“The mission of the MEFACOOG is to foster continuing improvements in women’s healthcare. The goals of the MEFACOOG are to support continuing Medical Education – Undergraduate, Graduate and Postgraduate, Research Programs, Faculty Development and Development of Educational Networks in women’s healthcare.
Letter from the Chair,
MEFACOOG Board Members

Mark A. Kalchbrenner, DO, Chair

Our MEFACOOG Council Members for 2007-2008 includes:

Mark A. Kalchbrenner, DO …………. Chair
Carl Della Badia, DO ……………… Vice Chair
Ernest F. Thompson, DO ………………… Secretary-Treasurer
Kedrin E. Van Steenwyk, DO ……….. Trustee
Amelia Roush, DO …………………. Trustee
Eric Carlson, DO ………………….. Trustee
Steve Buchanan, DO …………………… Executive Vice President

During this time of year, I can’t help reflecting on where things have been and where they are going. When I consider these questions for MEFACOOG, I am proud of how far we have come since our inception in 1999. Through the generosity of our members and corporate partners, we have grown our corpus and continued to develop our educational projects.

This year has been positive for our foundation. Eric Carlson, D.O., has become a valuable new member of the foundation Board. Duramed has become a new platinum member of our Corporate Partnership Council. Continued support of our Student Scholars Program has encouraged initiation of a National Student Society to help educate osteopathic students about women’s health issues and allow them to become familiar with ACOOG.

The coming year also looks bright. Carl Della Badia, D.O., will assume the responsibilities of Chair of MEFACOOG; but, we need some help. We need an ACOOG Life Member to volunteer for a Board position. We need to continue to show our appreciation to Corporate Partners. As each of you considers year end contributions, please keep your Medical Education Foundation in mind.

Thank you all for your support. I hope you find time in your busy schedule for family and friends this holiday season.

Mark Kalchbrenner
DO, FACOOG (Dist)
Chair, MEFACOOG Board of Trustees

June Murphy, DO

I am very pleased to announce that the Wyeth/MEFACOOG Resident Reporter Program at the 74th Annual Convention was a great success. Twenty-five resident reporters were involved and all provided excellent summaries of their assigned lectures. Wyeth Pharmaceuticals has graciously sponsored the resident reporter program for the past 11 years, which has allowed many residents to attend our annual conference, when they would have otherwise been unable to do so. Three of the summaries were selected for an expanded review paper, which follow for your reading pleasure.

Dr. Virginia Burnett did an excellent review of hormone replacement therapy, based on Dr. Packin’s lecture at the annual conference. Dr. Ibrahim Farhat also did an excellent review on cord blood banking, based on an lecture by David Harris, Ph.D. Dr. Carl Christie also did an excellent comprehensive review regarding robotics surgery techniques, based on Dr. Brunvoll’s lecture. I am sure you will find their excellent reviews as educational as I have. Thank you to all of our resident reporters as well as Wyeth and MEFACOOG for their support of the resident reporter program.

2007 Editor of the MEFACOOG / WYETH Resident Reporter Scholarship Program

June Murphy, DO

Dr. Virginia Burnett did an excellent review of hormone replacement therapy, based on Dr. Packin’s lecture at the annual conference. Dr. Ibrahim Farhat also did an excellent review on cord blood banking, based on a lecture by David Harris, Ph.D. Dr. Carl Christie also did an excellent comprehensive review regarding robotics surgery techniques, based on Dr. Brunvoll’s lecture. I am sure you will find their excellent reviews as educational as I have. Thank you to all of our resident reporters as well as Wyeth and MEFACOOG for their support of the resident reporter program.
I have always enjoyed scrubbing into the operating room knowing that the next case I would be a part of would be a laparoscopic procedure. I would get excited but yet would have to wait patiently after creating my umbilical incision and inserting the verse needle for the abdomen to fill with CO2 gas. A trocar would then be placed followed by the camera and finally begin the view of what my heart wanted to see, a survey of the abdomen and pelvis in order to repair the pathology of a patient.

There is also another joy. After the repair is completed the patient is able to be sent home that very same day because we the patient and the doctor chose that her procedure would be a minimally invasive case via laparoscopy. I have always felt this is a beautiful thing in medicine and that the instruments should get better and economical over time.

