eJOURNAL

July — August 2011

THE PRESIDENT'S MESSAGE

Prepare for Montpellier: listen to the accordion

Professor Hans Evers
WES President

Endometriosis is an enigma.

At least that's what each textbook mentions in one way or the other. If all women show retrograde menstruation and if the reflux consists of viable endometrial fragments, why then do not all of them develop endometriosis?

If refluxed endometrium is self-tissue, how is it recognised, and how does the peritoneal garbage collection and disposal system – the macrophages and natural killer cells – know it should be removed and destroyed in order to prevent its fearsome implantation on the peritoneal lining?

For a long time we have had many questions and few answers. Many women have endometriosis, few have symptoms. In some, extensive endometriosis is a chance finding during laparoscopic sterilisation, in others, with debilitating pain, a few red spots is all you can find. Dozens of factors, in the menstruum, in the blood, in the peritoneal fluid, have been described which occur at significantly different rates in women with and without endometriosis. But, if so many differences exist, doesn't this mean to say that we have not found the real cause yet?

Jed Babbin, former US deputy undersecretary of defense said, in January 2003: "Going to war without France is like going deer hunting without an accordion". Maybe we have gone to war on endometriosis too impulsively? With old-fashioned contrivances, with poor diagnostic tools, and with an imperfect therapeutic armamentarium.

Maybe we should pay more attention to the accordion? Now is the time to really make scientific progress. Fascinating new techniques in cell and molecular biology, population genetics, tissue typing, immunology and advanced medical imaging finally allow us to try and understand what happens when the first few viable fragments of functional endometrium detach from their basal layer and start their travel through the tubes. Customised medicines, personalised pharmaco-genetics, targeted drug delivery systems will follow.

Only when we understand endometriosis can we treat it. An exciting new phase in the quest for knowledge starts right now.

The results will be presented (in France!) in Montpellier.

Join in the excitement: come to Montpellier 4-8 September!

In this issue of the WES e-Journal

World Endometriosis Society

Central Business Office
89 Southgate Road
London N1 3JS
England
t +44 (0)77 1006 5164
www.endometriosis.ca
wes@endometriosis.org

ISSN 1993-3924

A WORD FROM THE EDITOR

We are in the home stretch!

A/Professor Luk Rombauts
WES e-Journal Editor

We are indeed on the home stretch towards WCE 2011 in Montpellier with exactly one month to go. Or in Tour de France parlance: we have just passed the last 1 km banner!

And what a Tour it was! This annual festival of sport grips me every time. As the French rightly claim this is the biggest yearly sporting event in the world. A magical mix with something for everyone. The vistas, the drama, the suspense, the modern gladiators: Contador, the Schleck Sandwich, and Cadel! Unfortunately, the timing of the broadcasting didn't suit us antipodeans. Nevertheless, we were more than happy to sacrifice lots of sleep to 'jell for Cadel' in the last few stages to make sure he clinched the coveted yellow jersey.

Hans Evers opens this edition of the eJournal for the last time as President. His wise words set the tone for the next meeting in Montpellier. A meeting everyone has been waiting for over three years. We all hatched our plans, we did the research, we wrote up the abstracts, and we will conquer the South of France!

Cadel Evans on that home stretch...

Whether someone will be able to convince our skeptical President that we have solved the enigma of endometriosis is something you will need to come and find out for yourself.

Our Guest Editor this time is Neil Johnson. He has written a very witty piece that creates the perfect introduction for the Consensus Meeting he is organising in Montpellier and which will follow the main programme.

His overview of what the endometriosis community has been up to in terms of randomised controlled trials over the last number of years makes for some very interesting reading. The added bonus is that you have all the recent RCT's published in the last four years listed in a handy table in preparation for Montpellier.

Now, where did I put my passport ?

UPCOMING MEETINGS

11th World Congress on Endometriosis (WCE2011)
4 – 7 September 2011
Montpellier, France

20th Annual Congress of the ESGE
21 – 24 September 2011
London, England

67th Annual Meeting of the ASRM
(see also page: 8)
15 - 19 October 2011
Orlando, USA

ESHRE Campus: Endometriosis and IVF
28 - 29 October 2011
Rome, Italy

>> COMPLETE CONGRESS SCHEDULE

20th SLS Annual Meeting and Endo Expo
14 – 17 September 2011
Los Angeles, USA

Endometriosis: the link between pathophysiology and treatment
16 October 2011
Orlando, USA

2011 Annual Fall Meeting on Chronic Pelvic Pain
20 – 22 October 2011
Las Vegas, USA

40th Annual Meeting of the AAGL
6 – 10 November 2011
Hollywood (Florida), USA

Endometriosis surgery: from "art and craft" to international consensus-defined science?

