination was not performed in 23 women who had an intact hymen. The mean values for POP-Q coordinates are presented in Table 2. South Asian women had the least organ mobility as compared with Caucasian and black women ( $P < 0.0001$ ). No difference was noted between groups for measurements of the genital hiatus and perineal body. In short, we found that black women had greater pelvic organ descent on both ultrasound and clinical examination and greater distensibility compared with South Asian and Caucasian women. Anterior compartment descent was the most common finding on Valsalva maneuver (Table 1). Multivariate modelling revealed that black ethnicity remained a significant factor for pelvic organ mobility on clinical examination ( $P = 0.024$ ).



**Figure 1** (a) Transperineal ultrasound image of pelvic floor in midsagittal plane on maximal Valsalva maneuver, showing descent of bladder (B), uterus (U), and rectal ampulla (R), relative to symphysis pubis (S). (b) Transperineal ultrasound image in axial plane, showing hiatal area (dotted outline).

**Table 1** Demographic characteristics and measurements of hiatal distensibility and pelvic organ mobility on three-dimensional transperineal ultrasound in South Asian, Caucasian and black South African nulliparous women

Parameter	South Asian (n = 41)	Caucasian (n = 69)	Black (n = 97)	P
Age (years)	26.3 ± 4.6	23.6 ± 4.1	25.7 ± 4.5	< 0.001
Body mass index (kg/m <sup>2</sup> )	22.7 ± 5.0	23.9 ± 4.4	25.6 ± 5.0	0.004
Levator hiatal area				
At rest (cm <sup>2</sup> )	10.94 ± 3.14	11.58 ± 2.65	13.60 ± 3.25	< 0.0001
On PFMC (cm <sup>2</sup> )	9.13 ± 2.60	9.54 ± 2.34	10.75 ± 2.27	< 0.0001
On Valsalva (cm <sup>2</sup> )	14.59 ± 4.74	15.24 ± 5.03	18.10 ± 4.97	< 0.0001
Bladder neck descent (mm)*	9.20 ± 5.18	10.68 ± 7.13	12.60 ± 6.92	0.02
Bladder descent on Valsalva (mm)*	15.44 ± 3.90	15.91 ± 6.45	11.82 ± 6.38	< 0.0001
Uterine descent on Valsalva (mm)*	23.31 ± 6.29	26.42 ± 6.75	20.09 ± 7.23	< 0.0001
Rectal ampulla descent on Valsalva (mm)*	7.70 ± 6.16	9.39 ± 6.16	2.91 ± 8.00	< 0.0001

Data are given as mean ± SD. \*Pelvic organ mobility measured in only 165 patients (South Asian, n = 33; Caucasian, n = 61; black, n = 71) due to error in data acquisition and storage. PFMC, maximum pelvic floor muscle contraction.

**Table 2** Comparison of position of pelvic organ prolapse quantification (POP-Q) coordinates between South Asian, Caucasian and black South African nulliparous women

POP-Q coordinates	South Asian (n = 31)	Caucasian (n = 49)	Black (n = 62)	P
Ba (cm)	-2.6 (-3 to -1)	-1.9 (-3 to 2)	-1.6 (-3 to 1)	< 0.0001
C (cm)	-5.7 (-6 to -4)	-5 (-6 to -2)	-3.4 (-5 to 0)	< 0.0001
Bp (cm)	-2.6 (-3 to -1)	-2 (-3 to 1)	-1.6 (-3 to 1)	< 0.0001
Gh (cm)	3.5 (2.5 to 5.0)	3.5 (2.5 to 4.5)	3.5 (2.5 to 5.0)	0.813
Pb (cm)	4 (3 to 5)	4 (3 to 5)	4 (3 to 5)	0.998

Data are given as mean (range). Ba, most distal position of upper anterior vaginal wall; Bp, most distal position of upper posterior vaginal wall; C, most distal edge of cervix; Gh, genital hiatus; Pb, perineal body.

## DISCUSSION

In this multiethnic South African nulliparous population, we found significant differences between ethnic groups as regards levator hiatal area and pelvic organ mobility, both on ultrasound and on clinical examination. To date, studies on ethnic differences in pelvic floor anatomy have focused largely on Caucasian women, using clinical examination<sup>2-4</sup>. Although it is widely accepted that pelvic

floor trauma as a consequence of vaginal childbirth is a significant factor for pelvic floor dysfunction, it is likely that congenital/hereditary factors need further exploration<sup>18,19</sup>.

Our finding of increased levator hiatal area and pelvic organ mobility among black women are similar to the recently published findings of Shek *et al.*<sup>8</sup>. In our study, bladder neck, bladder, uterine and rectal descent were all significantly greater in black women as compared

with South Asian and Caucasian women. Using the same methodology and ultrasound model, Shek *et al.* explored pelvic organ support in 76 healthy nulliparous Ugandan volunteers<sup>8</sup>. The mean levator hiatal area in black women in our study was 13.6 cm<sup>2</sup> at rest and 18.1 cm<sup>2</sup> on Valsalva, which compares with 15.7 cm<sup>2</sup> at rest and 22.8 cm<sup>2</sup> on Valsalva for the Ugandan volunteers. Levator hiatal area and pelvic organ descent were significantly greater in Ugandan women compared with Caucasians, which is consistent with our findings. In our study, South Asian women demonstrated the smallest levator hiatal areas (at rest, on PFMC and on Valsalva) and the least pelvic organ mobility compared with Caucasian and black women. Interestingly, compared with Caucasians ( $n=161$ ), East Asian women ( $n=16$ ) were also found to have significantly less pelvic organ mobility of the anterior and posterior vaginal compartment both in early pregnancy and postpartum<sup>20</sup>.

The strengths of our study include the three-way comparison of ethnic groups which, to our knowledge, is the first such study in the literature. Another strength is the use of identical methodology to the only other African study by Shek *et al.*<sup>8</sup> and inclusion of a POP-Q examination in nulliparae who were sexually active. While the three ethnic groups we examined are not fully representative of the South African population, they come close. The South African demographic profile in 2014 revealed that black Africans comprised 79.2% of the total population, with white, Asian and mixed race constituting ethnic minority groups (20.8%).

Limitations of our study include the fact that our patients were recruited from a gynecology clinic and may not be fully representative of the general population. However, they were seen for contraceptive advice or other gynecological conditions, with none presenting with symptoms of pelvic floor disorders, limiting potential selection bias. Furthermore, ultrasound acquisition and clinical examination were performed by the same researcher (Z.A.) who was thus not blinded to ethnicity. To overcome this potential bias, volumes were de-identified during acquisition and analyzed 6–8 weeks later; hence, the ultrasound data presented here should not be confounded by assessment bias. However, level of education and type of work were not enquired about and these could be potential confounders. Power calculations were not performed due to absence of such data in the literature at the time of study planning in 2011. Lastly, although women with mixed ethnicity were excluded, we acknowledge that their inclusion might have added further information.

Regardless of those potential shortcomings, it seems highly likely that black nulliparae show increased levator hiatal dimensions and pelvic organ mobility compared with other ethnic groups. A plausible explanation could be that both muscle and connective tissue support structures may be more elastic and/or distensible in black women than in Caucasians or South Asians. Such differences in the biomechanical properties of pelvic organ support tissues may be due to differences in lifestyle, nutritional factors

and/or genetic/congenital factors, and further studies are needed to separate these. It is possible that such differences may be attributable to morphological variations in the dimensions of the bony pelvis in different ethnicities. This seems unlikely, however, given that we found larger hiatal dimensions and more organ descent in black women while a study of bony dimensions documented smaller pelvic diameter in this ethnic group compared with Caucasians<sup>21</sup>.

Both pelvic organ mobility and levator hiatal dimensions have been shown to be predictors of delivery outcome in pregnant women, an issue that deserves further study<sup>22–24</sup>. Regardless of causation, one could speculate that the increased pelvic floor distensibility in black women might be protective of childbirth trauma, i.e. levator avulsion, and may result in a shorter second stage of labor, which make our findings of potential obstetric interest<sup>24</sup>. We are currently undertaking a study to evaluate changes in pelvic floor morphology pre- and post-delivery in black South African primigravidae and will test this hypothesis once recruitment is complete. Long-term follow-up of these nulliparous women using the same methodology will be useful to identify other potential risk factors of pelvic floor dysfunction over time.

In conclusion, the results of this study support our primary research hypothesis that there are significant ethnic differences in pelvic floor functional anatomy, differences that may well affect both connective tissue and muscle<sup>25</sup>. This is evident both on pelvic floor ultrasound and on clinical examination. The combination of greater distensibility and pelvic organ mobility in black South African women compared with Caucasians and South Asians deserves further study.

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# Prolapse symptoms are associated with abnormal functional anatomy of the pelvic floor

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## Abstract

**Introduction and hypothesis** The etiology of pelvic organ prolapse (POP) likely includes over-distension or tears (avulsion) of the levator ani muscle. However, there is a lack of studies evaluating the association between symptoms of POP and these factors. This study was designed to determine the association between POP symptoms and clinical prolapse stage on the one hand, and pelvic floor functional anatomy on the other hand.