I was fascinated at the presentation of March 28th that in some way you can call it an instrument or maybe you can call it the future replacement of humans. Well, they have at least replaced the human hand. I was introduced to robotic surgery.

Dr. Gary Brunvoll spoke of the next level of laparoscopic surgery which we may all need to look forward to attaining. He went on to testify of how robotic surgery seems to have an advantage over doing laparoscopic surgery strictly via the human hand. He spoke of increased dexterity and showed a video recording of a laparo robotic arm.

The patients had the benefit of a quicker return to work by an average of one week and a median of 2 weeks as opposed to minilaparotomy. The robotic arms also had the advantage of less frequent complications and seem to be the most beneficial in cases of high complexity were laparoscopic approach is still desired.

I have been in the operating room with a masterful laparoscopic surgeon. The most impressive cases that I have assisted on was lysis of adhesions in a patient with stage four endometriosis and a completely obliterated cul-de-sac. After that procedure I remember speaking with the surgeon. I ask his opinion as what did he think the outcome might have been if the case would’ve been done via laparotomy. His response was that he would not attempt such a sensitive and delicate creation of surgical planes via laparotomy and a great advantage to laparoscopy was the ability to have increased visualization of the magnified planes. The surgery ended with an impressive result of freeing up the patient’s uterus that was smoothly attached to her large bowel, ovaries and throughout her cul-de-sac. I remember thinking to myself that it was a good experience to see a surgery of such high complexity therefore I know that I would never attempt one. However, I must say after observing the robotic arm’s carefulness and deliberately controlled movements I do feel encouraged that one day I may be able to engage in complex surgeries such as stage four endometriosis with the robots assistance.

There are some difficulties with the robotic arm. Rogers et al commented on the lack of ease in maneuvering instruments around the robot by the staff members because of its large size. This contributed to an increase in setting up time and operating room time. There was also a higher cost per procedure of up to $1400 higher than outpatient minilaparotomy. As expected there is a learning curve for both the physician and the staff working with this new equipment. I have known doctors report they are now spending one third to a half less time doing cases as their learning curve improves. Rogers et al however did not show an improvement in the mean operating time in the cases they observed. However, patients which are not good candidates for minilaparotomy such as those with high body mass indexes, robotic assisted surgery may be helpful in their care. Rogers et al.

“...The patients had the benefit of a quicker return to work by an average of one week and a median of 2 weeks as opposed to minilaparotomy. The robotic arms also had the advantage of less frequent complications...”

(Continued on Page 4)
What is expected in the future? Probably most of us do expect that equipment shall become smaller, more inexpensive, easier to use and the amount of operating time needed to set up and change instruments on the robotic arm will be greatly decreased. There is further work being done which includes smaller motors to decrease the size of the robotic tower, adjusting the robot towers location to possibly hanging from the ceiling or wall to increase points of access to the patient Dharia et al. Integration of images is another exciting and prospectively useful enhancement which may be upcoming for robotic surgery. Integration of images may be able to allow the surgeon the ability to evaluate blood supply by real-time ultrasound or identify a lesion by integrated magnetic resonance imaging Dharia et al.

Since the first use of robotic assistance in gynecological surgeries described by Mettler et al. gynecologic procedures that are currently being performed by robotic assistance includes: Tubal reanastomosis, myomectomy ovarian transposition, Burch procedure, Colpopexy, hysterectomy, dermoid cystectomy, oophorectomy, salpingooophorectomy, salpingectomy, tubal ligation Dharia et al. The robotic arm seems to be the way of the future for laparoscopic surgeries especially in the field of gynecology. Gynecologists are using this technology at a very high rate and this is expected to continue.

I remember during the beginning of my residency it being said that if you play a lot of video games during your childhood you will be very good at laparoscopic surgery. A future with this robotic arm in mind brings that concept of playing a video game full circle. It has now brought us to a point where performing surgery is no different than moving joysticks. The notion of the movement of joysticks however does not diminish the ability of this phenomenal and relatively new technology to change the lives of both the physician and patient. Complex cases become more feasible and the situation of pique and shriek does not mean hopelessness for the patient. However, may identify patients for referral to an advanced robotic assisted laparoscopic surgeon.