Neil Johnson, MD

Honorary Associate Professor, University of Auckland
Consultant, National Women's Health and Repromed Auckland, New Zealand

neil.johnson@adhb.govt.nz

A/Professor Neil Johnson

Introduction
The issue of the evidence base – or lack of it – in our field is one we must face up to from time to time. Thus the theme I have chosen for this contribution to the Guest Editors' series is 'Endometriosis surgery – from art and craft to science?'

The surgical artisans of yesteryear took an artistic approach to their craft. There were many skilful and precise surgical craftsmen from previous eras. However, there has been a tendency to adopt the latest surgical technique because it seems logical (or worse, because it demonstrates the technical skill of the surgeon) rather than because it fulfils the stringent criteria for effectiveness that we now demand for non-surgical interventions.

As we approach the 11th World Congress on Endometriosis, and particularly as the pre- and post-congress meetings will respectively define research directions in endometriosis for the next three years and, perhaps ambitiously, will endeavour to make global consensus statements on the management of endometriosis, we must ask where we can come up with confident consensus from the wealth of endometriosis publications.

Level 1 evidence, generally producing a 'GRADE' of recommendation of high quality evidence (Atkins et al, 2004 on behalf of the GRADE Working Group), where further research is 'very unlikely to change our confidence in the estimate of the effect' (assuming that the trial is of adequate power, well designed and free from bias, and the trial population is sufficiently directly related to our own patients for direct inferences to be drawn) all flows from a good quality randomised controlled trial (RCT).

RCTs published from 18 May to 21 June 2011
A review of the literature for endometriosis research published between 18 May and 21 June 2011 reveals one publication relating to a randomised controlled trial (RCT) examining the management of endometriosis (Hoo et al, 2011).

This RCT aims to assess the effect of temporary ovarian suspension (for 36-48 hours) at the time of laparoscopic surgery for severe pelvic endometriosis on the prevalence of post-operative ovarian adhesions.

Hoo and colleagues are to be congratulated firstly for registering their clinical trial (**ISRCTN24242218**), a requirement now for publication of a randomised trial in any reputable peer reviewed journal that has improved the transparency of reported results from clinical trials (Guo et al, 2009).

However the authors have also chosen to publish this trial protocol in the peer reviewed literature. This not only shores up the transparency of reporting of the trial results, but it allows critical comment from the scientific community at the design and initiation phase of the trial.

Such peer review prior to initiation of the trial might allow the trialists to refine the design of their study, to develop it into one that is of utmost quality in terms of answering a relevant clinical question in the best possible way. The trial is also an ambitious attempt to endeavour to assess a surgical technique, as it is well recognised that clinical trials of surgical interventions are notoriously challenging (Johnson, 2010).

This trial protocol, in common with all trial protocols, has weaknesses. The main issue is that the primary outcome is the severity of adhesions, rather than a clinically relevant outcome of importance to women themselves. The design is therefore related to detecting presence of adhesions or not, and participants are randomised to having a left versus a right unilateral ovarian suspension for 36-48 hours.

The statistical issues are not straightforward when it is ovaries, rather than women, that are randomised. The primary outcome, a surrogate outcome even for the extent of adhesion formation (albeit one justified by the authors based on previous studies), will be the ultrasound assessment of restricted ovarian mobility in conjunction with inability to separate the ovary from the peritoneum of the lateral pelvic wall and/or Pouch of Douglas. The presence, intensity and site of post-operative pain will only be secondary outcomes.

Effectiveness of ovarian suspension in preventing post-operative ovarian adhesions in women with pelvic endometriosis: A randomised controlled trial

BMC Womens Health 2011;11:14.

Hoo WL, Saridogan E, Cutner A, Pandis G, Jurkovic D.

