

# **THE FATE OF PROXIMALLY EXCLUDED ILIAC ARTERIES FOLLOWING OPEN REPAIR OF ABDOMINAL AORTIC ANEURYSMS**

*by*

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**Date: 15<sup>th</sup> January 2015**

## ABSTRACT

### **The fate of proximally excluded iliac arteries following open repair of Abdominal Aortic Aneurysms.**

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**Introduction:** Aneurysms occur throughout the length of the aorta, with a large proportion occurring in the infra-renal segment of the abdominal aorta (least 9 to 10 times more common than thoracic aortic aneurysms). Aneurysmal disease of the aorto-iliac segment which commonly occurs as a result of a degenerative process is invariably a progressive entity. Concomitant iliac artery aneurysms have been noted to occur in 15-40% of patients with abdominal aortic aneurysms (AAAs). As a result, following open AAA repair, there is a concern regarding the progressive enlargement of the iliac arteries.

**Purpose:** The aim of this study was to investigate the long term outcome of proximally excluded common iliac arteries (CIAs) following open bifurcated abdominal aortic aneurysm (AAA) repair.

**Methods:** Baseline clinical and demographic data of 165 consecutive patients undergoing open AAA repair between April 2004 and April 2014 was collected. The aorta and iliac segments were measured in the 120 available preoperative Computed Tomographic (CT) angiograms. A single postoperative CT scan was performed and measurements recorded in 46 patients available for follow-up. The patients were grouped according to the type of surgical repair, open tube graft repair or bifurcated graft repair to the common iliac (CIA), external iliac artery (EIA) or common femoral artery (CFA).

**Results:** Entered into the study were 165 patients (133 men, 32 women) with a mean age of 66 years and a mean AAA diameter of 6.7cm (range 5.1 – 10.3cm). After a median follow-up of 49 months, 46 patients (88 CIAs) were available for a single postoperative CT scan. There was an overall significant decrease in the CIA diameter for proximally excluded iliacs, with a t-statistic: 3.005 (critical value at 5% significance 2.021) for CFA reconstruction and a t-statistic: 2.267 (critical value at 5% significance 2.021) for EIA reconstructions. In contrast, open tube graft repair was associated with significant CIA growth, t-statistic: -2.583 (critical value at 5% significance 2.0). Additional aneurysms were identified in non-contiguous arterial segments in 21% of the 46 patients available and 9% of these patients had multiple (>3) aneurysms.

**Conclusion:** Open bifurcated AAA repair with proximal exclusion of CIAs appears safe and effective in intermediate and long term follow-up with no observed CIA growth. On the other hand, open tube graft repair is associated with significant future CIA growth although this is not associated with any risk of re-intervention.

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## **DEDICATION**

*I solemnly dedicate this piece of work to my wife (Dr Busisiwe Mapasa-Dube) and my son (Likhwa Mutongi Dube). You sacrificed immensely to make this possible and without your support and encouragement, my MPhil dissertation would not have been successfully completed.*

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## **ABBREVIATIONS**

<b>AAA</b>	Abdominal Aortic Aneurysm
<b>AAAs</b>	Abdominal Aortic Aneurysms
<b>CFA</b>	Common Femoral Artery
<b>CIA</b>	Common Iliac Artery
<b>CIAs</b>	Common Iliac Arteries
<b>CT</b>	Computed Tomography
<b>EVAR</b>	Endovascular Aortic Aneurysm Repair
<b>IIA</b>	Internal Iliac Artery
<b>MINORS</b>	Methodological Index for Non-Randomised Studies
<b>PTFE</b>	Polytetrafluoroethylene

# **Chapter 1**

**The fate of proximally excluded iliac arteries following open repair of Abdominal Aortic Aneurysms:**

**A systematic review and meta-analysis of available literature.**

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## **BACKGROUND**

An abdominal aortic aneurysm (AAA) is defined as a permanent focal aortic dilatation of 3cm or more (or 50% increase) in either antero-posterior or transverse diameter and predominantly occurs in the infra-renal segment as a result of degenerative disease<sup>1</sup>. The prevalence of AAAs as derived from cohort and screening studies ranges from 4-8 % in the sixth to eighth decade of life<sup>2</sup>. Historically there has been controversy regarding the management of ectatic or aneurysmal iliac arteries at the time of open AAA repair. Isolated iliac aneurysms account for 0.6 to 7% of all abdominal aneurysms<sup>3-5</sup>. The incidence of synchronous iliac and aortic aneurysms varies from 5-46 %<sup>6-7</sup>.

Endo-aneurysmorrhaphy for arterial aneurysms was first described by Rudolph Matas in 1888<sup>8-9</sup>. This procedure involved ligating branches of an aneurysm from within its sac. In 1923, Matas performed the first successful aortic aneurysm repair by ligating the aorta. The patient is reported to have died 18 months later from tuberculosis. However, despite this initial breakthrough, the following decades were associated with a stunting of progress in aortic aneurysm repair. At the turn of the 20<sup>th</sup> century, there was an evolution in surgical technique with the introduction of the vascular anastomosis by Alexis Carrel<sup>10</sup>. In 1952, Dubost performed the first open AAA repair using a thoracic aortic homograft from a recently deceased 20 year old donor<sup>10</sup>. This work by Dubost ushered in the modern era in aortic aneurysm repair. Introduction of Vinyon N cloth as an aortic prosthesis by Voorhees, Jaretski and Blakemore overcame the problem of the limited availability of the homograft. Transformation of prosthetic technology came as a result of the introduction of Polyester by Debakey. The invention of new knitting machine technologies to make seamless prosthetic grafts of various sizes and configurations triggered a refinement in surgical technique and wider availability of grafts. This pioneer work has subsequently undergone continuous evolution and refinement in both surgical technique and graft composition.

Juan Parodi transformed AAA management in 1991 when he made the first report on endovascular aortic aneurysm repair (EVAR) <sup>11</sup>. He utilised available balloon expandable stents in combination with standard polyester grafts to create a device that could be delivered through the femoral artery. This device was advanced into the aorta and deployed to effectively exclude an infra-renal aortic aneurysm. Initially introduced as an option for the management of AAAs in candidates with borderline fitness, EVAR has become the first line intervention in most vascular units worldwide accounting for more than 80% of all AAA interventions in current practice<sup>12</sup>. Current endovascular devices intended for EVAR come in a variety of configurations. Although most devices consist of modular components that are

assembled in situ to improve ease of device delivery, some endografts are composed of a single or uni-body construction. Bifurcated devices are the most commonly used, but aorto-uni-iliac devices which require an adjunctive femoral-femoral bypass are available for cases with challenging anatomy. Both passive and active fixation devices are available to improve fixation and sealing of the aneurysm. Despite the transformative impact of EVAR, open AAA repair still accounts for a significant portion of aneurysm intervention and remains a mainstay of vascular surgery. With progressive refinement in operative technique and perioperative care, centres of excellence now report a 30 day mortality of 0-5% for infra-renal AAA repair<sup>13</sup>.

The debates in open AAA management are centred on the choice of grafts, tubular as opposed to bifurcated grafts. When bifurcated grafts are used, the debate involves the location of the distal anastomosis; common iliac arteries (CIA), external iliac arteries (EIA) or common femoral arteries (CFA). The decision to use a tube graft as opposed to a bifurcated graft is influenced by various factors such as, the quality of the aortic bifurcation and size of the iliac arteries. The tube graft repair is perceived as a simpler technique with less operative time and less blood loss<sup>36</sup>. A bifurcated graft is used when the iliac arteries are aneurysmal or in cases of concomitant occlusive disease. However this repair is associated with longer operating times and higher risk of injuries to ureters, iliac veins and hypogastric plexus.

When performing an open repair for an AAA, the surgeon has to make appropriate operative decisions concerning the type of prosthetic graft (tube or bifurcated) <sup>21</sup>. This decision is based on a careful evaluation of preoperative imaging and intra-operative findings. Some concern develops when the common iliac arteries are ectatic or aneurysmal as to whether a bifurcated graft can be used given the risk of further aneurysmal changes<sup>21</sup>. Because no clearly defined selection criteria are available on the use of tube versus bifurcated grafts, the 2 alternatives have been used in varying proportions in different case series. In a multicentre review of 2 052 patients undergoing open AAA repair, a tube graft was used in 621 (30%) and bifurcated in 1 431 (70%) <sup>14</sup>. In a retrospective study involving 246 patients, 66% had tube graft repair and only 34% were repaired with bifurcated grafts<sup>15</sup>.

Open AAA repair is performed as a trans-peritoneal or retroperitoneal approach depending on institutional influence and surgeon preference. Proximal control is obtained above or below the renal arteries based on the morphology of the AAA (infra-renal or juxta-renal). This may involve division of the left renal vein with selective re-anastomosis. The proximal anastomosis is performed in an end to end fashion on grossly normal aorta. The site of the distal anastomosis depends on the condition of the aortic bifurcation and the state of the iliac

arteries as determined by pre-operative imaging and operative findings. The use of bifurcated grafts to the femoral arteries leaves the pelvic circulation dependent upon retrograde flow from the femoral arteries. Ligation of the external iliac arteries would leave the pelvis and the distal gastrointestinal tract at risk of ischaemia if there is inadequate collateral circulation. Continued flow in a diseased iliac circulation after open AAA repair might intuitively be expected to put the iliac circulation at risk for subsequent aneurysmal degeneration, particularly when the arteries are already dilated to some degree.

The long term durability of open AAA repair was reported on by Conrad et al (2006) in a single institution study <sup>16</sup>. Only 28% of the initial cohort of 540 patients was available for surveillance imaging after a mean follow up of 87 months. A straight tube graft was placed in 47% of patients and the remaining 53% had bifurcated reconstructions. The distal target for the bifurcated grafts was the iliac arteries in 41% and common femoral arteries in only 12% of the patients. On surveillance imaging, a total of 72 iliac artery aneurysms were detected (iliac diameter > 2cm). Only (4%) of all iliac aneurysms detected required subsequent intervention. Unfortunately it is very difficult to make solid conclusions based on this study due to the small numbers involved and the limited duration of follow up. Despite the low pick up rate of clinically significant aneurysms, the natural history cannot be elucidated because there is no mention of the initial size of iliac arteries prior to AAA repair.

Kalman et al (1999) reported on the value of late computed tomographic (CT) scanning in identification of vascular abnormalities after AAA repair<sup>17</sup>. In this study, CT scan follow-up exam was done on a cohort of 94 out of 251 patients, 8 years after open AAA repair. These patients were extracted from the registry of the Canadian Society for Vascular Surgery. They defined an aneurysmal iliac artery as that greater than 18mm in diameter. Iliac aneurysms were detected in 30.8% of the subset that had undergone tube graft repair but however the study does not mention the fate of the iliac arteries in bifurcated graft recipients.

The fate of proximally excluded ectatic or aneurysmal iliac arteries following a bifurcated open AAA repair has not been well researched. The natural history of such iliac arteries is not well understood. There are case studies and small volume cohorts described in the literature<sup>21</sup>. Only in the past decade due to widespread use of cross-sectional imaging, has there been a trigger to study the long term outcome of open AAA repairs.

**Keywords:**

Iliac artery aneurysm, abdominal aortic aneurysm, open repair

**ABSTRACT**

**Background:** Concomitant enlarged iliac arteries (aneurysmal or ectatic) are common in patients with abdominal aortic aneurysms (AAAs). In the case of open AAA repair, the choice of whether to perform a bifurcated graft repair with proximal exclusion of enlarged common iliac arteries must be weighed against the risk of future enlargement of the iliac arteries and the need for re-intervention. This literature review examined the fate of untreated ectatic and aneurysmal common iliac arteries (CIA) after open bifurcated or tube graft repair of infra-renal AAAs.

**Methods:** MEDLINE, EMBASE, CINAHL and Cochrane databases were searched for manuscripts published between January 1980 and July 2015, using the terms “abdominal aortic aneurysm” and “aneurysm/or iliac artery aneurysm.” Assessment of the methodologic quality of the manuscripts was done using the checklist of the Cochrane collaboration and the Methodological Index for Non-randomized Studies (MINORS) quality score. Publications studying the follow-up of iliac artery aneurysms after abdominal aorta aneurysm repair were selected. The exclusion criteria used for study selection were abstracts, reviews, duplicates and non-English manuscripts. The primary outcome measure was the increase of iliac artery diameter during follow-up. The secondary outcome was the subsequent re-intervention rate from metachronous iliac artery growth detected at follow-up. Pooling of data was only performed when studies reported the outcome of interest with comparable cohorts.

**Results:** Only 3 studies of open AAA repair were deemed suitable for analysis. Ectatic iliac arteries had a diameter progression of 1.7 to 1.8 mm during a follow-up period of 51.6 to 85.2 months. The aneurysmal iliac arteries showed a faster growth (2.3-3.0 mm) in a follow-up period of 50.4 to 85.2 months. In the total open AAA repair cohort, the re-intervention rate for CIA aneurysmal transformation was <1%.

**Conclusion:** After open tube graft AAA repair, there is an overall slow growth in size of the CIAs during follow-up, with a pooled assessment of arteries  $\geq 18$  mm showing a mean growth of 2.56 mm at 60 months of follow-up. This literature review underscores the need for a well designed prospective study on the fate of proximally excluded CIAs following open bifurcated AAA repair given the low quality of evidence currently available.

## INTRODUCTION

The management of enlarged common iliac arteries (CIAs) at the time of abdominal aortic aneurysm (AAA) repair remains a subject of significant debate. The location of the iliac anastomosis during open repair must all be weighed against the natural progression of the CIA diameter and the risk of rupture or need for re-interventions. Hence, proximal exclusion of ectatic or aneurysmal CIAs during bifurcated open AAA repair carries a theoretical and unproven risk of CIA diameter progression.

Tube replacement instead of bifurcated grafting is associated with a reduction in operative time, blood loss, and mortality after intact and ruptured AAAs but the fate of the preserved CIAs with prograde perfusion has been poorly studied. The present review evaluated the fate of CIA diameter progression after open AAA repair by performing a systematic review and meta-analysis of the available literature.