REFERENCES

Cord Blood Stem Cells
and Regenerative Medicine

Ibrahim Farhat, DO

Inspired by a lecture by David T. Harris, PhD

Stem cell research is an issue receiving lots of attention secondary to the numerous possibilities and advancements that can be achieved by their use. Dr. David T. Harris, Ph.D. presented "Cord Blood Stem Cells and Regenerative Medicine" with an objective to help understand the current and future uses of umbilical cord blood stem cells in transplantation and in regenerative medicine. Dr. Harris discussed four main issues regarding stem cells. The first being, how cord blood stem cells are collected and banked. The second, the current uses of cord blood stem cells in transplantation. The third, the future use of cord blood stem cells in regenerative medicine. The fourth, the advantages of cord blood stem cells compared to other stem cell sources.

The Cord blood is collected in 2-5 minutes and is shipped overnight to a storage facility for processing. Seventy to 100cc of cord blood can be collected after a typical vaginal or surgical delivery. The sample must be received within 32 hours of collection. The stem cells can remain in storage for long periods of time. Stem cells that had been frozen for at least 10 years have been thawed out and researchers have been able to recover at least 90-95% of the original cells.

Cord blood transplant rate has increased dramatically in the last decade, rising from nearly zero in 1994 to approximately 6000 in 2005. Diseases most commonly treated with cord blood stem cells currently are childhood and adult hematologic malignancies and a variety of genetic blood disorders. Examples include; leukemia, lymphoma, multiple myeloma, sickle cell disease, aplastic anemia, etc. Cord blood stem cells have been also transplanted into adults. Just as in bone marrow, transplant into adults was found to be half as effective; however, there was a significant decrease in side effects, and in graft vs. host disease. Cord blood transplant, as expected, was also found to more successful in related donors as opposed to unrelated donors. According to Gluckman E, et al in a 1997 NEJM article, Outcome of cord blood transplantation from related and unrelated donors, the one-year survival rate for related and unrelated transplants was found to be 63% compared to 29%, respectively. This improved outcome of related transplantation was also evaluated by Wagner J, et al. and Kurtzberg J, et al. in Allogenic sibling umbilical-cord blood transplantation in children with malignant and non-malignant disease, and Placental blood as a source of hamatopoietic stem cells for transplantation into unrelated recipients, respectively.

The percentage of acute graft vs. host disease was stated to be 3% and 42% for related and unrelated transplantation.

In discussing future applications of stem cells, Dr. Harris mentioned several studies and advancements in the treatment of cardiovascular disease, corneal regeneration, and possible future treatment of spinal cord injuries and the treatment of diabetes in kids. Several studies on rats with induced myocardial infarcts have shown that with the introduction of stem cells within several days of the infarct, the pumping function of the heart can be spared and scar tissue can be prevented. The stem cells injected into the coronary circulation were found in newly forming vessels, in essence, creating a natural bypass. The stem cells did not become myocytes, however, the endothelium of the newly formed vessels; secreted angiogenic genes that helped the heart heal itself without scarring. Another application that cord blood stem cells are being used for is corneal regeneration. Limbal stem cell deficiency leads to conjunctival epithelial ingrowth, neovascularization, chronic inflammation, and recurrent epithelial defects. The pathology may result from direct trauma of limbal stem cells, as in chemical or thermal burns, Stevens-Johnson syndrome, multiple surgical procedures, contact lens wear, or severe infections. With the end result being decreased visual acuity and severe discomfort. The cord blood stem cells are capable of differentiation into an epithelial phenotype that is morphologically indistinguishable from corneal epithelial cells. These cells can also restore the limbus system and express corneal specific

(Continued on Page 6)
Cord Blood Stem Cells . . .
(Continued from Page 5)

cytokeratin k3, and since the cornea does not have blood vessels, someone else’s stem cells can be used.

The use of cord blood stem cells has also been very promising for advancements in the treatment of spinal cord injuries and diabetes type 1. These stem cells have been shown to be able to differentiate into the glial cells and astrocytes, thus helping the CNS repair itself after an injury when given within a couple day window. However, the stem cells have not shown an ability to become motor neurons. Even more promising is the use of the cord blood stem cells for the treatment of diabetes in kids. In a study of children with type 1 diabetes intractable to treatment, giving stem cells IV after minor ablation of the immune system had tremendous benefits. The children formed islet cells and began creating their own insulin, required less exogenous insulin, and their blood sugar levels were much better controlled. Though lots of advancements have been made, cord blood stem cells still possess a significant amount of potential for the future.