BACKGROUND: Endometriosis is a common benign condition, which is characterized by the growth of endometrial-like tissue in ectopic sites outside the uterus. Laparoscopic excision of the disease is frequently carried out for the treatment of severe endometriosis. Pelvic adhesions often develop following surgery and they can compromise the success of treatment. Ovarian suspension (elevating both ovaries to the anterior abdominal wall using a Prolene suture) is a simple procedure which has been used to facilitate ovarian retraction during surgery for severe pelvic endometriosis. The study aims to assess the effect of temporary ovarian suspension following laparoscopic surgery for severe pelvic endometriosis on the prevalence of post-operative ovarian adhesions.
METHODS: A prospective double blind randomised controlled trial for patients with severe pelvic endometriosis requiring extensive laparoscopic dissection with preservation of the uterus and ovaries. Severity of the disease and eligibility for inclusion will be confirmed at surgery. Patients unable to provide written consent, inability to tolerate a transvaginal ultrasound scan, unsuccessful surgeries or suffer complications leading to oophorectomies, bowel injuries or open surgery will be excluded. Both ovaries are routinely suspended to the anterior abdominal wall during surgery. At the end of the operation, each participant will be randomised to having only one ovary suspended post-operatively. A new transabdominal suture will be reinserted to act as a placebo. Both sutures will be cut 36 to 48 hours after surgery before the woman is discharged home. Three months after surgery, all randomised patients will have a transvaginal ultrasound scan to assess for ovarian mobility. Both the patients and the person performing the scan will be blinded to the randomisation process. The primary outcome is the prevalence of ovarian adhesions on ultrasound examination. Secondary outcomes are the presence, intensity and site of post-operative pain.
DISCUSSION: This controlled trial will provide evidence as to whether temporary ovarian suspension should be included into the routine surgical treatment of women with severe pelvic endometriosis.
TRIAL REGISTRATION: ISRCTN24242218.

The strengths of the trial are that it endeavours to confirm a hypothesis generated from non-randomised studies; it is randomised and double-blinded (with the use of a sham suture to ensure participant blinding); allocation concealment will be adequately maintained by use of opaque sequentially-numbered envelopes and use of varying block sizes.

The sample size calculation is also a strength of the trial, as it is based on pilot data concerning adhesion occurrence based on a similar ultrasound assessment to that planned in the trial, in the same unit, and suggests that 50 participants will be required to show a halving of the occurrence of adhesions.

How often are RCTs assessing management of endometriosis published?

May-June 2011 was a standard month, as it appears that two RCTs are published every 3 months in PubMed indexed journals.

My PubMed search from the beginning of 2007 to date with keywords 'endometriosis' and 'randomised' or 'randomized' in the title produced 200 hits.

My further scrutiny of the titles suggested that at least 31 primary RCTs and three RCT protocols of interventions in the management of women with endometriosis (that could be recognised by reference to randomised, randomized or similar reference in the title suggesting an RCT) were published in English in Pubmed-indexed journals in the most recent 54 months. Additional to this, there were 14 PubMed-indexed systematic reviews of RCTs published, nine of which were Cochrane reviews or updates.

The tables on the next two pages summarise the published RCTs from 2007 to date and describes the interventions studied. Trials reporting a positive efficacy result have been marked with an asterisk.

These 34 publications from the beginning of 2007 to date included only three RCT protocols (one of which was the trial protocol published by Hoo et al, 2011). This represents a reasonable number of published trials on the management of endometriosis, given that as many as 80% of registered trials involving women with endometriosis may not be published (Guo et al, 2009).

Eight (24%) of the 36 RCTs assessed surgical interventions. This contrasts with the much smaller percentage of primary surgical RCTs in gynaecology as a whole, fewer than 8% of the total number of RCTs in gynaecology prior to 2007 (Johnson et al, 2008).

This probably reflects the recognised importance of surgery in managing endometriosis.

It may, however, also reflect a greater willingness of those now conducting RCTs to rise to the challenge of designing, conducting, and completing trials of surgical interventions than has traditionally been the case.

Have any of these trials unearthed the blockbuster intervention for endometriosis? Although this seems unlikely, a surprisingly high number reported a positive efficacy result (16* from 31 completed RCTs).