**Methods** This prospective observational study included 258 patients seen at a tertiary urogynecological unit with symptoms of POP as defined by pertinent ICIQ questions. After informed consent and a detailed history including ICIQ responses, 3D transperineal ultrasonography was performed using a GE Voluson i ultrasound system. Offline analysis was performed on de-identified datasets.

**Results** The mean age of the patients was 60.6 years (25–91 years) and their mean BMI was 29.8 kg/m<sup>2</sup> (18–53 kg/m<sup>2</sup>). Levator defects were found in 78 (32.4%) of the patients

and the defect was bilateral in almost half of these patients ( $n = 36$ ). There were significant associations between awareness and visualization of a vaginal lump on the one hand and hiatal area measurements as well as diagnosis of avulsion on the other. Interference with everyday life was significantly associated with hiatal area and prolapse stage, but not with avulsion.

**Conclusions** There is a significant association between awareness, visualization and/or feeling of a vaginal lump and abnormal pelvic floor functional anatomy, that is, hiatal ballooning and levator avulsion.

**Keywords** Levator avulsion · Pelvic organ descent · Prolapse symptoms

## Introduction

Symptomatic female pelvic organ prolapse (POP) is a common gynecological problem that negatively affects various quality of life domains [1]. Although the pathophysiology is still poorly understood, both macroscopic trauma ('avulsion') and microtrauma (irreversible overdistension) to the levator ani muscle are regarded as causative factors in at least some forms of symptomatic female POP [2]. The first prospective study to demonstrate a direct association between levator trauma and vaginal childbirth was published in 2005. In a prospective observational study of nulliparous women, levator avulsion was diagnosed using 3D transperineal ultrasonography between 2 and 6 months postpartum in 14 (36%) of 39 women delivered vaginally [3]. Subsequent prospective observational studies found that levator avulsion occurs in 13–36% of vaginally parous women and is also prevalent in patients presenting for urogynecological evaluation [4–6]. Levator avulsion is more common in patients with major

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prolapse and a risk factor for prolapse recurrence [7–10]. In an observational longitudinal cohort study of 269 primigravidae, levator avulsion was diagnosed in 21% of those with vaginal delivery, and these women reported more troublesome vaginal symptoms according to the validated International Consultation on Incontinence Questionnaire–Vaginal Symptoms (ICIQ-VS) [5, 11].

While early studies of pelvic floor symptoms focused primarily on evaluating the relationship with prolapse stage, a few studies have evaluated the association with functional pelvic floor anatomy using ultrasonography [12, 13]. In addition, most of the data in the literature were obtained in Caucasians. We sought to determine the relationship between the most commonly reported vaginal symptoms of POP (awareness of lump/bulge; visualization of lump/bulge and the need for digitation to empty the bowels) and clinical prolapse stage, levator hiatal area at rest, on maximum pelvic floor muscle contraction (PFMC) and on Valsalva maneuver, and levator avulsion, in a multiethnic population.

## Materials and methods

Between June 2013 and March 2015, women who attended a tertiary urogynecology clinic with symptomatic POP were invited to participate in a prospective observational study on pelvic floor morphology in South African women as part of an ongoing PhD thesis. After providing informed consent, patients were requested to empty their bladder. Clinical examination was performed with the patient in the supine position with the hips and knees flexed at 90°. Prolapse was staged according to the POP-Q method [14]. To assess levator muscle morphology 3D/4D transperineal pelvic floor ultrasonography (TPUS) was performed with a GE Voluson i system using a 4–8 MHz RAB probe with an acquisition angle of 85°. Volume datasets were de-identified and acquired at rest, on maximum PFMC and on maximum Valsalva maneuver by the first author.

Levator hiatal areas were measured at rest, on maximum PFMC and on maximum Valsalva maneuver 6–8 weeks after volume acquisition using 4D View version 10 software, following the rendered volume method described previously [15]. Measurements were obtained by the first author, blinded against all clinical data. Tomographic ultrasound imaging (TUI) on maximum PFMC was used to diagnose levator avulsion as previously described [16]. Figure 1 illustrates marked distension (ballooning) of the levator hiatus on maximum Valsalva maneuver and the corresponding midsagittal plane in a woman presenting with a cystocele [17].

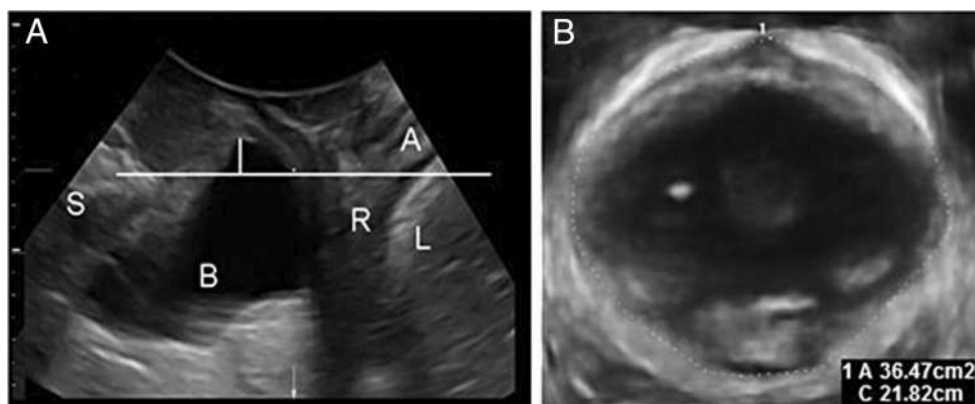
Patients completed the ICIQ-VS which is routinely used at our urogynecology clinic. This study was approved by the National Research Ethics Committee (University of Pretoria, 226/2011). Statistical analysis was performed after normality testing which included histogram analysis and/or Kolmogorov-Smirnov testing using SPSS version 23. Our null hypothesis was defined as “prolapse symptoms/clinical prolapse stage are *not* associated with levator hiatal area and avulsion of the levator ani muscle as diagnosed by TPUS.”

To determine the relationship between commonly reported vaginal symptoms/POP-Q stage and levator avulsion, chi squared statistics were used since avulsion is a binary variable. The ICIQ produces four-point or five-point Likert responses, and thus we used analysis of variance tests to determine the relationship between vaginal symptoms and levator hiatal area (at rest, on maximum PFMC and on maximum Valsalva maneuver). A  $p$  value  $<0.05$  was considered statistically significant.

## Results

The datasets from 5 of 263 women recruited had missing information. Thus, 258 women were included in the study. Their mean age was 60.6 years (range 25–91 years), their median parity was 3 (range 0–9) and their mean BMI was 29.8 kg/m<sup>2</sup> (range 18–53 kg/m<sup>2</sup>). Of the 258 women, 254

**Fig. 1** Transperineal 3D ultrasound images in the midsagittal plane in a woman presenting with a cystocele. **a** Measurement of cystocele descent. **b** The corresponding axial view shows marked distension (ballooning) of the levator hiatus on maximum Valsalva maneuver (*S* pubic symphysis, *B* bladder, *R* rectal ampulla, *L* levator ani, *A* anal canal)



**Table 1** Demographic characteristics of the 258 included women

Parameter	Value
Age (years), mean $\pm$ SD	60.64 $\pm$ 12.1
BMI (kg/m <sup>2</sup> ), mean $\pm$ SD	29.83 $\pm$ 6.3
Parity, median	3
Recall of assisted delivery, <i>n</i> (%)	38 (14.7)
Previous prolapse surgery, <i>n</i> (%)	55 (21.3)
POP-Q stage, <i>n</i> (%)	
I	19 (7.4)
II	124 (48.1)
III	96 (37.2)
IV	19 (7.3)
Avulsion, <i>n</i> (%)	78 (32.4)

(98.5%) were vaginally parous. Previous assisted delivery was recalled by 38 women (14.7%), and 55 (21.3%) had undergone a previous prolapse operation. The study cohort was racially diverse: 31 (12%) Asian, 107 (41.5%) Black, and 120 (46.5%) Caucasian; ethnicity was self-reported. POP-Q stage II was detected in 124 patients (48.1%) and POP-Q stage III or IV in 115 (44.5%). The demographic characteristics of the 258 women are shown in Table 1. Only 236 datasets were analyzed for levator avulsion as 22 patients could not perform a pelvic floor muscle contraction, and four could not perform a Valsalva maneuver despite repeated coaching, leaving 254 datasets for hiatal area assessment.

Table 2 shows the associations between questionnaire answers, POP-Q staging and ultrasound measurements of functional pelvic floor anatomy. Statistically significant associations were found between awareness of lump or bulge in the vagina (question 5a of the ICIQ-VS), feeling and visualization of the lump or bulge (question 6a) and levator avulsion ( $p = 0.003$ , and  $p = 0.000$ , respectively)

and for all measurements of hiatal area and POP-Q stage. Interference with everyday life was statistically significantly associated with POP-Q stage ( $p = 0.009$ ) and hiatal area on Valsalva maneuver ( $p = 0.028$ ) but not with levator avulsion. The correlation between visualization of bulge and interference with everyday life and hiatal area at rest did not reach statistical significance ( $p = 0.052$  and  $p = 0.065$ , respectively). Exclusion of women with previous prolapse surgery did not materially change these results.