## METHODS

**Literature search:** The MEDLINE databases were searched for papers published between January 1980 and February 2015 using the keywords "Aortic Aneurysm, Abdominal"(MeSH) and "Iliac Aneurysm"(MeSH)<sup>18</sup>. The EMBASE database was searched with the terms "abdominal aorta aneurysm" and "aneurysm/or iliac artery aneurysm." The CINAHL database was also checked for relevant studies with the keywords MH "Aortic Aneurysm, Abdominal" and 'iliac aneurysm.'" The Cochrane database of Systematic Reviews was searched with the words "abdominal aortic aneurysm." The search was not restricted to any language, but in the systematic review, only studies published in English were taken into account.

**Validity assessment:** After relevant titles were identified, all abstracts were read, and eligible articles were retrieved. A manual cross-reference search of the references of relevant manuscripts was performed to identify other studies not found in the search. Only studies published in English were included. No unpublished data were included. A full search strategy is available at request. The methodologic quality of the articles was assessed using the Cochrane collaboration checklist and the Methodological Index for Non-randomized Studies (MINORS) quality score, with a maximum score of 16 for non-comparative studies and 24 for comparative studies<sup>19</sup>.

**Fig 1: MINORS SCORE<sup>19</sup>**

Methodological items for non-randomized studies	Score <sup>†</sup>
<ol style="list-style-type: none"> <li>1. <b>A clearly stated aim:</b> the question addressed should be precise and relevant in the light of available literature</li> <li>2. <b>Inclusion of consecutive patients:</b> all patients potentially fit for inclusion (satisfying the criteria for inclusion) have been included in the study during the study period (no exclusion or details about the reasons for exclusion)</li> <li>3. <b>Prospective collection of data:</b> data were collected according to a protocol established before the beginning of the study</li> <li>4. <b>Endpoints appropriate to the aim of the study:</b> unambiguous explanation of the criteria used to evaluate the main outcome which should be in accordance with the question addressed by the study. Also, the endpoints should be assessed on an intention-to-treat basis.</li> <li>5. <b>Unbiased assessment of the study endpoint:</b> blind evaluation of objective endpoints and double-blind evaluation of subjective endpoints. Otherwise the reasons for not blinding should be stated</li> <li>6. <b>Follow-up period appropriate to the aim of the study:</b> the follow-up should be sufficiently long to allow the assessment of the main endpoint and possible adverse events</li> <li>7. <b>Loss to follow up less than 5%:</b> all patients should be included in the follow up. Otherwise, the proportion lost to follow up should not exceed the proportion experiencing the major endpoint</li> <li>8. <b>Prospective calculation of the study size:</b> information of the size of detectable difference of interest with a calculation of 95% confidence interval, according to the expected incidence of the outcome event, and information about the level for statistical significance and estimates of power when comparing the outcomes</li> </ol> <p><i>Additional criteria in the case of comparative study</i></p> <ol style="list-style-type: none"> <li>9. <b>An adequate control group:</b> having a gold standard diagnostic test or therapeutic intervention recognized as the optimal intervention according to the available published data</li> <li>10. <b>Contemporary groups:</b> control and studied group should be managed during the same time period (no historical comparison)</li> <li>11. <b>Baseline equivalence of groups:</b> the groups should be similar regarding the criteria other than the studied endpoints. Absence of confounding factors that could bias the interpretation of the results</li> <li>12. <b>Adequate statistical analyses:</b> whether the statistics were in accordance with the type of study with calculation of confidence intervals or relative risk</li> </ol>	
<p><sup>†</sup>The items are scored 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). The global ideal score being 16 for non-comparative studies and 24 for comparative studies.</p>	

**Definition:** Ectatic iliac arteries are defined as 13mm to 18 mm. Aneurysmal iliac arteries are defined as those >18 mm according to the Ad Hoc Committee on Reporting Standards of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery<sup>20</sup>.

### **Inclusion and exclusion criteria**

#### ***Types of studies***

Manuscripts were eligible for inclusion if the following criteria were met: Publications dealing with patients undergoing open AAA repair with synchronous ectatic or aneurysmal iliac arteries, studies with adequate follow-up and describing growth of the iliac aneurysms, articles in English, human studies, and available full text. Exclusion criteria for study selection were studies not providing follow-up by imaging with ultrasound or computed tomography (CT) scan, case reports, and reviews. Studies focussing on the fate of iliac arteries after endovascular aortic aneurysm repair (EVAR) were also excluded.

#### ***Patients***

All patients undergoing open AAA repair with synchronous ectatic of aneurysmal iliac arteries were included.

### ***Outcome measures***

The primary outcome measure was the total increase of the CIA diameter during follow-up. The secondary outcome measure was the need for re-intervention due to metachronous iliac artery growth. Pooling of data was only performed when studies reported the outcome of interest with comparable cohorts.

### ***Data analysis***

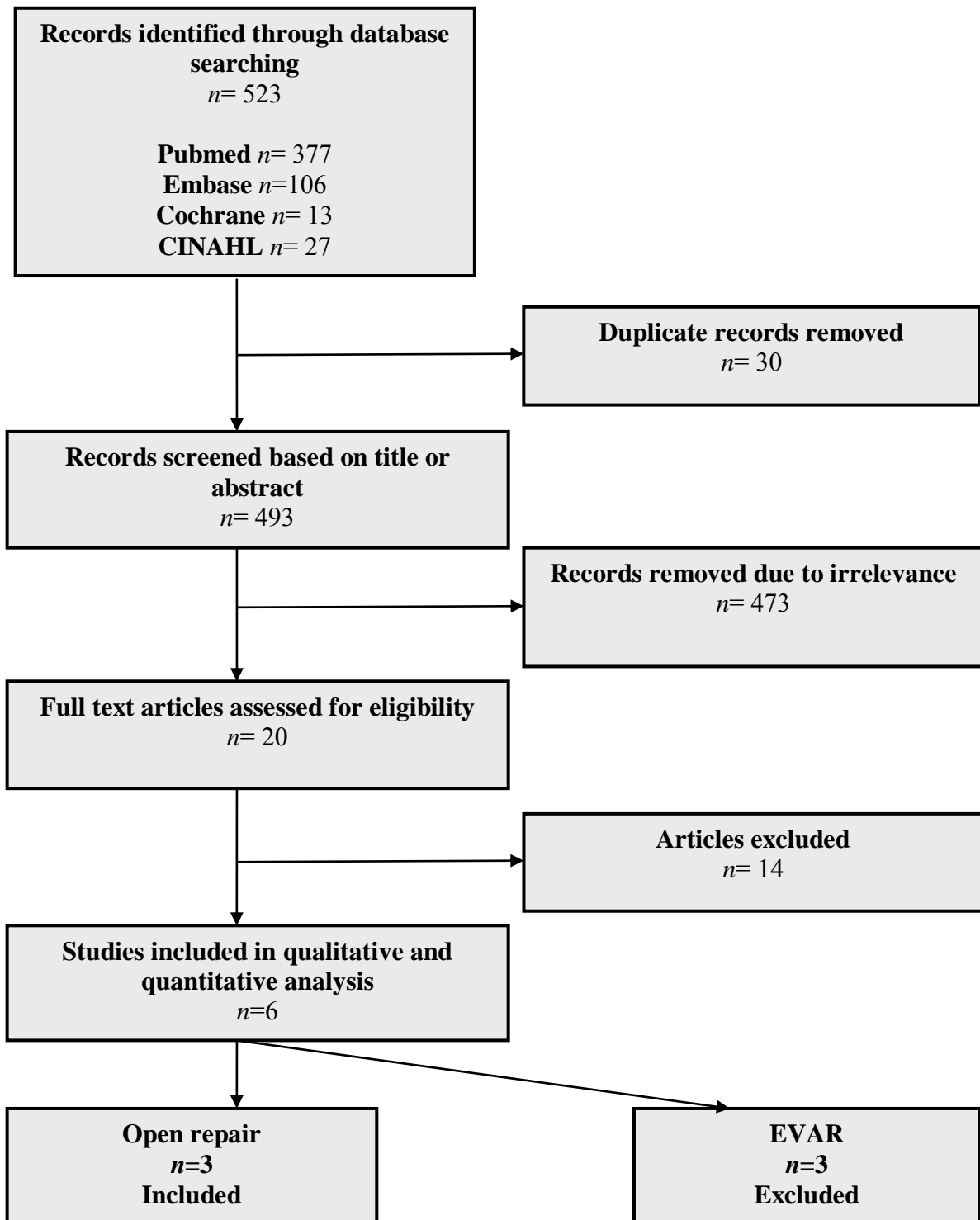
Meta-Analyst 3.1 software (Tufts University, Medford, MA, USA) was used for the meta-analysis. To provide a reliable outcome and to gain sufficient homogeneity of the pooled data, only three comparable studies were used for pooled analyses. Common iliac artery growth rates were pooled using a random-effects model. The presence of heterogeneity between the studies was assessed by using a forest plot and by performing a  $\chi^2$  heterogeneity test, and the  $I^2$  index was calculated.

## **RESULTS**

### ***Description of studies***

The flowchart for the systematic review is shown in Fig 2. Initially, 532 publications were identified in the literature search, from which 493 articles were screened by the title or abstract, and 25 articles were retrieved for more detailed information. Electronic links to related articles and references of selected articles were hand searched as well. The study excluded duplicate publications and papers that reported on (or parts of) the same study population. After reading the retrieved articles and the application of our inclusion criteria, only three relevant articles were selected. The 3 studies selected all reported on the fate of CIAs after tube graft repair.

**Fig 2: Flow Chart of Literature Search<sup>18</sup>**



EVAR (Endovascular Aortic Aneurysm Repair)

### ***Progression of CIA diameter***

The included studies described 422 patients. The patients in the studies were grouped by treatment and iliac size. The study groups are summarized in Table 1.

**Table 1: Included Studies<sup>18</sup>**

Study	N	Study type	Operation type	Iliac arteries (number)	Iliac artery size mm	Follow-up (months)	Total growth (mm)	MINORS SCORE
Hassen-Khodja et al. 2006 <sup>14</sup>	147	Prospective	Tube graft repair	59	≤12	66	1	12
				53	13-18	51.6	1.7	
				35	>18	50.4	2.3	
Ballota et al. 2008 <sup>33</sup>	201	Comparative study	Tube graft repair	92	≤12	85.2	1.1	12
				63	13-18		1.8	
				46	>18		2.4	
Sala et al. 2002 <sup>15</sup>	74	Prospective	Tube graft repair	42	≤12	68.3	N/A	10
				13	13-18		N/A	
				19	>18		3.0	

N= Number of Patients (Sample size)

Measurements of iliac artery diameter were performed perpendicular to the direction of tortuosity on the widest part of the target vessel. Newer generation measurement tools (center lumen line reconstructions) were not utilised. The cut-off size in the open repair group was divided according to the criteria of the Ad Hoc Committee on Reporting Standards of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery, (ectatic common iliac arteries: 13–18 mm and aneurysmal common iliac arteries: >18 mm)<sup>20</sup>. Ectatic CIA arteries had a diameter progression of 1.7 to 1.8 mm during a follow-up period of 51.6 to 85.2 months. The aneurysmal iliac arteries after open AAA repair showed a faster growth of 2.3 to 3.0 mm in a follow-up period of 50.4 to 85.2 months. All studies were of moderate quality using the MINORS scoring scale (Fig: 1).

**Table 2: MINORS Score (6 Best performing Studies)<sup>18</sup>**

<i>MINORS score</i>	<i>Study</i>					
	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>
A clearly stated aim	2	2	2	2	2	2
Inclusion of consecutive patients	2	1	2	2	1	2
Prospective collection of data	2	1	2	2	0	2
Endpoints appropriate to the aim of the study	2	2	2	2	2	2
Unbiased assessment of the study endpoint	2	2	2	2	1	1
Follow-up period appropriate to the aim of the study	2	2	2	2	2	1
Loss to follow up less than 5%	0	0	0	0	0	0
Prospective calculation of the study size	0	0	0	0	0	0
Total	12	10	12	12	7	10

*Minors*, Methodological Index for Non-randomized Studies

**KEY: 1.Hassen-Khodja et al, 2. Sala et al, 3. Ballota et al, 4. Kirkwood et al,  
5. Falksammer et al, 6. Hakaim et al**

**Table 3: Excluded Studies<sup>18</sup>**

N= number patients (Sample size)

Study	Reason of exclusion	N	Conclusion
Bruen et al. 2009 <sup>21</sup>	Review		A bifurcated graft in moderate size aneurysms <30mm and younger patients
Armon et al. 1998 <sup>22</sup>	Cohort	215	Follow-up CIA aneurysm without operation
Dosluoglu et al. 1999 <sup>25</sup>	Presentation of retrospective study concerning 1865 AAAs and 46 iliac aneurysms	46	
Conrad et al. 2007 <sup>16</sup>		152	No growth was provided, only prevalence
Plate et al. 1985 <sup>26</sup>		1087	No growth was provided, only prevalence
Richards et al. 2009 <sup>27</sup>	Natural history, no operation	191	CIA growth 5.7% ( $\pm 0.5\%$ ) per annum.
Huang et al. 2008 <sup>28</sup>	Natural history of iliac aneurysm	438	Expansion rate
Agu et al. 2008 <sup>29</sup>	Development of landing site aneurysm, after EVAR.	297	7 patients developed iliac aneurysm. All patients with type 1b endoleak. Growth from 12mm (10-15mm) to 23.5 mm (16-27mm) Follow-up 72 months.
Timaran et al. 2005 <sup>24</sup>	Feasibility of EVAR, landing site ectatic arteries <20mm.	178	Follow-up 24 months. Growth of size was not reported.
England et al. 2008 <sup>30</sup>	Feasibility of EVAR, landing site ectatic arteries	117	Growth size not specifically reported. Only discussion one-third with a growth of more than 5mm.
Adiseshiah et al 2010 <sup>23</sup>	Long term results of EVAR	50	No size was reported
Malagari et al. 2004 <sup>31</sup>	Feasibility of EVAR, landing site ectatic arteries	58	No growth was reported
Kalman et al. 2003 <sup>17</sup>	Observational study concerning follow-up after open repair	251	No growth rate was provided
Hill et al. 1998 <sup>32</sup>	Fate of iliac arteries after Aorto-bifemoral bypass	32	Retrograde perfusion of diseased iliac arteries is safe.