Cord blood stem cells do also offer numerous advantages over bone marrow. Simplified collection process, does not require surgical harvest, viral infections less common, increased long-term immune recovery, and lower risk of graft vs. host disease. In a recent clinical trial, 68 adult patients with hematologic disorders received allogenic cord blood transplants, 90% achieved engraftment, and graft vs. host disease was significantly less compared to bone marrow transplants, 20% vs. 35-55% respectively. The use of cord blood stem cells instead of bone marrow has also been proven to decrease the mortality rate in adults over 50 that require transplants. This improvement in mortality rate is thought to be due to the high levels of chemotherapy required prior to bone marrow transplants as opposed to the low levels required for transplant of cord blood stem cells.

In summary, clinical studies over the past 15 yrs have demonstrated the efficacy, safety and almost limitless potential of cord blood stem cells. Cord blood stem cells can be easily collected, and stored, and long term cryopreservation has no adverse effect. Researchers have been able to recover at least 90-95% of the original cells that had been frozen for at least 10 years. Cord blood-derived stem cells are clinically useful in a variety of disease states; leukemia, lymphoma, multiple myeloma, sickle cell disease, aplastic anemia, diabetes, spinal cord injury, corneal transplants, etc. Cord blood stem cells do also offer numerous advantages over other sources; simplified collection process, does not require surgical harvest, viral infections less common, increased long-term immune recovery, and lower risk of graft vs. host disease. Cord blood stem cells possess significant future potential through expansion, gene therapy, and cell specific therapies.

Lecturer:
David T. Harris, PhD
74th Annual Conference
March 27-31st, 2007
Palm Springs, CA

“Cord blood stem blood cells do also offer numerous advantages over bone marrow. Simplified collection process, does not require surgical harvest, viral infections less common, increased long-term immune recovery, and lower risk of graft vs. host disease.”
Menopause is a major transitional event in a woman’s life, characterized not only by reproductive changes, but also the initiation of profound but gradual health changes that can greatly impact quality of life and has enormous health implications in regards to cardiovascular health, bone mass and fracture risk, cancer risk and cognitive function. By the year 2050 it is estimated that over 20% of the American population will be older than 65 years of age, the majority of them being women. As the average life expectancy of women is approximately 80 years, it is critical for healthcare providers to fully understand this period in a woman’s life and the available treatments (of which hormone replacement plays a key role) to maximize a woman’s health and well-being.

Dr. Packin’s lecture provided an excellent overview of the initial views and controversy over hormone replacement therapy, as well as summarized major clinical trials and their impact on patient management. Before the WHI (Women’s Health Initiative, 2002), hormone replacement was thought to be a ‘fountain of youth’, prevent aging in women. This included preventing not only hot flashes and skin changes, but also heart disease, osteoporosis, CNS degeneration, colon cancer, weight increases, and macular degeneration. However, meta-analysis of animal and preliminary studies raised concerns regarding hormonal effects on the incidence of breast cancer, ovarian cancer, endometrial cancer, thromobembolic events and cardiovascular disease.

The first study to address these concerns was the Heart and Estrogen/Progestin Replacement Study (HERS), a secondary prevention trial to assess the incidence of nonfatal and fatal myocardial infarction. This study showed an increased risk of myocardial infarction within the first year of hormone replacement, with an overall decrease at years four and five of use. There did not appear to be a decrease in cardiovascular risk in postmenopausal women with pre-existing heart disease.

The WHI in 2002 was groundbreaking in that it was both a prevention study and an epidemiological study. Not only did it address whether hormone replacement had any preventative benefits, but did it using the most common estrogen/progesteron on the market, making it an excellent epidemiological study as well. The WHI study was stopped early due to a statistically significant increase in risk of cardiovascular disease and venous thromboembolic events, as well as an increase in invasive breast cancer. Important information lost in the media-hype was that hormone replacement also had benefits, primarily preventing bone fractures and decreasing the incidence of colorectal cancer. Overall consensus of the study was that hormone therapy should not be used for the primary prevention of cardiovascular disease and that risks must be weighed with the benefits before use. Particular instances would be a perimenopausal woman experiencing severe menopausal symptoms where short-term therapy may have greater benefit than risk or a woman with premature menopause at a higher risk of osteoporosis.