## Discussion

This prospective observational study in a multiethnic population demonstrated strong correlations between abnormal functional pelvic floor anatomy and the core symptoms of POP defined according to the ICIQ-VS. This correlation was strongest for core symptoms such as awareness of lump/bulge and visualization or feeling of lump/bulge on the outside. Associations were weaker for the question on digitation to defecate. This is not surprising as the need for digitation has been shown to be positively associated with true rectoceles for which there is no strong link with abnormal levator ani anatomy [9, 18]. Of note, we chose to test the relationship between abnormal functional pelvic floor anatomy and the core symptoms of POP, as the other questions (“Are you aware of pain in your lower abdomen”, “Are you aware of soreness in your vagina”, “Do you feel that you have a reduced sensation in or around your vagina”) are nonspecific for POP, and statistical analysis did not reveal significant correlations with levator avulsion, levator hiatal area or POP-Q stage. ICIQ question 14 investigated by us is much less specific (“Overall, how much do vaginal symptoms interfere with your everyday life?”) as it would also be

**Table 2** Associations ( $p$  values) between pelvic floor symptoms and POP-Q stage, hiatal area measurements and levator avulsion in the 258 included women

Symptom	POP-Q stage ( <i>n</i> = 258) <sup>a</sup>	Hiatal area ( <i>n</i> = 254) <sup>a</sup>			Avulsion ( <i>n</i> = 236) <sup>b</sup>
		At rest	On maximum pelvic floor muscle contraction	On Valsalva maneuver	
1. Are you aware of a lump or bulge coming down in your vagina?	0.001	0.001	0.025	0.001	0.003
2. Do you feel a lump or bulge come out of your vagina, so that you can feel it on the outside or see it on the outside?	0.001	0.016	0.021	0.001	0.001
3. Do you have to insert a finger into your vagina to help empty your bowels?	0.320	0.264	0.163	0.384	0.275
4. Overall, how much do vaginal symptoms interfere with your everyday life?	0.009	0.065	0.050	0.028	0.124

<sup>a</sup> ANOVA tests<sup>b</sup> Chi-squared test for levator avulsion

answered positively by women suffering, for example, from vaginal atrophy and/or dyspareunia.

The etiology of POP is thought to be multifactorial, but it is increasingly evident that in many instances prolapse is mediated by alterations in pelvic floor functional anatomy. There seems to be little doubt that major levator trauma is a factor in the pathogenesis of POP [9]. While a cause and effect relationship seems highly plausible for avulsion, the role of excessive hiatal distensibility, i.e. ballooning, is complex [19]. Since there is some evidence that ballooning often persists after a successful prolapse procedure, it may plausibly be considered a ‘cause’, but this remains unproven [20]. The findings of our study support this contention.

Considering that levator avulsion has a significant effect on both pelvic floor anatomy and function, it is not surprising that such trauma is associated with awareness and visualization of bulge [21–24]. Interestingly, this is not the case for other symptoms of pelvic floor dysfunction such as stress urinary incontinence, urge incontinence and anal incontinence [17, 25]. Dietz et al. [25] studied the relationship between levator avulsion and bladder function in 420 women presenting with pelvic floor dysfunction and lower urinary tract symptoms and found that women with avulsion were less likely to report stress urinary incontinence ( $p < 0.001$ ) and urodynamic stress incontinence ( $p = 0.065$ ) and were more likely to present with POP symptoms. The lack of association between levator avulsion and stress urinary incontinence/urodynamic stress incontinence and anal incontinence is most likely explained by the complex nature of the pathophysiology of urinary and fecal incontinence.

To our knowledge this is the first study conducted at a tertiary urogynecology clinic presenting data demonstrating an association between prolapse questionnaire components and abnormal functional anatomy of the pelvic floor. The multiethnic composition of our population could be considered a major strength, and we plan to report the findings of interethnic variation on pelvic organ descent and distensibility in a separate publication. Limitations of the study include the fact that ultrasonography and clinical examination were both performed by the first author. To overcome this potential bias, volumes were de-identified during acquisition and only analyzed 6–8 weeks later. Hence, the ultrasonography data presented here should not have been confounded by assessment bias. Also, we are aware that levator avulsion may be diagnosed at rest [26], but at the time of recruitment we decided to only allow diagnosis of levator avulsion on TUI during maximum PFMC, as originally described [16]. Finally, it would also be of interest to investigate the association between other symptoms of pelvic floor dysfunction (symptoms of bladder and sexual

dysfunction) and pelvic floor functional anatomy. We are in the process of performing such a study in this cohort.

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**Compliance with ethical standards**

**Conflicts of interest** None.

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# Interethnic variation in pelvic floor morphology in women with symptomatic pelvic organ prolapse

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## Abstract

**Introduction and hypothesis** There is a lack of epidemiological studies evaluating female pelvic organ prolapse in developing countries. Current studies have largely focused on women of white ethnicity. This study was designed to determine interethnic variation in pelvic floor functional anatomy, namely, levator hiatal distensibility and pelvic organ descent, in women with symptomatic pelvic organ prolapse in a multi-ethnic South African population.

**Methods** This prospective observational study included 258 consecutive women referred for pelvic organ prolapse assessment and management at a tertiary urogynaecological clinic. After a detailed history and clinical examination, including POPQ assessment, patients underwent a 4D transperineal ultrasound. Offline analysis was performed using 4D View software. Main outcome measures included levator muscle distensibility, pelvic organ descent, and levator ani defects (avulsion).

**Results** Mean age was 60.6 (range, 25–91) years, mean BMI 29.83 (range, 18–53). Points Ba and C were lower and the genital hiatus more distensible in black women (all

$p < 0.05$ ). They were found to have greater hiatal area ( $p = 0.017$  at rest,  $p = 0.006$  on Valsalva) compared with South Asians and whites and showed greater pelvic organ mobility (all  $p < 0.05$ ) than Caucasians on ultrasound. Levator defects were found in 32.2% ( $n = 83$ ) of patients and most were bilateral (48.2%,  $n = 40$ ), with significant interethnic differences ( $p = 0.014$ ).

**Conclusion** There was significant variation in clinical prolapse stage, levator distensibility, and pelvic organ descent in this racially diverse population presenting with pelvic organ prolapse, with South Asians having a lower avulsion rate than the other two ethnic groups ( $p = 0.014$ ).

**Keywords** Pelvic organ prolapse · Ethnicity · Pelvic organ descent · Levator avulsion

## Introduction

Interethnic differences are well documented for the bony anatomy of *Homo sapiens*. The bony skull, and more recently the pelvis, are most commonly used to determine biological affinity, i.e. gender and ethnicity in forensic anthropology and archaeology. Measurements of bony pelvic dimensions suggest that ethnicity might be determined with high accuracy (88%) [1–3]. Patriquin et al. studied consistent bony landmarks in os coxae of 100 white and black South African women of known age, sex, and ethnicity, and found statistically significant differences in 12 out of 13 measurements, i.e. white women had greater pelvic dimensions than black women, suggesting that ethnic differences in the bony pelvis might be highly significant [4].

Recently, there has been interest in studying the potential impact of ethnicity on the development of pelvic floor dysfunction (PFD) and variations in obstetric outcomes. Magnetic resonance imaging (MRI) and four-dimensional

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transperineal ultrasound (4D TPUS) studies have shown that there are significant ethnic differences in the female pelvic architecture as regards bony and soft-tissue pelvic dimensions and pelvic floor function [5–7].

Handa et al. compared soft-tissue dimensions between 178 Caucasian and 56 African–American primiparous women using MRI at 6–12 month postpartum. Apart from finding significant differences in both the pelvic inlet and outlet measurements (greater in Caucasian women), African–American women had statistically significantly greater pelvic floor descent measured by calculating the difference in descent of the posterior rectal wall from the pubococcygeal line on straining [8].

In a group of 207 asymptomatic nulliparous women, we have recently shown that, compared with white and South Asian women, black nulliparous women had statistically significantly greater levator distensibility and pelvic organ descent of the anterior, middle and posterior compartments as measured on 4D TPUS [9]. Similarly, Shek et al. have shown that there are significant differences in pelvic organ support and levator hiatal distensibility between black Ugandan and white nulliparous women using 4D TPUS [10]. This has not been tested in women with symptomatic pelvic organ prolapse (POP). The clinical significance of observed differences may well suggest that different pathophysiological mechanisms might exist in women with POP of different ethnicities that need further exploration.

The primary objective of this study was to prospectively analyse biometric indices of functional pelvic floor anatomy on clinical examination and pelvic floor ultrasound (hiatal distensibility and pelvic organ descent) in a multi-ethnic South African population presenting with symptomatic POP.