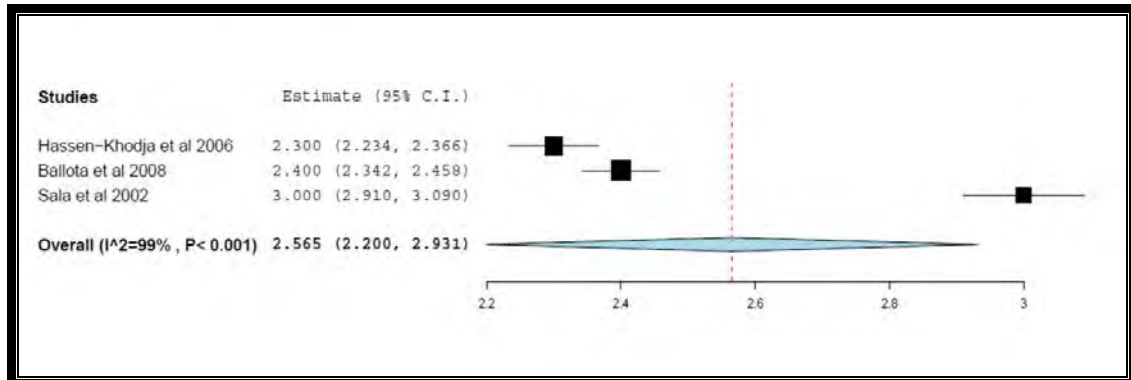
### ***Open repair studies***

Only three studies all focussing on the fate of CIA after open “Tube Graft AAA Repair” met the inclusion criteria<sup>14, 15, 33</sup>. Very few studies included an assessment of proximally excluded iliac arteries after open AAA repair<sup>17, 21, 32</sup>, but were not included in the assessment due to their low quality evidence as per MINORS score.

Hassen-Khodja et al focussed on the fate of iliac arteries after tube graft repair of AAA<sup>14</sup>. The study cohorts were divided into three groups: normal, ectatic, and aneurysmal iliac arteries, with CIA growth rates of 9.4%, 12.1%, and 12.7%, respectively, during a mean follow-up of 5 years. Only three of the primary 147 aneurysmal CIA patients (2%) required re-intervention. These three patients had a preoperative CIA diameter of 30 mm. Sala et al also determined the expansion rates of CIA after tube graft repair of AAAs in 74 patients with a mean follow-up of 68.3 months<sup>15</sup>. In the study cohort, 57% initially had normal iliac arteries, and the rest of the patients had ectatic or aneurysmal CIAs. There was an overall 1.5-mm growth in CIA size during the follow-up period. Eighteen patients displayed an increase in CIA diameter on postoperative CT imaging. In the entire study group, 10 patients had aneurysmal transformation of the iliac arteries, and notably, three of these iliac arteries were previously normal. However, none of the patients with aneurysmal iliac arteries required any re-intervention.

Ballota et al evaluated 201 patients with normal, ectatic, and aneurysmal iliac arteries<sup>34</sup>. After a mean follow-up of 7.1 years, 14 patients progressed from normal to ectatic CIAs and 9 patients progressed from ectatic to aneurysmal CIAs. The increase in the aneurysmal group was  $2.4 \pm 0.02$  mm (12.9%) after a mean of 7.4 years. However, none of the patients required re-intervention.

**Fig 3: Overall Pooled Data Analysis<sup>18</sup>**



As shown in Fig 3, the estimated pooled mean growth of the CIAs >18 mm in the patients with primary tube graft repair was 2.56 mm (95% confidence interval, 2.2-2.9 mm) at a follow-up of 5 to 7.4 years. The level of heterogeneity among included studies was significant ( $I^2 = 99%$ ).

## DISCUSSION

The prevalence of both ectatic and aneurysmal CIAs during intervention of AAAs is significantly high (up to 70%, depending on the study). However, the natural history pertaining to normal and enlarged CIAs after AAA intervention has not been well studied. A retrospective study by Kalman et al on the value of late imaging after open AAA repair found a 30.8% prevalence of CIA aneurysms (>18 mm) after a mean of 129 months after surgery<sup>17</sup>. Similarly, Conrad et al in their study of the long-term durability of AAA repair, found 62 CIA aneurysms in 540 patients after a mean follow-up of 87 months<sup>16</sup>.

In this literature review only three open AAA repair studies were selected using the MINORS criteria<sup>14, 15, 33</sup>. These three studies selected had overall satisfactory sample sizes but no clarity regarding the nature of the prospective sample size calculation or rate of sample size attrition (loss to follow-up). All included open AAA repair studies were prospective in design, with an average sample size of 141 (Total 422 patients) and a mean follow-up of 73 months. The similarity in all studies was that most of the CIAs remained stable in size, and the largest growth was seen in the CIAs >18mm. The overall CIA growth ranged from 1 to 3 mm in the combined study population during a variable period of 50 to 80 months. As illustrated in Fig.2, pooled data analysis of the three open AAA repair studies shows an overall CIA growth

of 2.57 mm ( $P < .001$ )<sup>18</sup>. However, the re-intervention rate related to CIA aneurysmal changes was 2% in the three open AAA study cohorts. It is very difficult to draw practical conclusions from this assessment because of the heterogeneity in measurements of iliac growth. In addition, the pooled growth rate above is too marginal to be of any use in daily practice.

Similar to AAAs, CIA aneurysms are more prone to rupture when they reach a critical size; unfortunately, data on the natural history of untreated CIA aneurysms are scarce. McCready et al observed a growth rate of 4 mm/y and recommended repair when they reached 3 cm in size<sup>34</sup>. Santilli et al studied the rate of growth of isolated iliac artery aneurysms, mostly CIA aneurysms<sup>35</sup>. Iliac artery aneurysms sized <3 cm expanded at an average rate of 1.1 mm/year, whereas those sized >3 cm expanded by 2.6 mm/y. Because symptoms, including rupture, did not develop with iliac artery aneurysms <4 cm in diameter, the authors suggested repair for aneurysms sized >3.5 cm.

## **CONCLUSION**

Based on the currently available low quality evidence, it is very difficult to perform a systematic review on natural history studies regarding the fate of proximally excluded CIAs following bifurcated open AAA repair. This is mainly due to the small sample sizes, selection bias and limited follow-up in these studies. However, after tube graft repair, the above systematic review suggests that the CIAs remain stable with very small growth noted over an average interval of 60 months. Similarly, the overall re-intervention rate due to aneurysmal transformation of CIAs following tube graft repair is low (<1%). This literature review underscores the need for a well designed prospective study on the fate of proximally excluded CIAs following open bifurcated AAA repair given the low quality of evidence currently available.

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## **Chapter 2**

### **The fate of proximally excluded iliac arteries following open repair of Abdominal Aortic Aneurysms.**

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**Keywords:**

Iliac artery aneurysm, abdominal aortic aneurysm, open repair

**ABSTRACT**

**Purpose:** The aim of this study was to investigate the long term outcome of proximally excluded common iliac arteries (CIAs) following open bifurcated abdominal aortic aneurysm (AAA) repair.

**Methods:** Baseline clinical and demographic data of 165 consecutive patients undergoing open AAA repair between April 2004 and April 2014 was collected. The aorta and iliac segments were measured in the 120 available preoperative Computed Tomographic (CT) angiograms. A single postoperative CT scan was performed and measurements recorded in 46 patients available for follow-up. The patients were grouped according to the type of surgical repair, open tube graft repair or bifurcated graft repair to the common iliac (CIA), external iliac artery (EIA) or common femoral artery (CFA).

**Results:** Entered into the study were 165 patients (133 men, 32 women) with a mean age of 66 years and a mean AAA diameter of 6.7cm (range 5.1 – 10.3cm). After a median follow-up of 49 months, 46 patients (88 CIAs) were available for a single postoperative CT scan. There was an overall significant decrease in the CIA diameter for proximally excluded iliacs, with a t-statistic: 3.005 (critical value at 5% significance 2.021) for CFA reconstruction and a t-statistic: 2.267 (critical value at 5% significance 2.021) for EIA reconstructions. In contrast, open tube graft repair was associated with significant CIA growth, t-statistic: -2.583 (critical value at 5% significance 2.0). Additional aneurysms were identified in non-contiguous arterial segments in 21% of the 46 patients available and 9% of these patients had multiple (>3) aneurysms.

**Conclusion:** Bifurcated open AAA repair with proximal exclusion of CIA appears safe and effective in intermediate and long term follow-up with no observed CIA growth. On the other hand, open tube graft repair is associated with significant future CIA growth although this is not associated with any risk of re-intervention.

## INTRODUCTION

Aneurysms occur throughout the length of the aorta, with a large proportion occurring in the infra-renal segment (least 9 to 10 times more common than thoracic aneurysms)<sup>1</sup>. Aneurysmal disease of the aorto-iliac segment which commonly occurs as a result of degenerative process is invariably a progressive entity. Concomitant iliac artery aneurysms have been noted to occur in 15-40% of patients with AAAs<sup>2</sup>. As a result, following open AAA repair, there is a concern regarding the progressive enlargement of the iliac arteries (CIAs).

There is no accepted standard recommendation for surveillance imaging examination after routine open AAA repair. The detection of late arterial abnormalities is dependent on the development of new symptoms, incidental findings on routine physical examination, or on imaging performed for unrelated reasons. On the basis of the findings from the Canadian Aneurysm Registry, a routine follow-up CT scan is recommended 5 years after open AAA repair and then at serial intervals depending on abnormalities detected<sup>3</sup>. Such recommendations have only recently been adopted into some societal guidelines<sup>4</sup>.

Similar to a ruptured AAA, a ruptured CIA carries a high morbidity and mortality. Open repair of CIA aneurysms can also be challenging because of previous abdominal surgery with a high risk of iatrogenic injuries (iliac vein, ureteric, nerves), especially in obese patients. Options for open AAA repair invariably utilise prosthetic grafts either as a tube or bifurcated repair. Bifurcated repair frequently necessitates a distal anastomosis to the EIA or CFA. In this case, the CIAs are proximally excluded with pelvic circulation maintained by retrograde blood flow. This technique adds to surgical complexity and also theoretically portends to aneurysmal progression of the retrograde perfused CIA and internal iliac artery (IIA). On the other hand, tube graft repair is more attractive due to its simplicity, lower risk of venous, ureteric and nerve injury, but a calcified aortic bifurcation may make the distal anastomosis challenging. In addition, tube graft repair carries the poorly studied risk of aneurysmal transformation of the prograde perfused iliac arteries. Apart from anatomic considerations, the choice of reconstruction is also influenced by the patient's age, medical comorbidities, expected late survival and the overall complexity of the operation.

Very few studies have looked at the fate of iliac arteries following open AAA repair, most of these natural history studies have focussed on tube graft repairs. A historic study from the Mayo clinic reviewed a series of 1 112 patients who had open AAA repair between 1970 and 1976<sup>5</sup>. After a mean follow-up of 5.2 years, 6 new iliac aneurysms developed and 3 of these presented with rupture. However the criticism of the study is its non prospective nature with

very limited follow-up imaging performed in that era. Calcagno et al compared 2 groups of 39 patients who had tube graft and bifurcated repairs respectively<sup>6</sup>. At a mean follow-up of 6 years, none of the tube graft patients developed aneurysms compared to an increase in vascular and graft related complications in the bifurcated repair. This finding was in total contrast to the earlier findings of the Mayo study group.

After a tube graft AAA repair, studies suggest that the CIAs remain stable with very slow growth rates of 0.16 – 0.32mm/year, depending on the preoperative size of the arteries (normal, ectatic or aneurysmal)<sup>7</sup>. Some reports suggest that this growth rate is influenced by the initial CIA size, presence of synchronous aneurysms, duration of follow-up and other CT scan imaging criteria (aortic root and visceral aortic diameters)<sup>8</sup>. Only one prospective study has focussed on the outcome of proximally excluded CIAs after bifurcated open AAA repair<sup>9</sup>. Following open bifurcated AAA repair, some retrospective studies have shown minimal CIA growth with a negligible risk resulting from aneurysmal transformation<sup>6</sup>. However, a cautious interpretation of this natural history evidence is required due to the small non-prospective sample sizes, selection bias and long term attrition of sample sizes experienced in these studies.

Heterogeneous reporting on what constitutes ectatic and aneurysmal CIAs makes data interpretation challenging. Such a classification can only be possible if the average adult CIA diameters are known. There were 2 studies done in healthy subjects that aimed to answer this question<sup>10,11</sup>. The first study was from the American Population Study using conventional CT scan. The mean CIA diameter in 56 male subjects in their sixth to eighth decade of life was 1.17 – 1.30cm (SD 0.19-0.2). Utilising this data, CIA aneurysms were classified as those greater than 1.57-1.68cm (+/- 2SD from mean) depending on age. The second study was a Norwegian based ultrasound study on 160 patients. They found that males over the age of 50 years had a mean CIA diameter of 1.1cm. On this basis, they concluded that CIA diameters greater than 1.4cm (+/- 2SD) were aneurysmal. Depending on the references used, aneurysmal cut-offs of the CIA range from 15mm to 30mm. The later adoption of the Ad Hoc Committee of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery reporting standards by most authors in this subject has improved the uniformity of observations<sup>12</sup>.

The following cross-sectional study of a consecutive series of patients was designed to primarily assess the fate of proximally excluded CIAs following bifurcated open AAA repair. In addition the study aimed to show the overall outcome of CIAs after any form of open AAA repair (bifurcated or tube-graft).