SURGICAL INTERVENTIONS (8 RCTs)

Laparoscopic surgical excision versus ablation
Healey et al. Fertil Steril 2010;94:2536-40

Suturing versus electrocoagulation for endometrioma resection
[i] Coric et al. Arch Gynecol Obstet 2011;283:373-8, such as improvement of pain (or improvement in quality of life related to a reduction in pelvic pain) or fertility outcomes*
[ii] Pellicano et al. Fertil Steril 2008;89:796-9*

Laparoscopic versus open colorectal resection
Darai et al. Fertil Steril 2011;95:1903-8*

Laparoscopic ovarian cystectomy versus 3-stage endometrioma procedure
Lewis et al. Fertil Steril 2010;94:71-7*

Multimodal intraoperative analgesia
Costello et al. Fertil Steril 2010;94:436-43*

Recombinant interleukin-2 single versus double ultrasound guided instillation into endometriomas
Acien et al. Gynecol Obstet Invest 2010;69:203-11

Left versus right ovarian suspension trial protocol
Hoo et al. BMC Womens Health 2011;11:14

COMPLEMENATARY/ALTERNATIVE INTERVENTIONS (4 RCTs)

Acupuncture
Rubi-Klein et al. Eur J Obstet Gynecol Reprod Biol 2010;153:90-3*

Japanese style acupuncture
Wayne et al. J Pediatr Adolesc Gynecol 2008;21:247-57*

Japanese style acupuncture trial protocols
Schnyer et al. J Altern Complement Med 2008;14:515-22

Diet versus hormonal suppression versus placebo
Sesti et al. Eur J Obstet Gynecol Reprod Biol 2009;147:72-7*

INTERVENTIONS FOR INFERTILTY (2 RCTs)

Pentoxifylline
Creus et al. Hum Reprod. 2008;23:1910-6

Lipiodol
Johnson et al. Hum Reprod 2007;22:2857-62*

MEDICAL INTERVENTIONS (20 RCTs)

Oral estroprogestins
Muzii et al. J Minim Invasive Gynecol 2011;18:173-8

OCPs
Harada et al. Fertil Steril 2008;90:1583-8*

Longterm OCPs following endometrioma excision
Serrachioli et al. Fertil Steril 2010;94:464-71*

Cyclic versus continuous OCPs
Serrachioli et al. Fertil Steril 2010;93:52-6

Depot medroxyprogesterone acetate dose finding trial
Cheewadhanaraks et al. Gynecol Obstet Invest 2009;68:116-21

Medroxyprogesterone acetate versus Implanon
Walch et al. Contraception 2009;79:29-34

Triptorelin
Loverro et al. Eur J Obstet Gynecol Reprod Biol 2008;136:194-8

Leuprolide versus continuous OCPs
Guzick at al. Fertil Steril 2011;95:1568-73

Levonorgestrel intrauterine system trial protocol
Alhamdan et al. Rev Recent Clin Trials 2010;5:143-6

Levonorgestrel intrauterine system versus depot medroxyprogesterone acetate
Wong et al. Aust N Z J Obstet Gynaecol 2010;50:273-9

Levonorgestrel intrauterine system versus GnRHa
Manetta et al. Ultrasound Med Biol 2008;34:1914-8

Dienogest
Strowitzki et al. Eur J Obstet Gynecol Reprod Biol 2010;151:193-8*

Dienogest versus leuprolide
Strowitzki et al. Hum Reprod 2010;25:633-41*

Dienogest versus intranasal buserelin
Harada et al. Fertil Steril 2009;91:675-81

Letrozole and norethisterone versus letrozole and triptorelin
Ferrero et al. Reprod Biol Endocrinol 2011;9:88*

Lactobacillus gasseri OLL2809
Itoh et al. Cytotechnology 2011;63:153-61

Anti-TNFα
Koninckx et al. Hum Reprod 2008;23:2017-23

Pentoxifylline
[i] Alborzi et al. Hum Reprod 2007;22:2857-62; [ii] Kamencic et al. J Minim Invasive Gynecol 2008;15:62-6*

Raloxifene
Stratton et al. Obstet Gynecol 2008;111:88-96*

World Endometriosis Society Consensus
The forthcoming World Congress on Endometriosis will see a landmark consensus meeting on the management of endometriosis that endeavours to bring together the many professional societies from around the world and that has a strong patient focus, with representation from many national patient support groups.

The cornerstone of the consensus statement planned to emerge from the meeting, and expected to be submitted for publication by the end of 2011, will be the studies that give us high grade or level 1 evidence, namely RCTs.

Concluding comments – a place for an international consensus trial protocol review group?
So, to the current trial protocol from Hoo and colleagues. Will it show that the chance of adhesions is more than halved in ovaries that are suspended to the anterior abdominal wall for 36-48 hours where pelvic endometriosis has been excised?

If it does, is this a finding of more interest to surgeons than to women with endometriosis?