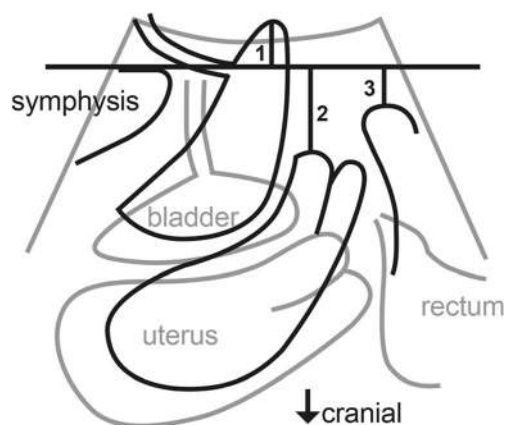
## Materials and methods

This study was conducted at the Steve Biko Academic Hospital tertiary urogynaecology clinic and included 263 women presenting with symptomatic female POP from June 2013 to March 2015. The hospital is located in an urbanised city and is the major referral centre for the province. After informed consent was obtained, clinical examination using the pelvic organ prolapse quantification system of the International Continence Society (ICS POP-Q) and completion of the International Consultation on Incontinence Modular Questionnaire Vaginal Symptoms (ICIQ-VS) questionnaire, all women had a pelvic floor assessment using 4D transperineal ultrasound using a GE Voluson i ultrasound system with a 8- to 4-MHz curved array volume transducer (GE Kretz Ultrasound, Zipf, Austria) as previously described [11, 12]. The acquisition angle was set at 85° to include the entire levator hiatus. For analysis of the central compartment, we excluded women after hysterectomy as imaging of the vault has yet to be validated. Data on ethnicity was self-reported.

The ultrasound methodology, in addition to offline volume analysis, has been described in detail for the same cohort in a previous study evaluating the association between pelvic floor symptoms and functional pelvic floor anatomy [13]. Ultrasound volumes were de-identified and analysed 6–8 weeks later using proprietary software 4D View version 10. Figure 1 is a schematic representation illustrating descent of the pelvic organs on Valsalva relative to the inferior margin of the pubic symphysis.

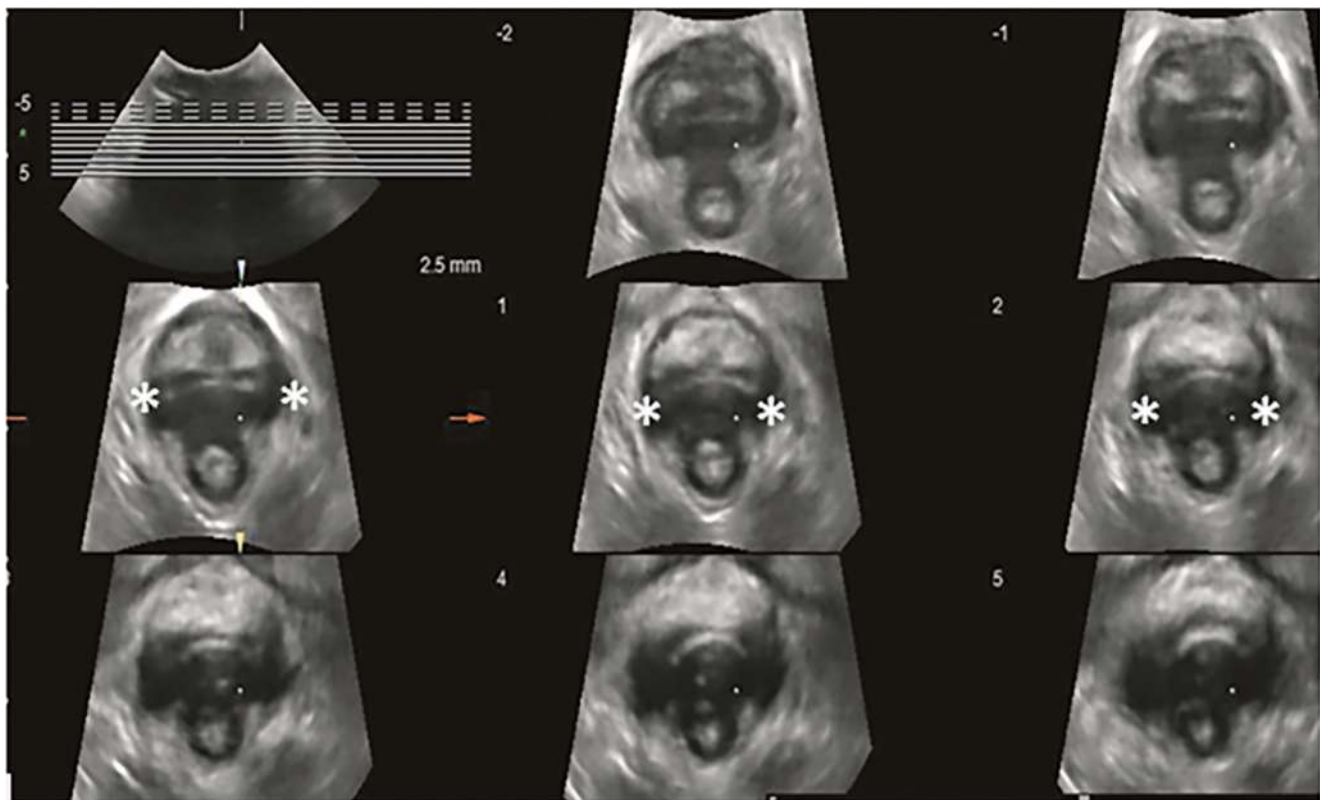
Multi-slice or tomographic imaging was obtained in the axial plane, with the interslice interval set at 2.5-mm intervals from 5 mm below to 12.5 mm above the plane of minimal hiatal dimensions, as described previously. Levator avulsion was diagnosed by visualising detachment of the pubovisceral muscle from the pelvic sidewall in the rendered axial volumes obtained at maximal pelvic floor muscle contraction (PFMC), or in volumes obtained at rest in those unable to contract ( $n = 22$ ) [14, 15]. Figure 2 demonstrates a bilateral levator avulsion on tomographic ultrasound.

This study was approved by the local Human Research Ethics Committee, University of Pretoria (226/2011). Statistical analysis was performed after normality testing (Kolmogorov–Smirnov testing) using IBM SPSS statistics v23 (IBM Corporation). To compare ethnic differences among the three groups, one-way analysis of variance (ANOVA) was performed and necessary adjustments for age, BMI, parity and previous prolapse surgery were controlled for in the analysis of covariance (ANCOVA). Pairwise comparison for ethnicity was performed using Bonferroni statistics. Fisher's exact test was used for comparing the prevalence of avulsion between ethnicities. A  $p$  value  $<0.05$  was considered statistically significant. Our null hypothesis was defined as “there is no ethnic variation in levator muscle distensibility, levator avulsion and pelvic organ descent in women presenting for symptoms of prolapse”.



**Fig. 1** Schematic representation of transperineal ultrasound at rest (*light grey*) and on Valsalva (*black*) illustrating measurements of maximal descent of the bladder (1), cervix (2), and rectal ampulla (3) against the reference of the inferior margin of the pubic symphysis





**Fig. 2** Tomographic ultrasound image illustrating bilateral levator avulsion on maximum pelvic floor contraction. The stars indicate detachment of the pubovisceral muscle from its insertion on the inferior pubic ramus

## Results

Two hundred and fifty-eight women were included in the analysis after excluding 5 cases because of missing data. The mean age was 60.6 (range, 25–91) years, mean vaginal parity was 3.6 (range, 0–9) and mean BMI 29.8 (range, 18–53). This study consisted of a racially diverse cohort, i.e. 12% Asian ( $n = 31$ ), 41.5% black ( $n = 107$ ) and 46.5% white ( $n = 120$ ). Table 1 shows the demographic characteristics for the entire population and for the three ethnic groups.

Black women were significantly more vaginally parous ( $p = 0.001$ ); previous prolapse procedures were more often reported by white women ( $p = 0.001$ ).

Table 2 shows the results of POP-Q coordinates on clinical examination. There were significant differences between the ethnicities studied, specifically for the anterior (Ba;  $p = 0.048$ )

and central compartment (C;  $p = 0.001$ ), in addition to genital hiatus and perineal body measurements ( $p = 0.001$ ). Post hoc test confirmed that the differences observed between blacks and whites regarding the anterior compartment, point C and genital hiatus (Gh) + perineal body (Pb) were statistically significant.