## **PATIENTS AND METHODS**

A cross-sectional study was done on a consecutive series of patients who underwent open infra-renal AAA repair at Groote Schuur Hospital between April 2004 and April 2014. This study was approved by the University of Cape Town Departmental (Surgical) and Human Research Ethics Committees. Patients who underwent secondary interventions for metachronous aneurysms in the aorto-iliac segment were excluded from the study. Patients with no available preoperative CT scan were included in the baseline demographic data. Information for each patient was collected using the Memento Database 3.8.5 (Luckydroid Application 2015), within which 140 variables were collected per patient.

All operations were trans-peritoneal approaches with supra-renal control, left renal vein division and choice of prosthetic graft all left at the discretion of the operating surgeon. The distal landing zone of the prosthetic graft was influenced by preoperative CT scan imaging (aortic bifurcation disease and aneurysmal or occlusive iliacs) and operative findings. Demographic data (age, sex, comorbidities), preoperative and postoperative data including clinical presentation, aneurysm extent, operative conduct and complications were recorded and transferred to the Excel 2010 spreadsheet software program (Microsoft, Redmond, Wash). The “vital status” of the study group (alive/deceased) was assessed using hospital records and telephonic interviews. All traceable patients were invited for routine clinical assessment, duplex ultrasound and a single postoperative CT angiogram of the chest to the lower extremities.

In all cases, preoperative and postoperative arterial diameter measurements were made using the same technique at the same level for each patient. Arterial tree diameter measurements were made starting from the aortic root to the aorto-iliac and common femoral artery (CFA) segments. Any aneurysms detected at any other sites were systematically recorded. In the tortuous segments of the arterial tree, diameter measurements were done perpendicular to the direction of tortuosity so as to correct for oblique axial slices. In cases where digital copies of the CT images were not available, arterial size measurements were done manually (using callipers) from plain film images. Indirect measurements using volume rendered 3-dimensional reconstructions were not used in this study. Common iliac artery ectasia and aneurysms were defined using the criteria of the Ad Hoc Committee on Reporting Standards of the Society for Vascular Surgery and International Society of Cardiovascular Surgery<sup>12</sup>. A CIA was, therefore considered ectatic if its diameter was between 13 and 18mm, and it was considered aneurysmal when it was >18mm in diameter or more.

**Statistical analysis:** Descriptive statistics, including means, ranges and proportions were calculated as appropriate. All statistical analyses were performed using the SPSS 10.0 statistical software package (SPSS Inc., Chicago, Ill). All values are expressed as mean  $\pm$  SD. Univariate analysis was performed on all clinical, morphologic and other variables assessed using the Student t-test (2-tailed) for continuous variables and  $\chi^2$  analysis or the Fisher exact test (2-tailed), as appropriate for categorical variables. Significant growth in the iliac arteries was assessed using a t-statistic calculation determined by a critical value at 5% significance.

## **RESULTS**

Between April 2004 and April 2014, 165 consecutive patients underwent open repair of infra-renal AAA, in which 133 (81%) were males and 32 (19%) were female. Demographic and clinical characteristics are summarised in Table 1.

**Table 1: Demographic Data**

<b>Variable</b>	<b>Value</b>
Patients, No (%)	165 (100)
<b>Sex, No (%)</b>	
Male	133 (81)
Female	32 (19)
<b>Age, years</b>	
Mean +/- SD	66 +/- 5
AAA size, mean (cm)	6.7 +/- 2.1
Mean ASA Status	3
Cardiovascular risk factors, No (%)	74 (45)
Pulmonary risk factors, No (%)	43 (26)
Renal risk factors, No (%)	21 (13)
Hypertension, No (%)	123 (76)
Diabetes Mellitus, No (%)	32 (19)
Smokers, No (%)	97 (59)
Peripheral Arterial Disease, No (%)	27 (16)

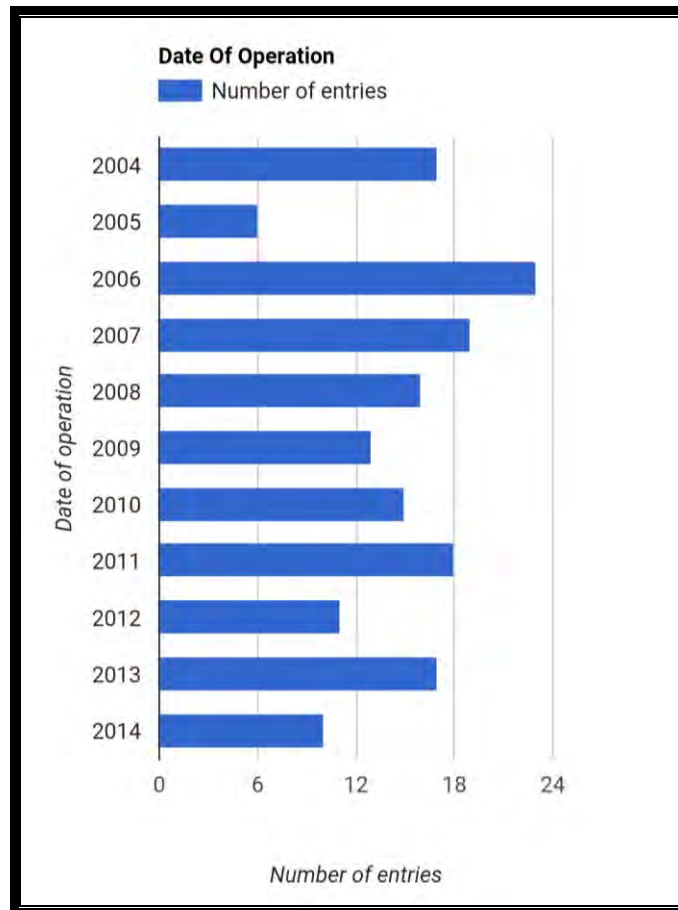
**Table 2: Operative Data**

n=total number

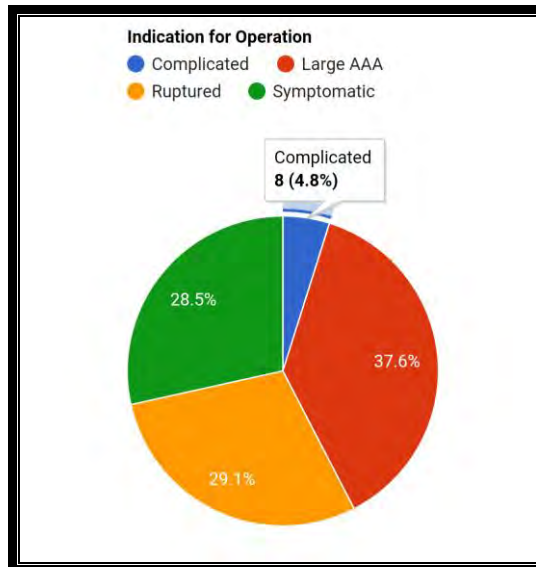
<b>Graft material</b>	<b>n (%)</b>
Dacron	162 (98)
PTFE	3 (2)
<b>Graft Reconstruction</b>	
Tube	58 (35)
Bifurcated	107 (65)
<b>Proximal Clamp</b>	
Infrarenal	139 (84)
Suprarenal	26 (16)
<b>Distal Target</b>	
Aorta	58 (35)
Common iliac	27 (16)
External iliac	32 (19)
Common Femoral	48 (30)

The annual cumulative tally of patients is illustrated in Fig 1. The commonest indication for AAA repair was a large asymptomatic AAA in 62 patients (38%), followed by ruptured AAAs in 48 patients (29%). Three patients were excluded due to subsequent requirement for surgery as a result of metachronous CIA and IIA aneurysms.

**Fig 1: Annual Tally of Patients (Total 165)**

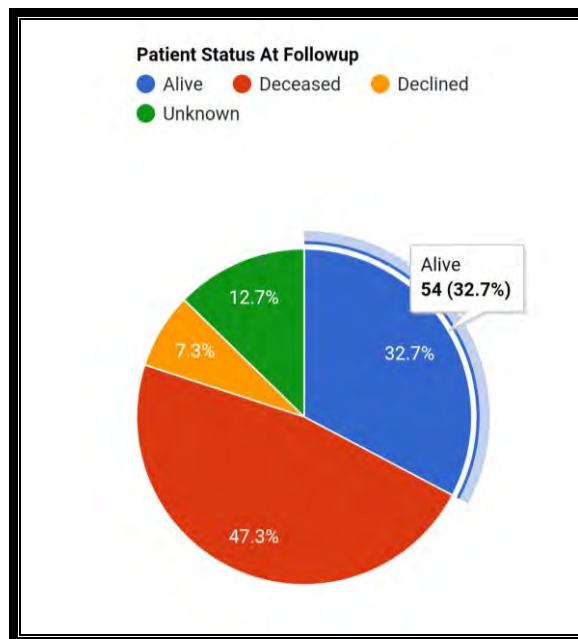


**Fig 2:**



**Baseline indication for operation (165 patients)**

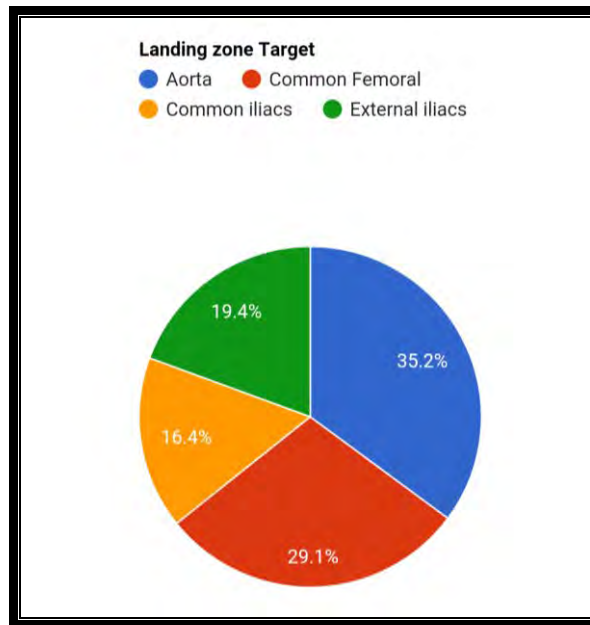
**Fig: 3**



**(%) 165 Patients: Median Follow-up 49 months**

Seventy-three percent of patients (120) had preoperative CT scans available, 92% were electronic images and 8% were plain film images. The mean AAA diameter was 6.7cm (range 5.1 – 10.3cm). The proximal cross-clamp position was suprarenal in 26 (16%) and infrarenal in the remaining 139 (84%). Left renal vein division was documented in 9% and inferior mesenteric artery re-implantation in 4% of the operative notes. The average anaesthetic estimated blood loss was 200mL and average blood transfusion of 2 packed red blood cells per patient. All patients had prosthetic grafts placed, most of which (98%) were Dacron (DuPont, Wilmington, Del). Tube graft repair was done in 58 (35%) of patients and the remaining 107 (65%) patients had bifurcated reconstructions. The distal target for the bifurcated repairs was the CIA in 27 (16%) patients, EIA in 32 (19%) patients and CFA in 48 (30%) patients.

**Fig 4: Location of Distal Anastomosis**



**Table 3: CIA Diameter Measurements**

CIA diameter	(92 CIAs) n=46	(88 CIAs) n=46
	Preoperative	Postoperative
Normal up to 12mm	49	32
Ectatic (13 – 18mm)	25	33
Aneurysmal more than 18mm	18	23

The perioperative mortality (30 day) was 11% and major complications (Cardiovascular, Renal and Pulmonary) occurred in 28% of patients. Sixty-six patients were confirmed alive in July 2014 within an average follow-up of 49 months (range: 3 months to 10 years) and the overall mortality (early and late) was 47%. Fifteen percent of the late deaths were confirmed cardiac events but in over 20% the cause of deaths were unknown. However only 46 (28%) of the surviving patients were available for postoperative CT scan imaging. The mean age (baseline) of this patient group was 65 years.

At the time of follow-up CT imaging, the postoperative arterial size measurements are illustrated in Table 3. In the subgroup of patients who had a postoperative CT scan (46 patients), 88 CIAs were available for comparative parametric testing (**t-test**). Despite isolated enlargement of some CIAs on follow-up, the overall t-test revealed a decrease in the size of

the CIA (**t-statistic** 3.203: critical value at 5% significance 1.96). A total of 26 (56%) patients in this subgroup had proximally excluded iliac arteries (15 CFA and 11 EIA landing zones). Individual parametric testing of 28 CIAs in the CFA landing zone and 20 CIAs in the EIA landing zone groups was done. There was an overall significant decrease in the diameter for proximally excluded CIAs, with a **t-statistic**: 3.005 (critical value at 5% significance 2.021) for CFA reconstruction and a **t-statistic**: 2.267 (critical value at 5% significance 2.021) for

EIA reconstructions. In this proximally excluded cohort of patients, 8% of the CIAs were noted to be thrombosed and 5% of the CIAs were aneurysmal at the second CT imaging assessment.