Even if ovarian suspension ultimately proves to be a surgical blockbuster intervention, the use of prevalence of adhesions as the primary outcome may undermine the impact of this trial. Trials of adhesion prevention have long been hampered by looking at the occurrence of adhesions rather than outcomes of importance to patients. Whilst it seems unlikely that ovarian suspension will be plagued by the problems affecting some adhesion prevention agents – increased pain in spite of reduced adhesions – surely the important question is whether suspending the ovaries reduces pain, improves quality of life or improves fertility. Perhaps the current trial will lead to another RCT that examines outcomes of greater interest to women.

There has been a genuine improvement in the quality of clinical trials in gynaecology in recent years (Selman et al, 2008). Can we now bring the wisdom of international consensus to bear at the design phase of trials to further drive this quality?

Those diligent enough to publish their trial protocol, as Hoo and colleagues have done, receive the benefit of peer review from the journal in which they choose to publish, and may also receive critical comment from the wider scientific community after publication.

It is worthy of consideration whether, in the field of endometriosis, a group of international experts in endometriosis and clinical trial methodology could be established to provide peer feedback to those establishing a trial – after all, with only 8 published RCTs per year (even if this represents as little as 20% of the total number of trials initiated), this would not be an onerous workload for such a group.

Perhaps the World Endometriosis Society should consider the establishment of such a group, so that enthusiasts such as Hoo and colleagues, who are designing a trial and seeking expert peer review, could choose to submit to this body? Not to regulate or restrict, but to build on their ideas to arrive at the optimal trial protocol.

Such a structure could form a platform for improving coherent and collaborative strategies for research directions in endometriosis clinical trials and could complement the activities of the group led by Professor Peter Rogers defining future directions for endometriosis research and the World Endometriosis Society Research Foundation (WERF) that funds endometriosis research.

Trials supported by international consensus may be better designed and examine the most important outcomes, thus becoming higher impact for maximum benefit to clinicians — but most importantly to women with endometriosis!

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Selman TJ, Johnson NP, Zamora J, Khan KS. Gynaecologic surgery from uncertainty to science: evolution of randomised controlled trials. Hum Reprod 2008;23:827-31.

WCE2011 UPDATE

The home stretch...

There is less than one month until WCE2011 opens it doors for the—now more than 1000 pre-registered–delegates, who have decided to come to Montpellier to contribute to the next chapter of endometriosis.

WCE2011 will be the largest ever meeting dedicated to endometriosis alone with >500 oral and poster presentations, including six key note lectures, ten main seminars, three poster sessions, eight free communication sessions, three pre-congress courses, one (official) debate—and a congress party at one of the world's oldest medical schools.

The final programme is now online and you can register at **www.wce2011.com**

Rodolphe Maheux Travel Award helps get four young scientists to Montpellier

Earlier this year WES announced the Rodolphe Maheux Travel Award, which has been established to enable young scientists and clinicians to attend WCEs to present their research [WES eJournal 2001;13(1):8]. After much deliberation (there's an awful lot of dedicated people in the field of endometriosis now!) the "RMTA Committee" is delighted to announce that WES is able to provide funding for these young researchers to attend WCE2011:

Alison Hey-Cunningham
University of Sydney, Australia

Endometrial expression of neuropilins in women with endometriosis

Alison is presenting her work on Monday 5 September at 15.20 (S#3-5) in room "Einstein".

Katie May
University of Oxford, United Kingdom

Endothelial cells progenitor cells in endometriosis

Katie is presenting her work on Tuesday 6 September at 07.00 -08.00 in the poster area "Citadelle" (topic = diagnosis).

Mutinda Kyama
Institute of Primate Research, Kenya

Massive ectopic endometrial necrosis occurs before development of induced endometriosis in baboons

Mutinda is presenting his work on Wednesday 7 September at 14.30 (FC#5-4) in room "Joffre B".

Qing Xue
First Hospital of Peking University, China

Hyperthermilation of the CPG island span from EXON II to third intron activates steroidogenic facto-1 in the stromal cells of endometriosis

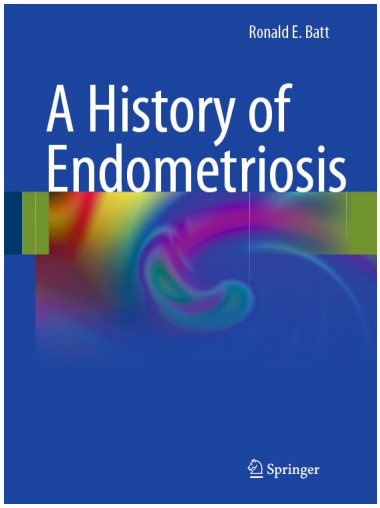
Qing will be presenting her work on Wednesday7 September at 15.10 (FC#5-8) in room "Joffre B".