On 4D ultrasound volume data acquisition, 4 women were unable to produce a proper Valsalva manoeuvre, despite coaching, leaving 254 datasets for levator distensibility/area assessment. Black women were found to have statistically significantly greater hiatal areas at rest ( $p = 0.017$ ) and on Valsalva ( $p = 0.006$ ) compared with Asians and whites. Bonferroni post-hoc test revealed that this difference was mainly between blacks and South Asians for both rest ( $p = 0.01$ ) and Valsalva volumes ( $p = 0.006$ ). Black women showed greater pelvic organ descent on Valsalva in all three

**Table 1** Demographic characteristics of the entire group. Age, BMI, and vaginal parity presented as a mean (SD); and assisted delivery and previous prolapse procedure as a number (%)

Demographic characteristics	Entire population	South Asians ( $n = 31$ )	Caucasians ( $n = 120$ )	Blacks ( $n = 107$ )	$p$ value
Age (years)	60.64 (12.19)	61.32 (12.35)	61.73 (11.87)	59.23 (12.47)	0.290
BMI (kg/m <sup>2</sup> )	29.83 (6.37)	27.84 (4.21)	29.79 (6.54)	30.30 (6.64)	0.402
Vaginal parity	3.6 (1.82)	3.5 (1.47)	3.1 (1.42)	4.2 (2.12)	0.001
Assisted delivery	38 (14.7)	3 (9.7)	24 (20)	11 (10.3)	0.429
Previous prolapse procedure	55 (21.3)	8 (25.8)	36 (30)	11 (10.3)	0.001

**Table 2** Pelvic organ prolapse coordinates (Ba, C and Bp, Gh, Pb, Gh + Pb) are reported in centimetres either below (–) or above (+) the hymen as per the ICS POPQ system. Positive values signify descent below the hymen

POP-Q Coordinates	Entire population	South Asians (n = 31)	Caucasians (n = 120)	Blacks (n = 107)	p value
Ba	+1.97 (1.05)	+ 1.91 (0.76)	+ 1.78 (1.16)	+2.13 (0.97)	0.048
C	+1.10 (1.31)	+ 0.76 (1.09)	+0.68 (1.17)	+1.66 (1.32)	0.001
Bp	+ 0.82 (1.16)	+0.50 (1.00)	+0.96 (1.12)	+0.64 (1.26)	0.202
Gh (cm)	5.95 (1.06)	5.50 (0.97)	5.76 (0.81)	6.52 (0.97)	0.001
Pb (cm)	3.36 (0.48)	3.32 (0.47)	3.30 (0.43)	3.43 (0.52)	0.100
Gh + Pb (cm)	9.31 (1.23)	9.09 (0.97)	8.80 (1.09)	9.95 (1.14)	0.001

*Gh* genital hiatus, *Pb* perineal body

compartments (all  $p < 0.05$ ) and these differences in descent seen on imaging were mainly between black and white women. Exclusion of women with previous prolapse surgery did not materially change these results.

Levator defects were found in 32.3% ( $n = 83$ ) of patients and most were bilateral (48.2%,  $n = 40$ ). Table 3 shows ethnic variations in levator distensibility, pelvic organ descent and avulsion, as examined by translabial ultrasound. South Asians showed a lower avulsion rate than the other two ethnic groups ( $P = 0.014$  on Fisher's exact test). The mean Oxford scores were significantly lower in those women with an avulsion (mean, 1.62 [right], 1.71 [left] compared with those without, i.e. 2.58 (right) and 2.57 (left);  $p = 0.001$ ).

For the analysis of symptoms, we tested positive responses to “most of the time” and “all of the time” of the ICIQ-VS questionnaire. The major core symptoms reported were for questions 4a (do you feel that your vagina is too loose or lax?); 5a (are you aware of a lump or bulge coming down in your vagina?); 6a (do you feel a lump or bulge come out of your vagina, so that you can feel it on the outside or see it on the outside?); and 8a (do you have to insert a finger into your vagina to help empty your bowels?), and the results are as

follows: 70.5% ( $n = 182$ ), 79.8% ( $n = 206$ ), 71.3% ( $n = 184$ ), 21.3% ( $n = 55$ ) respectively. There were no statistically significant interethnic differences in the prevalence of symptoms.

## Discussion

Pelvic organ prolapse (POP) is a significant health problem in developing countries, with an estimated mean prevalence of 19.7% (range 3.4–56.4%) [16–18]. However, most clinical and imaging studies on morphological changes of the pelvic floor musculature focus on nulliparous and multiparous white women presenting with pelvic floor dysfunction [7, 19–21].

Current studies on ethnicity emphasise epidemiological findings (i.e. prevalence and risk factors), as opposed to functional anatomical assessment. To our knowledge, this is the first study evaluating clinical and pelvic floor functional anatomy in a racially diverse South African population presenting with symptomatic POP. Furthermore, it includes a large cohort of black women (41.5%,  $n = 107$ ), thus illustrating that FPOP is common in this ethnic group. Although it has been shown

**Table 3** Pelvic floor biometry in South Asian, Caucasian, and black patients with symptomatic POP. One-way analysis of variance (ANOVA) was performed to determine mean differences between ethnicities, and pairwise comparison for ethnicity was performed using Bonferroni statistics

Parameter	Entire population	South Asians (n = 31)	Caucasians (n = 120)	Blacks (n = 107)	p value
Levator distensibility					
Hiatal area at rest (cm <sup>2</sup> )	26.04 (7.18)	22.60 (7.08)	26.23 (7.35)	26.77 (6.79)	0.017
Hiatal area on PFMC (cm <sup>2</sup> )	21.12 (6.41)	19.17 (5.51)	21.18 (6.70)	21.73 (5.85)	0.182
Hiatal area on Valsalva (cm <sup>2</sup> )	38.28 (9.69)	34.15 (8.28)	37.64 (9.76)	40.15 (9.59)	0.006
Compartmental descent					
Bladder position on Valsalva (mm)	–26.03 (11.22)	–25.86 (8.68)	–20.67 (6.11)	–26.31 (15.24)	0.022
Uterine position on Valsalva (mm)	–25.95 (11.60)	–17.70 (8.50)	–22.68 (11.08)	–29.09 (11.25)	0.048
RA position on Valsalva (mm)	–20.47 (8.41)	–15.17 (6.95)	–19.26 (7.61)	–26.01 (9.18)	0.029
Avulsion	83	4/31 (13%)	41/120 (34.2%)	38/107 (35.5%)	0.014*

Values are mean (SD) and negative values for descent signifies position below the pubic symphysis

PFMC pelvic floor muscle contraction, RA rectal ampulla

\*Fisher's exact test for South Asians vs all others

that age, parity, menopause, assisted delivery, and levator trauma are significantly associated with pelvic floor dysfunction, it is likely that women in developing countries are exposed to other potential risk factors for pelvic floor dysfunction, such as heavy lifting, younger age at first delivery, early resumption of household duties postpartum, poor nutrition and lower annual household income. Proper identification and description of these potentially modifiable risk factors may require further study.

The epidemiological evidence for the role of ethnicity as a potential risk factor for POP has long been debated and is conflicting. Hendrix et al. and Whitcomb et al. reported that African-American women demonstrated the lowest risk for POP compared with whites and other ethnic minorities (Hispanic, Asian and American-Indian) [22, 23]. In contrast, Bump found a similar prevalence of POP for black and white women referred for a urogynaecological evaluation (24 vs 23% respectively) [24]. Graham and Mallett evaluated the effect of ethnicity on POP and UI in 183 symptomatic African-Americans and 132 Caucasians, and found no significant ethnic difference in the presence and severity of POP [25]. Although this scientific debate on the ethnic distribution of POP continues, we have noted higher POP-Q stage compared with developed countries, with more than a third of symptomatic patients (36.4%) presenting with POP-Q stage 3 prolapse [26]. In a Caucasian exclusive cohort ( $n = 270$ ), 25.2% had the leading edge of the prolapse at or below the hymen, in contrast to our mixed population with the leading edge of the prolapse at almost +2 cm for the anterior compartment and +1 cm for the middle and posterior compartments [27]. This implies that patients present to our clinic with higher stages of prolapse than in developed countries, which is likely due to the nature of healthcare services in South Africa and/or other factors mentioned earlier.

With regard to avulsion, most studies in this field have reported on whites [28, 29]. The similar avulsion rates for whites (34.2%) and blacks (35.5%) is an interesting finding. The lower prevalence in South Asians is intriguing and may be due to a surprisingly low number of vaginally assisted deliveries in this group. We intend to study this issue in more detail in the future. As regards the reported symptoms, we have recently shown that there is a significant association between core prolapse symptoms, i.e. awareness, visualisation and/or feeling of a vaginal lump, levator hiatal distensibility and levator avulsion [13].

Limitations of the study include the fact that ultrasound acquisition and clinical examination were both performed by the first author (ZA). To overcome this potential bias for the analysis of imaging data, volumes were de-identified during acquisition and only analysed 6–8 weeks later, blinded against all clinical data, including ethnicity. Hence, the ultrasound data presented here should not be confounded by assessment bias, as the evaluation of imaging data was blinded against

ethnicity. The congruence of imaging and clinical findings, incidentally, argues against any such bias. The impact of higher socio-economic class, educational level, employment status, and differential access to primary care are various forms of selection bias that need to be further explored.