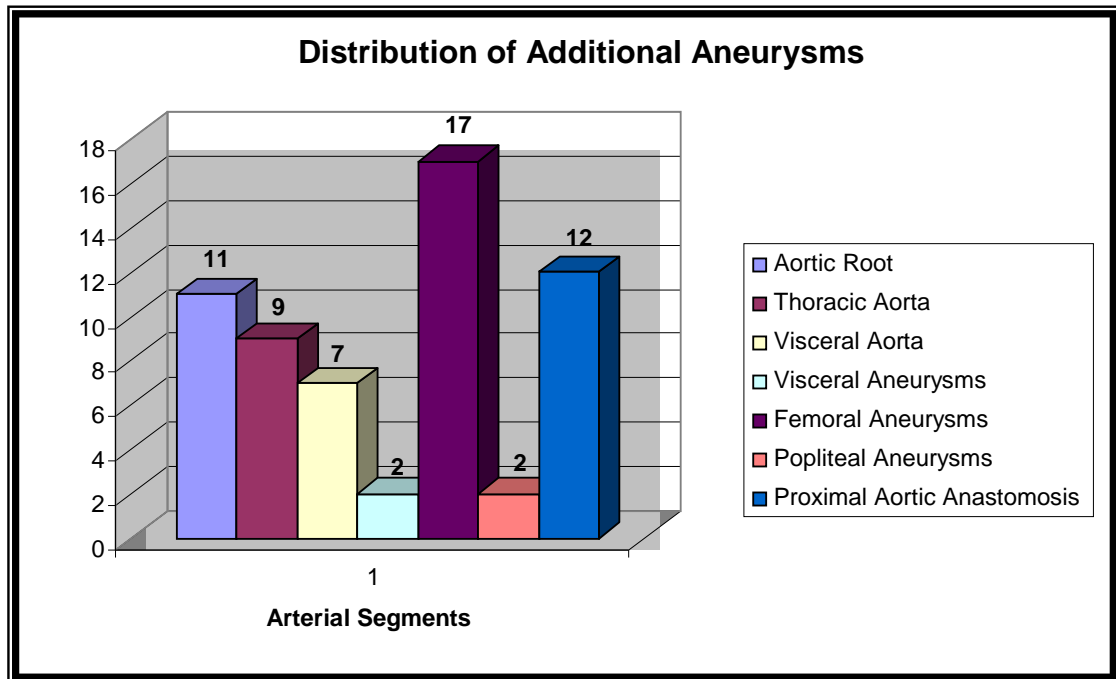
Of the 46 patients who had a second CT scan assessment, 20 patients had reconstructions with prograde CIA perfusion (7 patients: CIA bifurcated repair onto and 13 patients: tube graft aortic repair). Statistical assessment revealed significant CIA diameter progression in the tube graft reconstruction, overall mean growth 2.9mm. This was supported by a t-statistic of -2.583 (critical value at 5% significance 2.0). Similar to proximally excluded reconstructions, there was an overall decrease in CIA diameter for the subgroup with CIA bifurcated repairs onto CIAs. Additional parametric testing did not show any significant size progression of IIA and EIA.

**Table 4: Parametric t-test of CIA growth**

<b>Group n= number of CIAs</b>	<b>t-statistic CIA mean</b>	<b>Critical value at 5% Significance</b>	<b>Conclusion</b>
All patients with Postoperative CT n=88	3.203	1.96	Overall decrease in CIA size
Tube graft repair n=26	-2.583	2.0	Overall increase in CIA size
CIA repair n=14	2.507	2.074	Overall decrease in CIA size
EIA repair (proximally excluded) n=20	2.267	2.021	Overall decrease in CIA size
CFA repair (proximally excluded) n=28	3.005	2.021	Overall decrease in CIA size

During this surveillance CT imaging, additional aneurysms were identified in non-contiguous arterial segments in 21% of the 46 patients and 9% had multiple (>3) aneurysms. The most commonly detected aneurysms in order of decreasing frequency were CFA, proximal anastomotic and aortic root aneurysms. All aneurysms of the proximal anastomotic site were fusiform. The distribution of aneurysmal arterial segments is summarised in Fig: 5.

Fig: 5



## DISCUSSION

Our results showing an overall significant decrease in the size of CIAs, are in sharp contrast to most previous natural history studies. This finding was also seen in the subgroup of patients with proximally excluded CIAs (Anastomosis to EIA and CFA). In this primary study group, despite isolated increases in some CIA diameters, parametric t-test evaluation suggested an overall reduction in CIA size during follow-up. Contrary to other reports, it is unlikely that the lack of observed growth is related to gender. Ballotta et al suggested that including a large proportion of females may show blunted CIA growth due to their smaller calibre vessels<sup>7</sup>. This influence is unlikely in this study because females constituted only 19% of the study cohort. As stated the methods, some of the pre-operative CT scans were axial films and thus vessel measurements were done using manual callipers. This was in contrast to the electronic images in which electronic measuring tools were utilised. This could have resulted in inaccuracies of measurement and thus affecting the outcome of the observed reduction in iliac vessel diameters on subsequent follow-up. Since all measurements were performed by a single investigator, intraobserver variability could have affected the outcome of the study. We do not think that the overall observation of significant decrease in the size of CIAs could have been related to surgical technique as the iliac arteries proximal to the anastomotic sites were not ligated.

A subgroup analysis of the tube graft repair showed a significant mean CIA growth (2.6mm), which is almost similar to that described by other authors. The primary limitation of this study is the small sample size, only 120 of 165 patients had a baseline CT scan of which 46 patients obtained a postoperative CT scan and 88 CIA were available for comparative assessment. This study despite the consecutive series of patients is limited by its non-prospective, cross-sectional design (only one postoperative CT scan) with a widely variable duration of follow-up.

There is also some variation in the initial arterial measurements as some of the plain CT images required calliper measurements (instead of the electronic method). The accuracy of electronic measurements could have been improved by centre-line measurements utilising software such as 3-mensio (Pie Medical Imaging BV, Maastricht, Netherlands) and Osirix (Pixmeo, SARL). The above software tools which are commonly used in the sizing and planning of endovascular aneurysm repair (EVAR) may reduce the measurement errors associated with tortuous iliac arteries. However, despite the conflicting reporting standards for CIA sizes, adherence to the Ad Hoc Committee on Reporting Standards of the Society for Vascular Surgery and International Society of Cardiovascular Surgery reporting criteria ensured that our study is comparable to most of the recent CIA fate studies<sup>12</sup>.

It is very difficult to comment precisely on the evolution of the CIA size because only one postoperative CT scan was done and the interval between the initial and second CT scan is widely variable. There is only one study in the literature that prospectively investigated the fate of proximally excluded CIAs<sup>9</sup>. In this study, 32 patients had a bifurcated repair with anastomosis to the CFA. After a mean follow-up of 52 months, 5 aneurysmal CIAs thrombosed and 15 aneurysmal CIAs remained unchanged in size. Surveillance imaging showed a decrease in the size of some proximally excluded CIA (similar to our study), but the size reduction was not statistically significant. In addition to the initial small sample size in this study (32 patients), there was a high overall 4 year mortality of 45% further compromising comparative assessment.

Contrary to previous studies, there were no imaging criteria (aortic root, thoracic or visceral aortic size), that predicted the evolution of the CIA in our study<sup>7</sup>. Similarly, the initial size of the CIA was not predictive of growth. In keeping with the study by Conrad et al, postoperative CT imaging revealed aneurysms in other arterial segments<sup>13</sup>. These were mostly observed in the CFA, proximal anastomotic site and the aortic root. All proximal anastomotic site aneurysms were true fusiform dilatations in contrast to some observational studies in

which the majority were false aneurysms. Such an observation in our study could be due to an anastomosis being done on an enlarged but technically acceptable proximal neck. Two popliteal aneurysms were discovered on postoperative imaging, one of which was successfully repaired and the other thrombosed aneurysm managed expectantly.

The cause of death could not be established in more than 20% of late deaths. Similar to the concerns of Kalman et al, we cannot exclude iliac aneurysm rupture in that group of patients<sup>3</sup>. The 46 patients in whom a second CT scan was possible may therefore represent a significant selection bias explaining the lack of CIA growth in the overall cohort. The growth rate of CIAs following tube graft repair has not been clearly defined in most studies. Kasirajan et al (1998) and Dosluoglu et al (1999) reported no CIA growth over after a mean follow-up of 5 years in CIAs between 21 and 27mm<sup>14, 15</sup>. However due to the small sample sizes (9 patients in each study), it is difficult to make any solid conclusions. Kalman et al obtained a follow-up CT scan for 39 patients following tube graft repair of AAA<sup>3</sup>. After a mean follow-up of 129 months, the rate of post operative iliac aneurysms was 30.8%. However the true natural history was difficult to ascertain in this study because of the unavailability of preoperative CIA measurements.

Sala et al performed post operative imaging on 74 male patients after tube graft repair<sup>16</sup>. They reported 32 patients (43.2%) with enlargement of at least one CIA, of which 13 (17.6%) were ectatic and 19 (25.6%) were aneurysmal. Over a mean follow-up of 6 years, only 2 patients (2.7%) needed re-intervention. Based on these findings, they recommended tube graft repair for CIA less than 18mm and bifurcated repair for any CIA above that 18mm threshold required. However, Ballotta et al in their prospective natural history study had contrasting recommendations to the above<sup>7</sup>. They prospectively examined iliac arteries after tube graft repair in patients with CIA less than 25mm. A total of 201 patients were divided into 3 CIA size groups of normal, ectatic and aneurysmal in keeping with the Ad Hoc Committee on Reporting Standards of the Society for Vascular Surgery and International Society of Cardiovascular Surgery. There were 92 patients (45.8%) with normal arteries, 63 (31.3%) with at least one ectatic CIA and 46 (23.9%) with at least one aneurysmal CIA. Over a mean follow-up of 7.4 years, 5% of patients progressed from normal to ectatic and 10% from ectatic to aneurysmal CIAs. Only 3 patients with initially aneurysmal CIAs progressed to a diameter > 25mm. This led them to the conclusion that tube graft repair was a safe option in ectatic and mildly aneurysmal CIA.

Most reports suggest that CIA growth rate is influenced by the initial CIA diameter, with the fastest growth observed in aneurysmal iliac vessels. Such findings were reported by Hassen-

Khoja et al on a study of 147 tube graft repairs with a mean follow-up of 4.8 years and an overall CIA growth rate of 0.33mm/year<sup>8</sup>. One of the best CIA growth estimates is from Ballotta et al, with a growth rate of 0.16mm/year in normal arteries to 0.32mm/year in aneurysmal CIAs<sup>7</sup>. Santilli et al analysed a series of 323 CIA aneurysms in 189 patients with a mean follow-up of 31.4 months<sup>17</sup>. They observed a growth rate of 0.5 – 1.5mm/year in CIA of 3cm or less this growth rate increased to 2.6mm/year in CIA 3-5cm in diameter. In contrast, in our study the tube graft repair subgroup with significant CIA growth has a progression estimate of 0.73mm/year which is almost double the projected estimate of CIA growth. Unfortunately, due to the small sample in the tube graft repair group (13 patients; 26 CIAs), it is difficult to determine the effect of initial CIA size on future growth. Tube graft repair reduces the complexity of the operation and associated morbidity and in most cases is the preferred conduit for reconstruction. The above series had a high rate of bifurcated repairs (65% of repairs) likely due to the higher frequency of associated iliac aneurysmal or occlusive iliac disease.

## **CONCLUSION**

Open bifurcated AAA repair with proximal exclusion of CIA appears safe and effective in the intermediate and long term follow-up as shown in our series. On the other hand, open tube graft repair is associated with significant future CIA growth although this is not associated with risk of re-intervention. A late follow-up CT scan (5 years post surgery) is recommended to detect metachronous aneurysms including the fate of iliac arteries.

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# APPENDIX 1: Departmental Research Committee Approval



UNIVERSITY OF CAPE TOWN

## Department of Surgery

### Departmental Research Committee

**Professor Anwar Suleman Mall**

J-45 Room Old Main Building, Groote Schuur Hospital,  
Observatory 7925, South Africa

Tel (021) 406 6168/6232/6227 Fax (021) 448 6461

Email: [Anwar.Mall@uct.ac.za](mailto:Anwar.Mall@uct.ac.za)

25<sup>th</sup> September 2014

Dr B Dube  
Department of Surgery  
Groote Schuur Hospital  
University of Cape Town

Dear Dr Dube,

**RE: PROJECT 2014/091**

**PROJECT TITLE: The fate of proximally excluded ectatic or aneurysmal iliac arteries following bifurcated open abdominal aortic aneurysm repair**

The above proposal was reviewed by the Department of Surgery Research Committee and I am pleased to inform you that the committee approved the study.

Please use the above project number in all future correspondence.

Yours sincerely

**PROFESSOR ANWAR S MALL  
CHAIRMAN: RESEARCH COMMITTEE**

"OUR MISSION is to be an outstanding teaching and research university,  
educating for life and addressing the challenges facing our society."

## APPENDIX 2: Human Research Ethics Committee Approval



UNIVERSITY OF CAPE TOWN  
Faculty of Health Sciences  
Human Research Ethics Committee



Room E52-24 Old Main Building  
Groote Schuur Hospital  
Observatory 7925  
Telephone [021] 406 6338 • Facsimile [021] 406 6411  
Email: [sumayah.artefdien@uct.ac.za](mailto:sumayah.artefdien@uct.ac.za)  
Website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms)

16 October 2014

**HREC REF: 756/2014**

**Dr N Naidoo**  
Vascular Surgery  
E-22  
Vascular Lab  
NGSH

Dear Dr Naidoo

**PROJECT TITLE: THE FATE OF PROXIMALLY EXCLUDED ECTATIC OR ANEURYSMAL ILIAC ARTERIES FOLLOWING BIFURCATED OPEN ABDOMINAL AORTIC ANEURYSM REPAIR (Mphil-candidate-Dr B Dube)**

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

Before approval is granted, please address the following:

- Please supply an Informed Consent document as per HREC SOP and SA GCP guidelines.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

***We acknowledge that the following student: Dr Bhekifa Dube is also involved in this project.***

**Please quote the HREC reference no in all your correspondence.**

Yours sincerely

**PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE**

Hrec/ref:756/2014

## APPENDIX 3: Patient Consent Form

### Consent Form for Participation in a Research Study (HREC REF 756/2014)

<b>Name of Researcher(s)</b>
<b>Dr Nadraj Naidoo</b> (Principal Investigator) Contact: <b>email:</b> nadraj.naidoo@uct.ac.za <b>Cell:</b> 083 262 8651 E22 Vascular Lab Groote Schuur Hospital Ext 3324 <b>Dr Bhekifa Dube</b> (Co-Investigator)
<b>Title of study</b>
The fate of proximally excluded ectatic or aneurysmal iliac arteries following bifurcated open Abdominal Aortic Aneurysm repair.

Please read and complete this form carefully. If you are willing to participate in this study, ring the appropriate responses and sign and date the declaration at the end. If you do not understand anything and would like more information, please ask.