ANNOUNCEMENTS

...and, after WCE2011 the ASRM continues to pay attention to endometriosis with a strong programme at their 67th Annual meeting—please be there and keep moving our field forward:

ASRM PC #17: 16 October 2011 08.15-17.00
Endometriosis and the link between pathophysiology and treatment
ASRM Symposium: 17 October 2011 07.00-08.45
"Long-term management of symptoms of endometriosis"
ASRM Interactive Session: 18 October 13.15-14.15
"Endometriomas—treatment or no treatment for fertility"
Oral abstracts: 18 Oct 2011 16.15-18.15 and **19 Oct 11.15-13.00**
ASRM Poster sessions: 18 Oct 07.00-09.00
Special Interest Group: 18 Oct 18.15-19.00

Round table: Endometriosis and aromatase inhibitor treatment (E. Attar) - **17 Oct 13.15-14.15**
Round table: The use of aromatase inhibitors for the treatment of endometriosis (R. Casper) - **18 Oct 13.15-14.15**
Round table: The best approach to women with endometriosis undergoing ART (S. Palter) - **19 Oct 13.15-14.15**



A history of endometriosis

Author: Ronal E Batt
Publisher: Springer Verlag
Publication Year: 2011
ISBN: 978-0-85729-584-2

Target Audience: Academic Health Professionals, Medical Historians

Rating

Content: 📖📖📖📖📖
Readability: 📖📖📖📖📖
Interest: 📖📖📖📖📖
Overall: 📖📖📖📖📖

Available on Amazon.com

As a social science, history often engenders discomfort in the scientific community, including health professionals. Social sciences, you see, are not sufficiently 'scientific'.

Thankfully, *A History of Endometriosis* beautifully illustrates the folly of this assumption, by revealing the delightfully unexpected aspects of history: who would have known that our 21st Century understanding of endometriosis was shaped by the contributions of Johann Wolfgang von Goethe or Immanuel Kant? The cited 19th century descriptions of the inflammatory nature of what was come to be known as endometriosis also reinforce that one ignores history at one's peril!

The foundations of this book lay in the requirement of Dr Ronald Batt to fulfill his Doctorate of Philosophy in History and this approach is clearly evident in the meticulous research into the subject.

A History of Endometriosis is divided into twelve chapters, beginning with the fundamental scientific reorientation of the late eighteenth century that culminated in the emergence of Carl Freiherr von Rockitansky as the first full time anatomical pathologist of the modern era. The author then takes us on an extended journey to introduce Friedrich von Recklinghausen, Thomas Cullen, and John Sampson.

Each chapter entertains with remarkable insight into not only their work, but also the environment that shaped each revelation.

Amongst the gems in this collection is the revelation of DeWitt Casler's treatise to the American Gynecological Society in 1918 that inspired Sampson's theory. Remaining entirely true to the scientific writing genre, Dr Batt not only describes these personae, but also deliciously hints at the conflicts and machinations of these great leaders.

Extensive footnotes reference the text: initially distracting, but much like the 3D effects in *Harry Potter: The Deathly Hallows*—ultimately rewarding!

Appropriately, this work is entitled *A History of Endometriosis*. There is no reference to the antiquities, the work of the early anatomists of the middle ages or even an analysis of women in the history of endometriosis. However, this should not to be seen as an oversight. The author's epilogue resounds in his hope to stimulate critical debate, refinement, and further contribution. Inspired by this book, I trust that the definitive *THE History of Endometriosis* will not be too far away...

Undoubtedly, the narrow focus of this book will keep it off the Amazon Bestseller List, but this monograph has earned its place on the bookshelf of every Department of Reproductive Medicine and University.

Dr Batt has kindly insisted that all royalties from the sale of the book will go to the Rodolphe Maheux Travel Fund ...so that the next generation can continue to contribute to the history of endometriosis.

Reviewed by: A/Professor Anusch Yazdani
Associate Professor, University of Queensland, and Director of Research Development, QFG Research Foundation, Australia