In conclusion, we have found significant ethnic differences in clinical prolapse stage, levator distensibility and pelvic organ descent. Possible reasons include differences in bony pelvis, genetic inheritance of collagen endowment, lifestyle, nutritional factors and labour. POP is common in African-African women and to date this topic has been inadequately studied. The role of levator avulsion in the pathogenesis of prolapse is unlikely to vary greatly among the ethnicities examined, although interethnic differences deserve further study.

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#### Compliance with ethical standards

**Conflicts of interest** HP Dietz has received unrestricted educational grants from GE Medical. The other authors declare that they have no conflicts of interest.

**Previous presentation** NA

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# The impact of childbirth on pelvic floor morphology in primiparous Black South African women: a prospective longitudinal observational study

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## Abstract

**Introduction and hypothesis** There is a lack of prospective studies evaluating the impact of childbirth on the pelvic floor in non-white populations. We intended to study delivery-related changes in pelvic floor morphology in Black South African primiparae. We also intended to determine the impact of anatomical changes on symptoms in the postpartum period.

**Methods** A total of 153 nulliparous women between 35 and 39 weeks gestation were recruited from a district antenatal clinic. All women had a standardized interview, completed the International Consultation on Incontinence Vaginal Symptoms questionnaire followed by three/four dimensional transperineal ultrasonography. This was repeated at 3–6 months postpartum.

**Results** Of the 153 women, 84 (54.9%) returned at a mean of 4.8 months postpartum. Of these women, 60 (71.4%) had a vaginal delivery and the remainder a caesarean section (20 emergency and 4 elective). Overall, there were statistically significant increases in bladder neck descent ( $P = 0.003$ ), pelvic organ descent and levator hiatal distensibility (all  $P < 0.001$ ) at the postpartum assessment. Levator avulsion was diagnosed in nine (15%) of those delivered vaginally. Postpartum vaginal laxity was the commonest bothersome vaginal symptom, reported by 51 women (60.7%).

**Conclusions** There is significant alteration in pelvic organ support and levator hiatal distensibility postpartum, with more marked effects in women after vaginal delivery. Of Black primiparous women, 15% sustained levator trauma after their first vaginal delivery.

**Keywords** Childbirth · Pelvic floor morphology · Pelvic floor ultrasonography

## Introduction

An intact levator ani (LA) muscle complex is key to maintaining normal pelvic organ support [1, 2]. Although gross trauma to this muscle in the form of avulsion injury was described several decades ago, it is only recently that biomechanical derangements in the form of altered pelvic organ mobility,

levator hiatal distensibility and levator avulsion have been described and studied [3–6].

Using three/four dimensional transperineal ultrasonography (TPUS) levator avulsion has been shown to occur in 10–30% of women after delivery, and most studies have included women of Caucasian and Chinese ethnicity [4, 7–10]. It has recently been shown that, compared to Caucasians and Asians, Black Ugandan and Black South African nulliparous women have greater pelvic organ mobility and levator hiatal distensibility and therefore might be less susceptible to delivery-related trauma [11, 12]. Cheung et al. reported that primiparous East Asian women have thicker pubovisceral muscles, smaller levator hiatal area and less pelvic organ mobility than Caucasian women, supporting the evidence that interethnic variation is common [13]. It has been claimed that functional pelvic floor anatomy in Black South African women differs from that in Caucasian and Asian women [14, 15].

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However, there are currently no studies on the impact of childbirth on the pelvic floor in Black South African women.

We conducted a prospective longitudinal cohort study in Black South African primiparous women first to establish the impact of childbirth on LA morphology (pelvic organ mobility; levator distensibility and levator avulsion) by three/four dimensional TPUS and second to determine the effect on vaginal symptoms using the validated International Consultation on Incontinence Vaginal Symptoms (ICIQ-VS) questionnaire [16].

## Materials and methods

Between November 2015 and June 2016 consecutive primigravid women between 35 and 39 weeks gestation were recruited from a district antenatal clinic to participate in this study. Inclusion criteria were an uncomplicated singleton pregnancy, maternal age >18 years, and no previous pregnancy >20 weeks gestation. The following women were excluded from the study: those with pelvic floor disorders before pregnancy and those in whom an elective caesarean section (CS) was planned by the attending clinician.

After a standardized interview which included demographic details, medical history and body mass index (BMI), all women completed the validated ICIQ-VS questionnaire. This is a self-completion questionnaire composed of 14 questions assessing vaginal and sexual symptoms and impact on quality of life. The vaginal and sexual domains use a four-point or five-point Likert scale, and the symptom bother subquestion an 11-point scale. A higher score means more severe symptoms [16]. A clinical examination for pelvic organ prolapse (POP) using the International Continence Society Pelvic Organ Prolapse Quantification system (POP-Q) was then performed followed by three/four dimensional TPUS using a GE Voluson i with an 8-4 MHz volume transducer with the woman in the supine position and with an empty bladder [17]. Volumes were acquired at rest, and under maximum pelvic floor muscle contraction (PFMC) and maximum Valsalva manoeuvre. All patients were coached to optimize these manoeuvres (at least three attempts for PFMC and Valsalva manoeuvre) and to limit levator coactivation [18]. The volume data from the best PFMC and Valsalva manoeuvre was used for analysis. The ultrasound methodology used was as previously described by the third author [19, 20]. Figure 1 compares pelvic organ descent and levator hiatal distensibility in the antenatal and postpartum period, and shows significant changes.

The clinical and ultrasound examination and the ICIQ-VS questionnaire were repeated 3–6 months postpartum. Imaging was performed first (patients were requested to drape their abdomen up to the pubic symphysis) to blind the clinician to all delivery data. Discussion of their delivery and clinical

examination for POP were only allowed after the ultrasound examination. Postpartum data were retrieved from the patient maternity book at the time of the postpartum visit and/or from the hospital maternity register.

A GE Voluson i system with an 8-4 MHz volume transducer and acquisition angle set to 85° was used for 4D ultrasound data volume acquisition, with volume cine loops saved both on Valsalva manoeuvre and on PFMC [21]. Tomographic ultrasound imaging at an interslice interval of 2.5 mm was used to diagnose levator avulsion on maximal pelvic floor contraction. Discontinuity of the puborectalis muscle from its insertion on the inferior pubic ramus and a levator–urethral gap (LUG) greater than 25 mm in all three central slices were the diagnostic criteria used (Fig. 2) [22]. This method has been shown to be highly reproducible [23].

All imaging data were de-identified and analysed 8–12 weeks after the second ultrasound examination to minimize bias. Data were analysed offline using 4D View software (GE Medical Systems Kretztechnik, Zipf, Austria).

This study was approved by the local Human Research Ethics committee, University of Pretoria (226/2011). Power calculations were not performed as this was considered a pilot study. Statistical analysis was performed using SPSS v. 24 (IBM Corp., Armonk, NY). Normality was assessed graphically by histogram analysis and confirmed with the Kolmogorov-Smirnov test. A paired *t* test was used to assess for differences in mean values and an independent sample *t* test was used to determine the association between mode of delivery and birth weight. The chi-squared test was used to evaluate the association between levator avulsion and assisted delivery. A *P* value <0.05 was considered statistically significant.

## Results

A total of 153 women were recruited at a mean gestation of 36.6 weeks (range 35–39.4 weeks). Of these women, 84 (54.9%) returned for their postpartum visit at a mean of 4.8 months (range 3–6 months), and all data reported below pertain to this group. The mean age of the study population was 25.35 years (range 18–38 years) and the mean BMI was 30.09 kg/m<sup>2</sup> (range 20–60 kg/m<sup>2</sup>). There were no statistically significant differences in age (*P* = 0.431) or BMI (*P* = 0.945) between attenders and non-attenders. One patient died antenatally due to respiratory morbidity. Of the 84 women, 60 delivered vaginally (5 forceps and 4 vacuum) and the other 22 had an emergency CS (19 for cephalopelvic disproportion, 1 for antepartum haemorrhage, and 2 for failed induction). The remaining two women had an elective CS, one for hypertension and the other for breech presentation. There were no spontaneous breech deliveries in the vaginal group as these women are usually referred to a tertiary academic unit for further management. Demographic and delivery data are given in Table 1.