- I have had the research satisfactorily explained to me in verbal and / or written form (Synopsis) by the researcher.
YES / NO
- I understand that the research will involve: *(Review of my clinical records with collection of information relating to the repair of my abdominal aortic aneurysm. As part of routine clinical follow-up, I will undergo an ultra-sound/CT scan and the results will be used as part of the study.*
YES / NO
- I understand that I may withdraw from this study at any time without having to give an explanation. **This will not affect my future care or treatment.**
YES / NO
- I understand that all information about me will be treated in strict confidence and that I will not be named in any written work arising from this study.
YES / NO
- I understand that you will be discussing the progress of your research with others at Groote Schuur Hospital/University of Cape Town.
YES / NO

I freely give my consent to participate in this research study and have been given a copy of this form for my own information.

Name of Participant	Date	Signature
---------------------	------	-----------

Name of Researcher	Date	Signature
--------------------	------	-----------

For Further Information Regarding The Study Please Contact:

Human Research Ethics Committee  
 Room E52 – 24 Old Main Building  
 Groote Schuur Hospital  
 Observatory  
 7925

**Tel:** (021) 406 6338  
**Facsimile:** (021) 406 6411  
**Email:** sumayah.ariefdien@uct.ac.za

## APPENDIX 4: DATA COLLECTION SHEETS

Patient Demographics (Left Panel)	Patient Demographics (Right Panel)
<p><b>Name of patient *</b></p> <p>Name</p> <hr/> <p><b>Life Status</b></p> <p>Unknown</p> <hr/> <p><b>2nd CT Booking</b></p> <p>Not Booked</p> <hr/> <p><b>Hospital Number</b></p> <p>Hospital Number</p> <hr/> <p><b>Date of Birth</b></p> <p>[Greyed out]</p> <hr/> <p><b>Age</b></p> <p>[Spinner]</p> <hr/> <p><b>Sex *</b></p> <p>M</p> <hr/> <p><b>Race</b></p> <p>White</p>	<p>Not Booked</p> <hr/> <p><b>Hospital Number</b></p> <p>Hospital Number</p> <hr/> <p><b>Date of Birth</b></p> <p>[Greyed out]</p> <hr/> <p><b>Age</b></p> <p>[Spinner]</p> <hr/> <p><b>Sex *</b></p> <p>M</p> <hr/> <p><b>Race</b></p> <p>White</p> <hr/> <p><b>Email address</b></p> <p>email</p> <hr/> <p><b>Telephone</b></p> <p>Tel [Spinner]</p>

Patient Comorbidities (Left Panel)	Patient Comorbidities (Right Panel)
<p><b>BMI</b></p> <p>19 -25</p> <hr/> <p><b>Recent Weight Loss</b></p> <p>None</p> <hr/> <p><b>ASA *</b></p> <p>★ ★ ★ ★ ★</p> <hr/> <p><b>Smoker</b></p> <p>No</p> <hr/> <p><b>Hypertensive</b></p> <p>No</p> <hr/> <p><b>Diabetic</b></p> <p>No</p> <hr/> <p><b>Dyslipidaemia</b></p> <p>No</p> <hr/> <p><b>HIV status</b></p> <p>Negative</p>	<p><b>Arrhythmia</b></p> <p>No</p> <hr/> <p><b>Cerebrovascular Disease</b></p> <p>No</p> <hr/> <p><b>Peripheral Arterial Disease</b></p> <p>No</p> <hr/> <p><b>Renal Dysfunction</b></p> <p>No</p> <hr/> <p><b>COPD</b></p> <p>No</p> <hr/> <p><b>CCF</b></p> <p>No</p> <hr/> <p><b>Drug History I</b></p> <p>[Greyed out]</p> <hr/> <p><b>Additional Aneurysms</b></p> <p>[Copied to clipboard]</p>

15:06

✓ DONE CANCEL

COMORBIDITIES OPERATIVE DETAILS OPERATIVE OUTCOME

**Epidural**  
No

**Skin Incision**  
Midline

**Left Renal Vein Ligation**  
No

**Proximal Clamp**  
Infra-renal

**Graft Configuration**  
Tube

**Distal Target**  
Aorta

**Inferior Mesenteric Artery**  
Occluded

**Estimated blood loss**  
< 200ml

**Intra - op Transfusion**

15:06

✓ DONE CANCEL

COMORBIDITIES OPERATIVE DETAILS OPERATIVE OUTCOME

**Left Renal Vein Ligation**  
No

**Proximal Clamp**  
Infra-renal

**Graft Configuration**  
Tube

**Distal Target**  
Aorta

**Inferior Mesenteric Artery**  
Occluded

**Estimated blood loss**  
< 200ml

**Intra - op Transfusion**  
0 units

**Indication**  
Large AAA

15:07

✓ DONE CANCEL

OPERATIVE DETAILS OPERATIVE OUTCOME LABORATORY INVESTIGATIONS

**Inotropes**  
No

**Post op blood Transfusion**  
0 units

**Post op Renal Dysfunction**  
No

**Return to OR**  
No

**Myocardial Infraction**  
No

**Post op CVA**  
No

**DVT/Pulmonary Embolus**  
No

**Urinary tract infection**  
No

**Pneumonia**

15:07

✓ DONE CANCEL

OPERATIVE DETAILS OPERATIVE OUTCOME LABORATORY INVESTIGATIONS

**DVT/Pulmonary Embolus**  
No

**Urinary tract infection**  
No

**Pneumonia**  
No

**Re - intubation**  
No

**Wound Sepsis**  
No

**Length of ICU stay**  
ICU stay [↑] [↓]

**Length of Hospital Stay**  
Hospital stay [↑] [↓]

**Final patient disposal**  
Discharged home

15:07

✓ DONE CANCEL

OUTCOME LABORATORY INVESTIGATIONS FIRST DUP

**White Blood Count**

WBC ^ v

**Haemoglobin**

hb ^ v

**platelets**

plts ^ v

**haematocrit**

hct ^ v

**sodium**

na ^ v

**Potassium**

k ^ v

**urea**

urea ^ v

15:08

✓ DONE CANCEL

OUTCOME LABORATORY INVESTIGATIONS FIRST DUP

**creatinine**

creat ^ v

**cholesterol**

chol ^ v

**low density lipoprotein**

LDL ^ v

**high density lipoprotein**

LDL ^ v

**Fasting Glucose**

gluc ^ v

**HbA1c**

HbA1c ^ v

**INR**

INR ^ v

15:08

✓ DONE CANCEL

OUTCOME LABORATORY INVESTIGATIONS FIRST DUP

**Syphilis serology**

Negative ^

**Salmonella serology**

salmonella serology ^

**TEG parameters**

MA ^

**GFR**

GFR ^ v

**ERNA**

ERNA ^ v

**FEV1**

FEV1 ^ v

**Aortic wall microbiology**

aortic wall microbiology ^

**aortic wall histology**

aortic wall histology ^

15:09

✓ DONE CANCEL

STIGATIONS FIRST DUPLEX ASSESSMENT SECOND DU

**AAA size**

AAA size ^ v

**Duplex CIA Right size**

Right ^ v

**Duplex CIA Left size**

Duplex ^ v

**Duplex EIA size Right**

Duplex ^ v

**Duplex EIA size Left**

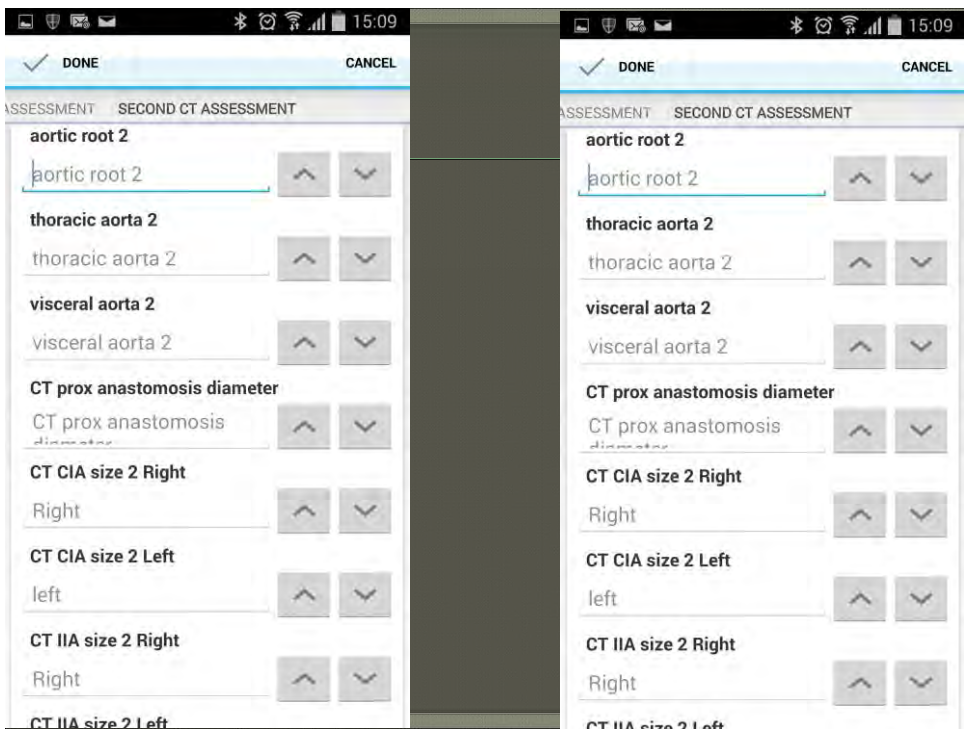
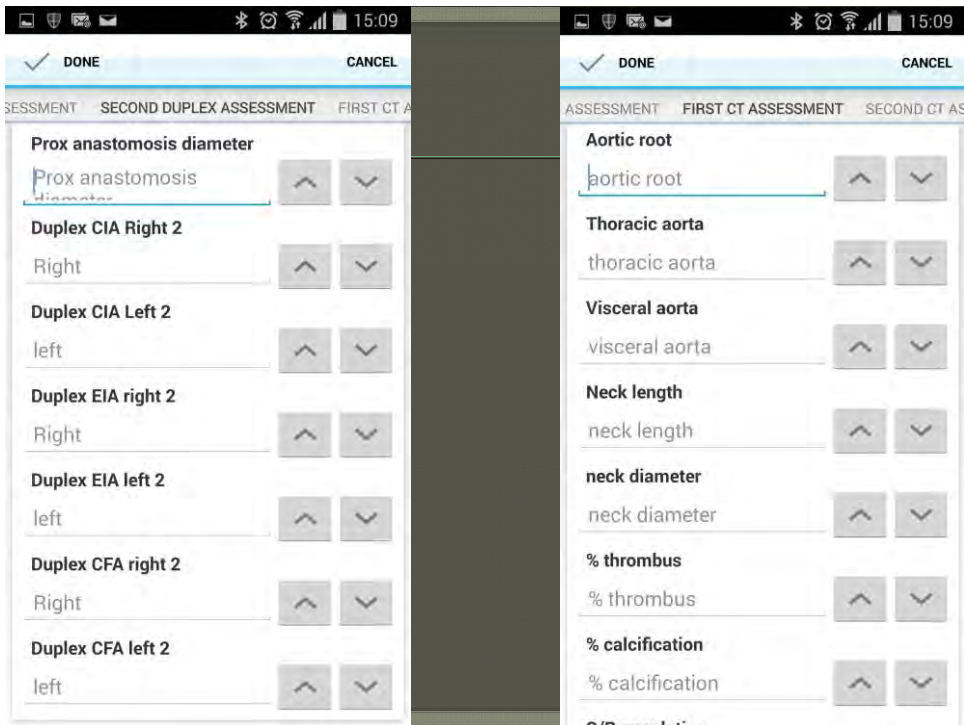
Duplex ^ v

**Duplex CFA size Right**

Duplex ^ v

**Duplex CFA size Left**

Duplex ^ v



## APPENDIX 5: Instructions For Authors



Before submitting a manuscript to the Journal of Vascular Surgery Publications, you must review the instructions listed below. Submitted manuscripts will be considered for publication in either the Journal of Vascular Surgery, the Journal of Vascular Surgery: Venous and Lymphatic Disorders, or the Journal of Vascular Surgery Cases. If your manuscript is selected for publication in the Journal of Vascular Surgery: Venous and Lymphatic Disorders you will be charged a fee for the color images included in your paper. The Publisher will collect this fee, which will be US \$650.00 for the first color image and US \$150.00 for each additional color image. Unless your figures are sufficiently complex to merit color, please submit charts and graphs in black and white. If your manuscript is accepted for the Journal of Vascular Surgery Cases, you will be charged a US \$500 publication fee.

Journal."

### Institutional Review

Manuscripts that involve research conducted on human subjects must follow the principles outlined in the Declaration of Helsinki (<http://www.wma.net/en/30publications/10policies/b3>) and include a statement in the Methods section stating that the experimental protocol and informed consent were approved by the Institutional Review Board, and that all subjects gave informed consent. Manuscripts that report animal experiments must include a statement in the Methods section stating that the study was approved by the Institutional Review Board and that the animal care complied with the Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council. Washington: National Academy Press, 1996 ([http://nap.edu/openbook.php?record\\_id=5140](http://nap.edu/openbook.php?record_id=5140)).

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In accordance with the International Committee of Medical Journal Editors (ICMJE), the Journal of Vascular Surgery Publications requires that clinical trials be registered in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. Relevant trials that began before July 1, 2007 must

be registered prior to editorial review. Registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or in ClinicalTrials.gov is acceptable. Registration must be indicated by providing the unique study number assigned by the approved registry on the Application for Publication form.

A CLINICAL TRIAL is defined by the ICMJE as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome.

HEALTH-RELATED INTERVENTIONS are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.

HEALTH OUTCOMES are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Detailed instructions and a tutorial for registering a trial are available at: <https://clinicaltrials.gov/ct2/manage-recs/how-register>.

Authors of unregistered trials, or those with inadequate information in the registry, will be given an opportunity to explain the reason that they failed to comply with this requirement, but it is expected that studies that fit the definition of a clinical trial be registered regardless of the country of origin since these rules are international.

More information about the ICMJE policies on Clinical Trial Registration are available at: <http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>.

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#### General Submission Guidelines

Using Our Online Submission Software. All new and revised manuscript files, required forms, and associated content must be submitted electronically through Editorial Manager (online at: <http://www.editorialmanager.com/jvs/default.asp>). Authors must be registered on the Editorial Manager web site. Use of Editorial Manager to upload submissions requires an internet connection, a valid email address, Adobe Acrobat Reader (free download at <http://www.adobe.com/products/acrobat/readstep2.htm>, and Microsoft Word 2003 - 2010. Complete submission instructions are provided on the Editorial Manager web site. Please note that all original and revised submissions formats and inclusions must be in accordance with the Information for Authors. Manuscripts that do not meet all submission requirements will be returned to the author for correction.

To upload a manuscript using Editorial Manager, authors must provide the following information during the submission process:

- a concise, informative, declarative title of the manuscript (Please review title

guidelines)

- the preferred name(s), initials, and surname of the author(s) and their highest earned academic degrees, listed in the order that these should appear if the manuscript is published
- departmental and institutional affiliations of each author
- a completed Application for Publication, including all financial or material support provided to the authors
- society notation (if applicable): the meeting, date, and place where the paper was presented
- the name, mailing and email address of the person to whom correspondence is to be addressed
- the name, mailing and email address of the author to whom requests for Reprints should be addressed (if Reprints will be available)

Electronic forms required for submission (click on each to go to form)

#### Application for Publication

This form is used to collect many important pieces of information, and is required for all submissions. This form must be completed by the Corresponding Author, and reviewed and approved by each author. The information collected on this form is provided to reviewers and Editors assigned to review the manuscript. A Competition of Interest Statement will be published with each accepted Basic and Clinical Research article based on the information provided on this form. Authors are required to specify their roles and meet the requirements for authorship, as listed in the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (<http://www.icmje.org/icmje-recommendations.pdf>). These requirements state that each author must contribute to a manuscript in each of the following areas:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

#### Identifiable Patient Consent Form (if applicable)

This form is required if your manuscript includes data which might reveal the identity of one or more patients.

#### Case Report Patient Consent Form (if applicable)

This form is required for ALL Case Report and Vascular Image submissions. If your institution has a standard form to obtain publication consent, that form may be used in place of this document. Consent forms do NOT need to be submitted with your manuscript files, but must be available upon request by the Editorial Office. A

statement regarding the patient(s') consent MUST be included in the text of your manuscript.

### Reviewer Response form (revisions)

#### Formatting Your Manuscript

Text formatting instructions. All text files must be prepared using: Microsoft Word, double spaced with Times New Roman 12-point font. Manuscripts must conform to standard English usage and are subject to editing in conformance with the policies of the Journal. For reference, authors may consult the American Medical Association's Manual of Style (AMA Manual of Style: A Guide for Authors and Editors. Iverson C, Christiansen S, Flanagin A, et al. 10th ed. New York: Oxford University Press, 2007) (AMA-10). The following changes have been made from the 9th edition of the AMA Manual of Style.

- Abbreviations no longer include periods (i.e., Dr, e.g., US, Jr, St, Rd)
- A capital P is now used for probability, and no zero is used before the decimal when the figure cannot exceed 1 ( $P < .007$ )
- The new style uses new abbreviations for some units of measure (L, liter; in, inch; ft, foot; yd, yard; mol, mole; mol/L, molar)
- Units of time in virgule constructions or tables are now abbreviated (ms, millisecond; s, second; min, minute; h, hour; d, day; wk, week; mo, month; y, year;)
- Units that are used as adjectives are now hyphenated (8-mL container, 10-cm visual analog scale)
- Instead of the use of superscript footnote symbols in tables (e.g., \*, †, ‡ §) AMA-10 uses superscript, italic, lowercase letters (e.g., a, b, c, d)
- For journals that haven't codified a style for electronic references, the AMA-10 contains approximately 50 examples of electronic references
- The abbreviations "Jr" and "Sr" are no longer set off by commas (e.g., Morton Menaker Sr, MD, performed the data analyses). Academic degrees are still set off by commas, as shown in the preceding example
- New rules for capitalization of computer terms and inter-capped compounds are provided
- E-mail only takes an initial capital when it begins a sentence; otherwise it takes a lowercase (e.g., e-mail)
- Trade name spellings are retained, even if they begin with a lowercase letter or contain internal caps (e.g., eBay, iBook, MiniPrep)
- A new subsection has been added to the grammar chapter that details samples of idioms, colloquialisms, slang, euphemisms, and clichés

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Generic drug names from the United States Adopted Name (USAN) should be used. Proprietary drug names may be cited in parentheses. Generic equipment names should be used whenever possible, and the proprietary name of the equipment must be cited in parentheses after the proprietary name. Cite the manufacturer and the city, state, and country of manufacture. Measurements of height and weight, etc., should be stated in metric units. Hematologic and clinical chemistry measurements can be stated

in System International (SI) units or non-SI units. Note that SI units are recommended in the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (<http://www.icmje.org/icmje-recommendations.pdf>). Only standard abbreviations should be used; avoid unusual or coined abbreviations. The first time any abbreviation is used it should be included in parentheses after the words it replaces. Abbreviations should not be used in the title or abstract.

Manuscripts should conform to the guidelines for reporting on vascular surgery. The following have been developed by the Ad Hoc Committee on Reporting Standards and accepted by The Society for Vascular Surgery:

- Venous severity scoring: An adjunct to venous outcome assessment. *J Vasc Surg* 2000;31:1307-12
- Recommended standards for reports dealing with lower extremity ischemia: Revised version. *J Vasc Surg* 1997;26:517-38
- Reporting standards in venous disease. *J Vasc Surg* 1988;8:172-81
- Reporting standards in venous disease: an update. *J Vasc Surg* 1995;21:635-45
- Suggested standards for reports dealing with cerebrovascular disease. *J Vasc Surg* 1988;8:721-9
- Suggested standards for reporting on arterial aneurysms. *J Vasc Surg* 1991;13:452-8
- Standards in noninvasive cerebrovascular testing. *J Vasc Surg* 1992;15:495-503
- Reporting standards for lower extremity arterial endovascular procedures. *J Vasc Surg* 1993;17:1103-7
- Recommended standards for reports dealing with arteriovenous hemodialysis accesses. *J Vasc Surg* 2002;35:603-10
- Reporting standards for endovascular aortic aneurysm repair. *J Vasc Surg* 2002;35:1048-60
- Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair. *J Vasc Surg* 2002;35:1061-6

Title page. A complete title page is required for all submissions and must appear at the beginning of the manuscript file. The title page must include:

- Title (please see guidelines below)
- All author names and corresponding institutions in the order in which they should appear in the final printed article
- Complete contact information for the corresponding author
- Presentation information (if applicable). Example: This study was presented in the plenary International Forum at the 2014 Vascular Annual Meeting of the Society for Vascular Surgery, Boston, Mass, June 5-7, 2014.

Title. Titles must be concise and accurately reflect the content of the manuscript. Furthermore, titles should be declarative, stating the topic and results when possible, rather than posing a question. This is important for assisting clinicians and researchers in locating an article on Medline once it has been published. Please make sure that your title:

- IS NOT in the form of a question.
- DOES NOT include "The First..." since these statements can not always be verified.
- DOES NOT include a colon or any other punctuation to make it two parts.
- DOES NOT Restate the article type: i.e. Case Report, Review etc.
- DOES NOT State the type of statistical analysis, i.e. Multivariate Analysis.
- DOES NOT include your institution Name.

Abstract. A structured abstract is required for all manuscripts except case reports and technical notes (both of which require a shorter, non-structured abstract), vascular images, special articles, editorials, and presidential addresses. Please include the abstract after the title page in the manuscript file. The abstract replaces the summary and ordinarily should clearly state, in approximately 250 words (but never more than 400 words), the main factual points of the article. The abstract should be informative, not descriptive. Detailed results should be included in the abstract because many readers only have access to abstracts and not the entire article. A structured abstract will include combinations of the following headings that apply and are informative, as described in detail in previous publications:

Haynes RB, Mulrow CD, Huth EJ, Altman DG, Gardiner MJ. More informative abstracts revisited. *Ann Intern Med* 1990;113:69-76

Ad Hoc Working Group for Critical Appraisal of the Medical Literature. A proposal for more informative abstracts of clinical articles. *Ann Intern Med* 1987;106:598-604

Typical abstract headings include:

- Objective: including a precise statement of the exact question(s) addressed by the study and, if appropriate, the hypothesis
- Methods: the basic study design and setting (ie, community referral center, ambulatory or hospitalized patients), the patient/subject selection method and number, eligibility criteria, proportion withdrawn, and the exact treatment or interventions
- Results: main outcome measure(s), the main results should be stated with statistical significance
- Conclusions: only conclusions supported by the study and their clinical application may be stated

Tables, figures, reference citations, and trademarked names should not appear in the abstract. Because many readers only have access to the abstract, it is essential that it contain numerical results and not simply summary conclusions.

Manuscript body

The manuscript file must include the title page, abstract, manuscript, and references. The usual sections for a full basic or clinical science manuscript include Introduction, Methods, Results, Discussion and Conclusion. Subheadings may be useful and help clarify the content in longer papers. Methods must be described in sufficient detail to allow others to reproduce the work. For established methods, appropriate references and a brief description are sufficient; but for new methods, appropriate details are

required. (NOTE: Please do not include statements that claim that this is the first time a procedure has been performed, reported, etc., as these claims are difficult to verify and may not be accurate.) If the description of the method is very long, the techniques should be summarized and referenced and the details provided as an appendix that will be published on the internet but not in print. For human studies, the following details are generally important: eligibility (inclusion and exclusion criteria), randomization methods, blinding methods, total consecutive patients enrolled, and number of exclusions or drop outs and reasons. For randomized controlled trials, the CONSORT document provides reporting guidelines that should be met in articles submitted to the Journal:

See Moher D, Schultz ICF, Altman DG for the CONSORT group. The CONSORT statement: revised recommendation improving the quality of reports of parallel group randomised trials. *Lancet* 2001;357:1191-4. Full details are available at <http://www.consortstatement.org/>. This article provides a checklist of the items that should be included in the report of the methods, results and discussion and the suggested details of a flow diagram that provides information on patient flow through the study. Observational studies should include these details as well.

Standards have been published that provide guidelines for reporting meta-analyses of the randomized controlled studies: See Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of randomized controlled trials: the QUORUM statement. *Lancet* 1999;354:1896-900.

Reporting standards have been published that provide guidelines for observational studies: See Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Metaanalysis of Observational Studies in Epidemiology [MOOSE] group. *JAMA* 2000;283:2008-12.

#### Redline manuscript (revisions)

A redline manuscript is required for all revised submissions and must meet all of the formatting requirements of the non-redlined manuscript. The redline manuscript must include the abstract and title page. The redline manuscript must be created using "Track Changes" in Microsoft Word, and must show every change that has been made in the revision. Manually highlighting, underlining or otherwise indicating the changes made is not sufficient. Detailed instructions about how to create a redline document may be found [here](#).

#### Illustrations (figures, charts, graphs)

Limit illustrations to those that amplify, and do not duplicate the text. A reasonable number of line or halftone illustrations will be reproduced. You may not submit more than the maximum number of figures permitted for the selected article type. Please review the instructions for the specific article type before proceeding. Inclusion of color illustrations is at the discretion of the Editor. Operative and pathology photographs should be in color. Other figures and charts should be black and white unless sufficiently complex to require color. Original drawings or graphs should be

prepared by computer software or by a professional artist.

All images must be submitted electronically via the Editorial Manager system as separate numbered files. Number your figures consecutively in Arabic numerals according to the order of citation in the text. All figures must be cited. This includes images that are intended to be “online only” appendices. (Example: Figure 1A, Figure 1B, Figure 2, Supplemental Figure 1, Supplemental Figure 2). TIFF, JPEG, and EPS files must have a resolution of at least 300 DPI at 3 inches wide. Microsoft Word and PowerPoint files are acceptable, as long as the illustration spans at least 3 inches in the document, the image is sharp, and all text is legible. Lettering or text used in the illustration must be at least 8-point font. Submissions that include figures that are embedded in the text of the manuscript, or that include figures that are compiled in one file, will be returned to you for correction. During the submission process, illustrations will undergo an Artwork Quality Check which will not function properly unless the images are uploaded as separate files.

When you submit files, please pay attention to the results of the Artwork Quality Check. If the results of the check indicate "pass", your image files are acceptable. If your results are "pass with warning", this does not necessarily mean that your figures are acceptable. To determine whether or not your illustrations will be acceptable for publication, note the number located in the top right-hand corner of the Artwork Quality Check results page. The resolution of each figure will be calculated at a size of 18 picas (3 inches) wide. If the resolution is 300 DPI or greater at a size of 18 picas (3 inches), it is appropriate for submission. Images that are less than 300 DPI at a width of 18 picas are unacceptable. You must correct your figures before proceeding. If you fail to improve the figure quality and you submit your manuscript, the submission will be returned for correction. For assistance, contact the Editorial Office at: [jvascsurg@vascularsociety.org](mailto:jvascsurg@vascularsociety.org).

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Previously published images. If a figure has been previously published, the legend must give full credit to the original source, and a letter from the original source giving permission to reproduce the figure must be uploaded with the submission. Submissions with previously published images that are not accompanied by an original written permission document will be returned to the author.

Life table graphs. Lines should be truncated when the standard error exceeds 10% and should have the "n" for each group at relevant time points along the x-axis. Because life table graphs are preferred for in-text inclusion, data tables should be submitted only for the online version of the manuscript if the authors desire to provide this level of detail.

Illustration figure legends

Legends must be numbered, double spaced and uploaded in a separate document file. Indicate original magnification and stain for photomicrographs.