**Fig. 1** Levator hiatus seen in rendered volumes antenatally (a) and postnatally (b) with a larger levator hiatal area on Valsalva manoeuvre. PS pubic symphysis, B bladder, U urethra, Cx cervix, RA rectal ampulla, PR puborectalis, V vagina, AC anal canal

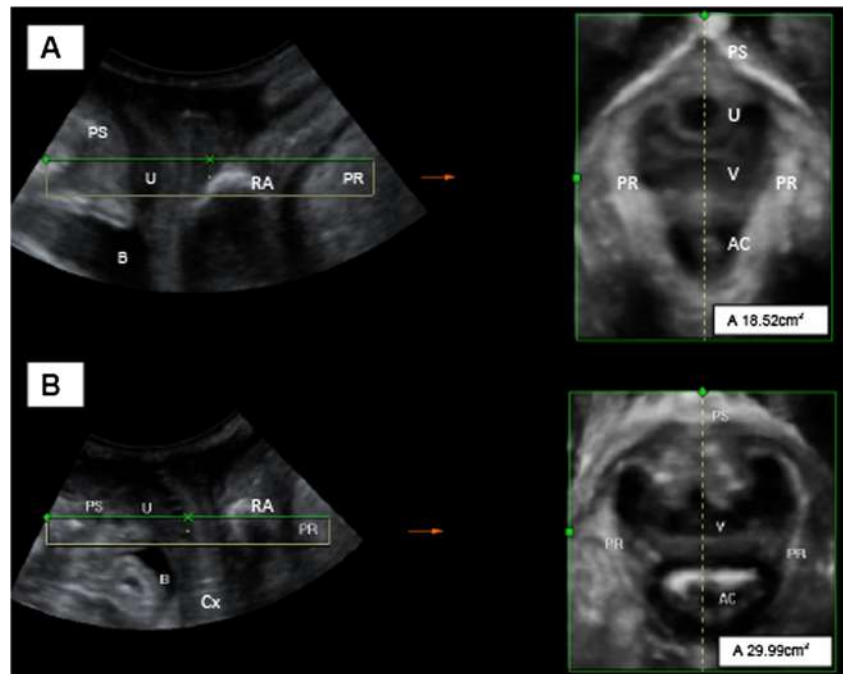
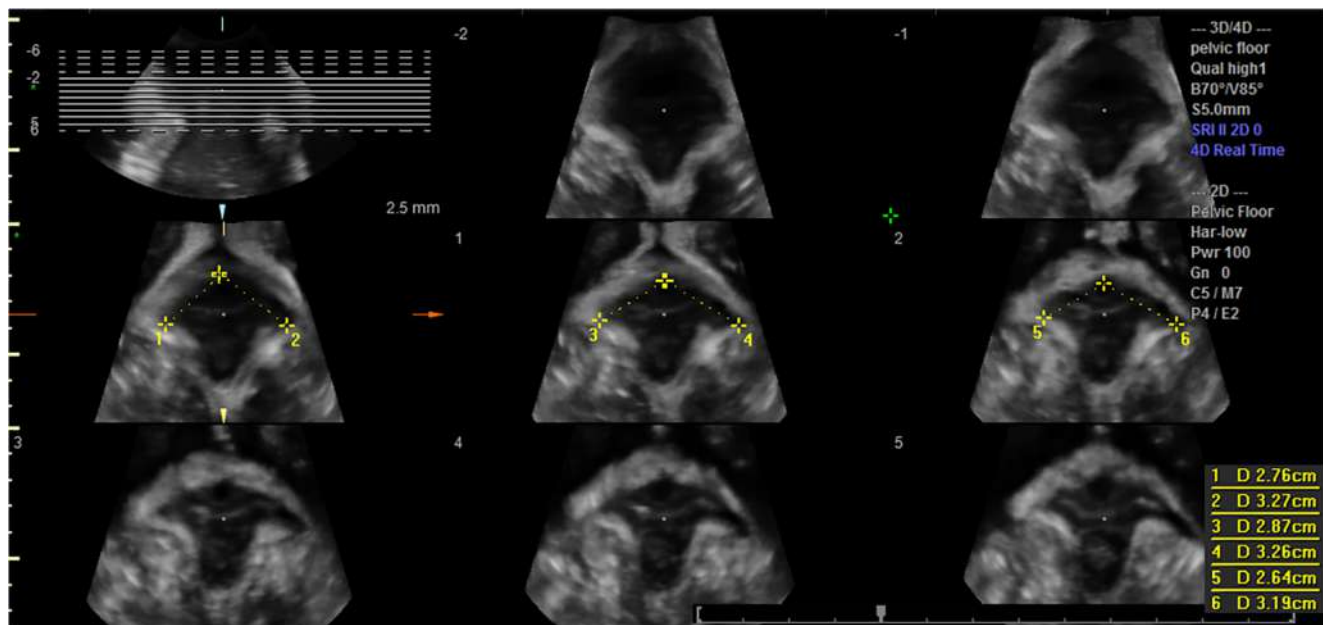


Table 2 shows functional pelvic floor anatomy imaging parameters obtained at baseline and after delivery.

Statistical analysis revealed significant differences in post-partum changes in pelvic organ mobility and levator hiatal distensibility between women after vaginal birth and those after CS (all  $P \leq 0.008$ ; Table 3). In all instances vaginal birth resulted in more marked changes. Levator avulsion was diagnosed in nine (15%) of women with vaginal delivery (two forceps, one vacuum and six spontaneous deliveries). No avulsions were diagnosed in the CS group. An independent

sample  $t$  test revealed a significant association between levator avulsion and anterior compartment descent ( $P = 0.039$ ), and the  $\chi^2$  statistic showed a significant association between avulsion and assisted delivery ( $P = 0.013$ ).

POP-Q examination results before and after delivery showed similar changes. In the anterior compartment, 33% of women (28/84) showed improved support and 58% (49/84) poorer support, with 27% (23/84) one stage worse and 13% (11/84) two stages worse than before delivery. Numbers with descent of the central and posterior



**Fig. 2** Tomographic ultrasound imaging illustrating bilateral levator avulsion as shown by a levator urethral gap of greater than 25 mm

**Table 1** Demographic and delivery data at 4.8 months postpartum in the 84 women analysed

Parameter	Vaginal delivery ( <i>n</i> = 60)	Caesarean section ( <i>n</i> = 24)	<i>P</i> value
Age (years), mean ± SD	24.64 ± 3.96	27.43 ± 3.99	0.007
Body mass index (kg/m <sup>2</sup> ), mean ± SD	29.50 ± 6.31	31.87 ± 8.28	0.166
Gestation (weeks), mean ± SD	36.55 ± 9.09	36.57 ± 7.96	0.687
Birth weight (kg), mean ± SD	3.083 ± 0.51	3.378 ± 0.47	0.012
Head circumference (cm), mean ± SD	34.41 ± 1.53	33.83 ± 1.80	0.293
Length (cm), mean ± SD	51.02 ± 2.73	51.30 ± 2.81	0.673
Assisted delivery, <i>n</i> (%)	9 (15)	–	
Episiotomy, <i>n</i> (%)	43 (71.6)	–	

compartments were too small to allow meaningful analysis. Table 4 shows the mean POP-Q coordinates before and after delivery. The anterior compartment (Ba) was more susceptible to change ( $P = 0.001$ ). There were no significant changes in the POP-Q coordinates in the CS group. Table 5 shows the mean ICIQ-VS scores before and after delivery. It is evident that the perception of vaginal laxity was a significant finding ( $P = 0.001$ ). The episiotomy rate was reported to be 71.6%.

## Discussion

To the authors' knowledge there are no published studies on the impact of childbirth on the pelvic floor support mechanisms as measured on 3D TPUS in Black African women. Hence this is likely to be the first prospective study to report altered postpartum levator morphology in Black South African women. For all measured parameters of functional pelvic floor anatomy a significant postpartum increase was found, especially in the vaginal delivery group. Other studies have shown similar alterations in pelvic floor morphology in women of other ethnicities

[4, 7–10, 24, 25]. Of note, a LUG of 25 mm has not yet been validated for Black South African women and we are aware that a cut-off of 23.65 mm has been suggested in Chinese women [26].

Increased pelvic organ mobility and levator hiatal distensibility are regarded as surrogate markers of pelvic floor trauma as a result of vaginal childbirth. Our finding of increased pelvic organ mobility in the vaginal delivery group is similar to that of Dietz and Lanzarone [4]. The study included 61 primiparous women recruited at a mean of 37.7 weeks gestation. In comparison with antepartum data, at 2–6 months postpartum pelvic organ mobility showed an increase in the anterior, middle and central compartments and there was an increase in levator hiatal area on Valsalva manoeuvre. There were no significant changes in ten women delivered by emergency CS [4]. Using transvaginal imaging, Toozs-Hobson et al. [27] demonstrated statistically significant changes in bladder neck mobility, and the mean differences in levator hiatal distensibility at rest, and PFMC and Valsalva manoeuvre at 6 weeks postpartum between women with vaginal delivery ( $n = 73$ ) and women with CS ( $n = 37$ ).