## Video clips

If accepted, videos will be published on the Journal Web site. Videos must be uploaded in either a QuickTime or MPEG format. Authors who want their videos accessible in a streaming format must also provide either a single SureStream file or three uniquely named single-rate clips (28.8, 56, T1) with an SMIL file to list the bandwidth choices. Video clips must meet production quality standards to be published on the web without modifications or editing by the editorial office. Authors should consider adding narration or explanatory captioning to video demonstrations of new techniques and procedures. The Journal can accept only video submissions that meet the Journal's formatting and image quality requirements. Authors will be notified if there are any problems with submitted files and asked to resubmit modified files. Image editing and correct formatting are the author's responsibility. Video clips accepted for publication will be posted to the Journal's Web site in both non-streaming format such as QuickTime and MPEG for optimal image quality and in a streaming video format for those who prefer faster downloading.

## Tables

Tables should supplement, not duplicate, the text. Results should not be summarized in a table; use a graph instead. Number your tables consecutively in Roman numerals according to the order of citation in the text. All tables must be cited, including tables intended to be supplemental "online only". Example: (Table I, Table II, Supplemental Table I, Supplemental Table II.) Because tables should be self-explanatory, provide a brief caption for each table. Tables must be created in a Microsoft Word using 12 pt. Times New Roman font. Double space your tables and upload them to Editorial Manager. Tables may be uploaded together in one Word document, with each table starting on a new page, or in separate files. They may not be embedded in manuscript document. Manuscripts with tables that do not meet these requirements will be returned to the author.

Abbreviations used in the table should be explained in a footnote; however, abbreviations that have been defined in the body of the text do not need to be spelled out or explained in the table. If a table or any data therein have been previously published, a footnote in the table must give full credit to the original source, and the original Publisher's permission to reproduce the table must be provided.

## References

Cite references selectively (using no more than 40); an extensive literature review is rarely necessary and only pertinent references should be given, (i.e., those that provide the basis for a key statement). References should be cited consecutively in the text by superscript Arabic numbers in the order in which they are first mentioned in the text, a table, or a figure. References should not be cited alphabetically. The reference list should be double spaced. References to articles in press must include authors' names, title of article, and name of journal. Personal communications and unpublished data are not to be cited as references; instead, indicate these sources in the text at the appropriate place and include the individual's preferred given name, initials, surname, title, city, and year of communication. A note of approval from the source for the statement should be appended to the manuscript. Make sure all

references have been verified. The accuracy of the references, including spelling of references in foreign languages, is the responsibility of the authors and is crucial so that they can be linked to the original citation in the web version. Authors should be certain that all references use the standard abbreviated journal names according to Index Medicus. This is imperative to ensure linking of references in the online version of the Journal. References that do not use the standard abbreviated journal names will not link. If there are six or fewer authors, list all; if seven or more, list only the first six, then et al. The format for references is described in detail in "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (<http://www.icmje.org/icmje-recommendations.pdf>). Examples follow:

- Format for journal articles: Josa M, Khuri SF, Braunwald NS, VanCisin MF, Spencer MP, Evans DA, et al. Delayed sternal closure: an improved method of dealing with complications after cardiopulmonary bypass. *J Thorac Cardiovasc Surg* 1986;91:598-603.
- Format for books: Berger HJ, Zaret BL, Cohen LS. Cardiovascular nuclear medicine. In: Goldberger E, editor. *Textbook of clinical cardiology*. 1st ed. St Louis: CV Mosby; 1982. p. 326-45

#### Society Notation

During the submission process, authors whose papers have been presented at a sponsoring society meeting must choose their sponsoring society and year of presentation from the available drop-down menu. An option of 'none' may be chosen by those authors whose submissions are not affiliated with a sponsoring society.

#### Statistical analysis

For manuscripts that contain statistically-analyzed data, please identify the co-authors responsible for the statistical analysis in the "Author Contributions" section of the Application for Publication. Please include the names of individuals who provided statistical analysis, but who do not meet the criteria for authorship, in an acknowledgement paragraph at the end of the manuscript.

#### Patient consent

Special care must be taken to exclude photographs/images that contain identifiable individual characteristics such as eyes, case numbers, initials, etc. Photographs of identifiable individuals must be accompanied by a completed Identifiable Patient Consent Form. This form must bear the signature of identifiable patients/volunteers. In cases where the patient/volunteer is a minor or incapable of signing the consent form, the signature of both living parents or guardians is required. This form must be uploaded with the manuscript files in Editorial Manager at the time of submission.

Patient consent is required for all Case Reports and Vascular Images submitted to our Journals. A statement regarding this consent must be included in the Case Report introduction and in the text of the Vascular Image. The authors must be able to provide consent forms if requested by the Editorial Office, but they are not required to upload them in Editorial Manager. If your institution does not have a standard

publication consent form, you may use the [Case Report Patient Consent Form](#).

## Requirements for Specific Submission Types

### Submission Limits for All Article Types

Type + Max Authors	Abstract (Words)	Body (Words)	Figures	Tables	Pages	References
Basic Research (8)	250-400	3200-3500	1 per page	1 per page	25	40
Clinical Research (8)	250-400	3200-3500	1 per page	1 per page	25	40
Case Report (6)	100	1200	3	0	12	20
Vascular Image (4)	N/A	350	4	0	1	3
Letter to the Editor (6)	NA	500	1	1	2	6
Review Article (8)	250-400	3500-5000	1 per page	1 per page	30	40
Vascular and Endovascular Techniques (6)	100-150	1200	1 per page	1 per page	16	10
Practice Management (6)	150-200	3000	1 per page	1 per page	20	30
Debates (2)	150-200	3500	1 per page	1 per page	30	40
Clinical Trial Update (6)	150-200	1000	1 per page	1 per page	10	20
Evidence Summary(6)	150	1500	Fig+Tab=5	Fig+Tab=5	15	30
Historical Vignette (3)	NONE	2500	3	3	20	15
Education Corner (8)	250-400	3200-3500	1 per page	1 per page	25	40

## Basic and Clinical Research

Basic Research Articles do not include human clinical information but may include those studies in which only group samples of human blood or tissue are used and the results/conclusions are research oriented.

- **Clinical relevance paragraph.** For Basic Research articles, the Journal requires a 100-word paragraph that describes the clinical relevance of the paper as it relates to its current or future clinical application. This paragraph will be printed immediately below the conclusion section of the abstract of the article but will not be included in the abstract that is available on Medline. The purpose of this section is to encourage clinical surgeons to read this work and to help them understand its significance.

Clinical Research articles involve human clinical information, descriptions of patient populations, and clinical applicability results/conclusions.

**Case Reports.** Case Reports will be considered for publication exclusively in the new Journal of Vascular Surgery: Cases. The publication fee is US \$500.00 for this online-only, open access, Journal. In return the copyrights for the published case will remain the property of the authors. Fees are not required until after manuscript acceptance. A Case Report will be only be considered for publication if it describes a new disease, important original observation, or a unique technical approach and succinctly reviews

the relevant literature. (NOTE: Please do not include statements that claim that this is the first time a procedure has been performed, reported, etc., as these claims are difficult to verify and may not be accurate.) Case Reports should not exceed 1200 words, three figures, and 20 references, with an overall limit of 12 typewritten double-spaced pages with 12-point font and 1-inch margins. A brief 100-word non-structured abstract, should emphasize the important message illustrated by the case(s). Consent to publish must be obtained for each patient described in the submission. A statement regarding patient consent must be included in the introduction. Written consent must be provided to the Editorial Office if requested. If your institution does not have a standard publication consent form, you may use the [Case Report Patient Consent Form](#).

**Innovative Techniques.** Innovative Techniques submissions will be considered for publication in the Journal of Vascular Surgery Cases. These articles are similar to the “Vascular & Endovascular Technique” section in the Journal of Vascular Surgery, however they have a 100 word non-structured abstract and a 1200 word body, include fewer than 5 cases and provide less than 6 months of follow-up. Innovative Techniques are practical and well-illustrated descriptions and technical tips of new or established operative and/or endovascular procedures. A brief description summarizing the author's views regarding the procedures advantages, disadvantages and outcomes should be included, with up to 10 references. The submission of supporting video is encouraged.

**Vascular Images.** Vascular Images will be considered for publication in the Journal of Vascular Surgery: Cases. The publication fee is US \$500.00 for this online-only, open access, Journal. In return, the copyrights for the published case will remain the property of the authors. Fees are not required until after manuscript acceptance. Select Vascular Images may be chosen to be published for the cover of the Journal of Vascular Surgery or the Journal of Vascular Surgery: Venous and Lymphatic Disorders. In that case these Images will not be considered open access and the fee will be waived. Submissions accepted for the Vascular Images Section present interesting vascular images and associated short educational summaries in a focused, case-report format. Consent to publish must be obtained for each patient described in the submission. A statement regarding patient consent must be included in the text of the manuscript. Written consent must be provided to the Editorial Office if requested, but consent forms do not need to be uploaded with your manuscript files. If your institution does not have a standard publication consent form, you may use the [Case Report Patient Consent Form](#). When submitting this type of manuscript, please make sure that you have designated which image should appear on the Journal cover. The Editor may not select an image from your accepted manuscript for the cover; however, it is required that you designate one image as the cover image before submission. Previously, published images will not be considered for this section. Color illustrations that are suitable for the Journal cover are preferred. Cover images must not include arrows, or any other added graphics and, whenever possible, text should be cropped out of the cover image. Appropriate images include radiographs, pathology, anatomy, operative findings, and other relevant clinical pictures. The images should illustrate features of vascular disease, including technical approaches. Illustrations and text must be confined to one printed page (no more than 350 words, with a limit of four illustrations: one for the cover and three that must fit in the right hand column). The Vascular images should possess both scientific and artistic merit.

Descriptions of images must be included in the text, and only key references should be provided (with a limit of three). Images must be of professional quality and meet the basic requirements for resolution specified in Illustrations (figures, charts, graphs).

Letters to the Editor/Responses. A letter containing 500 words or less, with no more than six references and one illustration or table, will be considered for publication if it amplifies a recent article in one of the Journal of Vascular Surgery Journals by extending or clarifying the original manuscript content, or by presenting an opposing interpretation of the results or conclusions. Letters may also be used to submit brief original observations or opinions. The authors of the original paper will be provided with an opportunity to respond to a Letter to the Editor. If the authors respond in a timely fashion, both the Letter to the Editor and the authors' Response will be published together. Letters accepted for publication may be copyedited.

Invited "Special Sections" Submissions. Although manuscripts for these "Special Sections" will generally be invited from specific authors, unsolicited submissions could be considered. Authors of unsolicited manuscripts should contact the Journal office to discuss their potential topic with the Assistant Editor prior to submission.

- Review Articles. Review Articles may be solicited by the Editors directly or in response to suggestions by prospective authors and will be evaluated as independent submissions without prior correspondence. They will be subject to peer review. These reviews are comprehensive with full reference lists.
- Vascular & Endovascular Techniques. Manuscripts for the "Vascular & Endovascular Techniques" section will be invited papers from recognized experts. They will be relatively short, practical and well illustrated descriptions and technical tips of new or established operative and/or endovascular procedures. Videos can be submitted and made available on the electronic version of the Journal. A brief description summarizing the author's views regarding the procedures advantages, disadvantages and outcomes should be included, with up to 10 references.
- Practice Management. Manuscripts for the "Practice Management" section will be invited papers focusing primarily on issues of interest to the practicing specialist, including office management issues, vascular laboratory management, sociopolitical topics, recruitment, and reimbursement issues. Topics will be of interest to both academic and nonacademic practitioners.
- Debates. Manuscripts for the "Debates" section will be invited papers describing a point/counterpoint debate between two recognized experts in the field concerning a controversial clinical issue. These debates will be introduced by a brief case vignette. Each expert will submit a defense of their position, as well as a response to their opponent's argument. These manuscripts may be accompanied by an invited expert commentary.
- Clinical Trials Update. Manuscripts for the "Clinical Trials Update" section will be invited papers from the Principal Investigators of ongoing clinical trials. The goal of this section is to update the readers on the status of these trials and to communicate the status of clinical investigations in a timely fashion. These manuscripts will likely be accompanied by an invited expert commentary.
- Evidence Summary. Articles in this section will summarize the available evidence on a topical issue in clinical practice of vascular surgery and

endovascular therapy. It will be a brief (1-3 pages) presentation of the published evidence, often in tabular form, relating to the subject. The goal of this section is to give the readers a ready wealth of evidenced information about a specific topic, which would positively and immediately influence their day to day practice.

- **Historical Vignettes in Vascular Surgery.** Manuscripts for the Historical Vignette section will be invited papers as well as free submissions from authors with an interest in Historical Vascular Heritage. The goal of this section is to remind and/or teach the readers about physicians and surgeons who have contributed previously. Also, other topics to include organizational efforts and procedures are to be considered. Manuscripts of a maximum of 2,500 words with approximately 3 figures, 10-15 references and no more than 3 authors are ideal.
- **Education Corner.** Manuscripts for the Education Corner will be invited papers as well as free submissions from authors with an interest in the training and education of vascular surgeons. The goal of this section is to discuss issues in the current training and education of vascular surgeons, including patient-specific education, continuing education, as well as national and international descriptions of the vascular surgery workforce. For the Education Corner, the maximum number of authors is 8, the abstract should be 250-400 words, and the body of the paper 3200-3500 words. There should be no more than 25 pages nor 40 references, and only 1 figure or table per page. These requirements are similar to the regular journal articles.

#### Other types of Submissions

- **Editorials.** The Editors may solicit an Editorial on an important manuscript or topic related to vascular surgery to emphasize or explain the significance and relevance of the work to a general vascular surgery audience or to present different views to assist the readers in making a decision on the application of the results and conclusions. The work should be objective and authoritative and should not exceed 1200 words in length. Even though Editorials are solicited, there is no prior commitment to publish them.
- **Presidential Addresses.** A Presidential Address from a meeting of The Society of Vascular Surgery and affiliated societies will be published after copyediting and optional review, which may provide suggested improvements. Authors submitting Presidential Addresses must also submit a completed Application for Publication.
- **Position Statements and Practice Guidelines.** Position Papers and Practice Guidelines developed under the auspices of The Society for Vascular Surgery will be published after approval by the Board of Directors of the Society.

#### After Manuscript Acceptance

##### Role of the Publisher

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