**Table 2** Functional pelvic floor anatomy imaging parameters obtained at baseline and after delivery. The postpartum increase in mean bladder neck descent and decreases in cystocele, uterus and rectal ampulla descent imply greater pelvic organ descent

Parameter ( <i>n</i> = 84)	Antepartum (35–39 weeks)	Postpartum (4.8 months)	<i>P</i> value
Pelvic organ descent (mm)			
Bladder neck	7.22 ± 3.68	9.69 ± 6.44	0.003
Cystocele	12.06 ± 4.77	8.93 ± 5.34	<0.001
Uterus	23.33 ± 5.63	18.66 ± 5.69	<0.001
Rectal ampulla	7.80 ± 7.13	5.3 ± 7.26	<0.001
Levator hiatal distensibility			
Midsagittal AP hiatal diameter (rest) (mm)	46.55 ± 5.02	51.42 ± 4.65	0.001
Midsagittal AP hiatal diameter (PFMC)(mm)	35.58 ± 5.06	42.47 ± 6.36	0.001
Midsagittal AP hiatal diameter (Valsalva)(mm)	53.98 ± 6.18	58.48 ± 7.82	0.001
Hiatal area (rest) (cm <sup>2</sup> )	18.15 ± 4.26	22.56 ± 4.54	0.001
Hiatal area (PFMC) (cm <sup>2</sup> )	14.30 ± 3.03	18.64 ± 4.3	0.001
Hiatal area (Valsalva manoeuvre) (cm <sup>2</sup> )	24.23 ± 6.48	31.39 ± 6.06	0.001

PFMC pelvic floor muscle contraction, AP anteroposterior



**Table 3** Changes in pelvic organ descent after vaginal birth and caesarean section. In all instances changes were toward more organ mobility and hiatal distensibility, and such changes were always more marked in women who delivered vaginally

Parameter	Mean postpartum changes		P value
	Vaginal delivery (n = 60)	Caesarean section (n = 24)	
Avulsion	9 (15%)	0	
Pelvic organ descent (mm)			
Bladder neck	2.37 ± 6.26	-0.84 ± 7.66	0.008
Cystocele	-2.91 ± 4.73	-3.7 ± 3.70	0.008
Uterus	-4.10 ± 5.55	-6.34 ± 4.29	0.001
Rectal ampulla	-1.49 ± 6.30	-2.50 ± 3.09	0.001
Levator hiatal distensibility			
Midsagittal hiatal diameter (rest) (mm)	+5.26 ± 3.3	+3.95 ± 2.79	0.001
Midsagittal hiatal diameter (PFMC) (mm)	+5.13 ± 7.14	+5.87 ± 4.29	0.001
Midsagittal hiatal diameter (Valsalva manoeuvre) (mm)	+7.17 ± 7.37	+3.27 ± 4.02	0.001
Hiatal area (rest) (cm <sup>2</sup> )	+4.76 ± 2.83	+3.53 ± 2.27	0.001
Hiatal area (PFMC) (cm <sup>2</sup> )	+4.60 ± 2.79	+3.67 ± 2.75	0.001
Hiatal area (Valsalva manoeuvre) (cm <sup>2</sup> )	+7.67 ± 5.18	+5.75 ± 2.69	0.001

PFMC pelvic floor muscle contraction

At a mean follow up of 5.3 months postpartum Shek and Dietz [7] found that the minimum hiatal area on Valsalva manoeuvre increased by 6% in women with normal vaginal delivery ( $n = 101$ ) and more so in those women who sustained levator avulsion. There was a significant reduction in the same parameter after caesarean delivery ( $n = 80$ ;  $P = 0.005$ ) [7]. Albrich et al. [24] using 3D TPUS found that these morphological alterations are evident as early as 48–72 h postpartum. There were significant increases in the midsagittal and coronal hiatal diameters as well as hiatal areas in women with vaginal delivery ( $n = 81$ ) compared with women undergoing CS ( $n = 76$ ) [24]. In the studies by Shek and Dietz [7] and Albrich et al. [24], data on pelvic organ mobility were not analysed.

While most studies have demonstrated improved organ support and less distensibility in women undergoing CS, the observation of impaired pelvic organ support after CS in our study is inconsistent with the literature. In the entire cohort, changes in pelvic organ support and pelvic floor distensibility persisted at 4.8 months postpartum, but these changes were

more significant in women with vaginal delivery, as indicated in Table 3. As the majority of women had an emergency CS for cephalopelvic disproportion in the second stage of labour, it is possible that a prolonged expulsive effort may be an explanation. Chan et al. [10] evaluated pelvic floor biometry at 1 year postpartum in 328 Chinese primiparous women and found no significant differences between the women with vaginal delivery ( $n = 252$ ) and those with caesarean delivery ( $n = 76$ ) except for hiatal distension. Avulsion was strongly associated with hiatal distension and subgroup analysis between elective CS ( $n = 13$ ) and emergency CS ( $n = 63$ ) revealed no significant differences in pelvic floor biometry [10]. The low number of women in this study precluded this analysis.

With regard to symptoms, there were statistically significant increases in the mean ICIQ-VS scores for vaginal laxity (question 4) and vaginal symptoms interfering with everyday quality of life (question 14; Table 5) at the postpartum assessment. Vaginal laxity is a complex issue that has been shown to be a bothersome concern which is rarely acknowledged or discussed [28–31]. Pauls et al. [28] conducted an internet-based survey of members of the International Urogynecological Association to assess attitudes and practices toward sexual health and vaginal laxity. The response rate was 25%, and 83% of respondents described vaginal laxity as under-reported by patients and 57% considered vaginal laxity as a bothersome quality of life condition [28]. Although a clear relationship between vaginal laxity and sexual function has not been established, women have reported favourable outcomes after surgery for vaginal laxity in both the short and long term [30, 32]. The complaint of vaginal soreness may be attributable to the high episiotomy rate.

**Table 4** Mean changes in POP-Q coordinates before and after delivery in the 84 women analysed

POP-Q coordinate	Postpartum	Postpartum	P value
Ba	-2.13 ± 1.06	-0.87 ± 1.30	0.002
C	-4.38 ± 1.5	-4.0 ± 0.92	0.567
Bp	-3.0 ± 0.00	-2.83 ± 0.40	0.363
Gh	2.2 ± 4.60	5.40 ± 0.54	0.219
Pb	3.33 ± 0.51	2.83 ± 0.40	0.076

The data presented are means ± standard deviations

**Table 5** Overall ICIQ-VS questionnaire scores before and after delivery in the 84 women analysed

ICIQ-VS question	Antepartum	Postpartum	<i>P</i> value
Q1: Are you aware of dragging pain in your lower abdomen?	0.54 ± 0.84	0.43 ± 0.86	0.401
Q2: Are you aware of soreness in your vagina?	0.28 ± 0.66	0.64 ± 1.07	0.006
Q3: Do you feel that you have a reduced sensation or feeling in or around your vagina?	0.04 ± 0.18	0.15 ± 0.59	0.118
Q4: Do you feel that your vagina is too loose or lax?	0.02 ± 0.15	1.43 ± 1.24	0.001
Q5: Are you aware of a lump or bulge coming down in your vagina?	0.02 ± 0.22	0.06 ± 0.32	0.409
Q6: Do you feel a lump or bulge coming out of your vagina, so that you can feel it on the outside or see it on the outside?	0.00 ± 0.00	0.02 ± 0.15	0.159
Q7: Do you feel that your vagina is too dry?	0.05 ± 0.30	0.65 ± 1.08	0.001
Q8: Do you have to insert a finger into your vagina to help empty your bowels?	0.02 ± 0.22	0.05 ± 0.44	0.657
Q9: Do you feel that your vagina is too tight?	0.00 ± 0.00	0.00 ± 0.00	– <sup>a</sup>
Q10: Do you have a sex life?	1.31 ± 0.64	1.02 ± 0.68	0.001
Q13: How much do you feel that your sex life has been spoilt by vaginal symptoms?	0.12 ± 0.77	1.40 ± 1.96	0.001
Q14: Overall, how much do vaginal symptoms interfere with your everyday life?	0.18 ± 0.78	2.90 ± 2.17	0.001

The data presented are means ± standard deviations

<sup>a</sup> The correlation for question 9 could not be computed as the standard error of the difference is 0

Thibault-Gagnon et al. studied the effects of delivery-related trauma in 294 primigravid women. At 5.2 months postpartum a special set of 51 questions was designed to assess the women's perceptions of changes to the pelvic floor and in sexual function. Vaginal delivery and levator avulsion were associated with an increased perception of vaginal laxity and reduced pelvic floor muscle efficiency [33]. While we observed a significant deterioration in pelvic organ support postpartum, both clinically and on ultrasound imaging, only four women reported prolapse symptoms, which again is consistent with the literature [4, 8]. With regard to levator avulsion, a prevalence of 15% in Black women is also consistent with the literature in Caucasian women [4, 7, 8, 24, 27, 33]. Unfortunately, the low number of women in this study precluded analysis of risk factors.

The limitations of the study include a low follow-up rate, which is difficult to remedy in a setting such as the one in which we performed this study. Work commitments and unavailability (visiting parents' home in another province) were the most common reasons for non-attendance. As a result, the relatively low number of women seen postpartum precluded a more detailed analysis of risk factors for changes in organ support or levator integrity. In addition, it is recognized that longer follow-up in the same group of women would be preferable since slow improvement over time has been described in other ethnic groups [34].

In summary vaginal childbirth results in a substantial alteration in pelvic floor functional anatomy as examined by 3D TPUS in Black South African primigravidae. Of vaginally delivered women, 15% suffered major trauma to the LA muscle.

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#### Compliance with ethical standards

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