Unfortunately, due to the negative media-hype, many women on hormone replacement abruptly stopped therapy, resulting in rebound of severe menopausal symptoms. There was no relief from other modalities such as soy products or conventional antidepressants and many women elected to just “live with it.” In 2005, a multidisciplinary group of healthcare providers (American Society for Reproductive Medicine [ASRM] Workshop) was

“As the average life expectancy of women is approximately 80 years, it is critical for healthcare providers to fully understand this period in a woman’s life and the available treatments (of which hormone replacement plays a key role) to maximize a woman’s health and well-being.”

(Continued on Page 8)
convened to address and weight the benefits and risks of hormone replacement therapy for symptomat-ic menopausal women. Their discus-sions focused on evidenced-based medicine and addressed efficacy of hormone therapy in regards to vasomotor symptoms, vulvovaginal problems, mood and sleep disorders, as well as assessed cancer and cardiovascular risks. Dose consideration (including mode of delivery) and safety profiles of different hormones were also evaluated.

The ASRM made several recommendations bases on their conclusions. The main recommenda-tion was that short-term treatment should never be denied young, healthy symptomatic women unless there is an absolute contraindica-tion. This was concluded after many women had almost immediate relief of vasomotor and urogenital symp-toms, as well as improvement in sexual dysfunction and psychologi-cal disturbances related to estrogen withdrawal, within one month of low-dose therapy. Other conclu-sions and recommendations include: 1) breast cancer was not prevented by cessation of hormone therapy, suggesting an acceleration of existing breast cancer not a promotion of breast cancer; 2) there is no effica-cious substitute for hormone re-placement for symptomatic women, as evidenced by studies on “natural” remedies and the profound relief found even with the lowest-dose hormone regimen; 3) extensive risk counseling of patients was required due to the unknown short-term risks of such therapy; and 5) therapy should be individualized to each patient and clinical scenario.

In essence, the WHI study demonstrated that blanket treatment of a population for primary preven-tion is not good practice. First, always identify at-risk patients and assess co-morbid risk factors for cardiovascular disease, osteoporosis, cancer, etc. Physicians may then tailor doses for the primary indication of symptomatic relief, with consideration given to different delivery modalities based on individual patient needs and other risk factors present. Only in the case of premature meno-pausal patients, should hormone therapy may be used for prevention of cardiovascular disease and bone fractures.

Acknowledgements: Thank you, Dr. Packin, for an informative and engaging lecture.

Lecturer:
Gary S. Packin, DO, FACOOG(Dist.)
74th Annual Conference
March 12th, 2007
La Quinta, CA

(Lecturer References)

Additional (Reporter) References
We are pleased to report that the financial review for 2006 reflected an increase in net assets for MEFACOOG. This year, as a percentage of the total, individual contributions increased over programatically directed corporate contributions. As you can see, the corporate contributions are channeled into programs that benefit education, research and faculty development:

- MEFACOOG/Wyeth Resident Reporter Scholarship Program—educating osteopathic OB/GYN residents at the ACOOG Annual Conference and reporting back to their programs and to the profession.
- MEFACOOG/Ortho Women’s Health Visiting Professor Program—educating osteopathic medical students and promoting career choices in obstetrics and gynecology.
- MEFACOOG/Berlex (now Bayer) Awards for Excellence in Poster Presentation—encouraging research and rewarding dissemination via poster presentation at the ACOOG Annual conference.
- MEFACOOG/Ortho Women’s Health Resident Research Grant—encouraging research in osteopathic OB/GYN residency and fellowship programs.

The 74th Annual Conference of the ACOOG hosted three ongoing funded lectureships. The tenth annual Barbara Hawkes Memorial Lecture funded by Ortho Women’s Health and Urology was also the College’s first memorial lectureship. This year’s lecture was given by Kedrin Van Steenwyk, DO. The sixth annual MEFACOOG Distinguished Lecture was presented by Ronald Ayres, DO. The second annual MEFACOOG Gail Goldsmith Memorial Lectureship was presented this year by Vivian Dickerson, MD. This was the second annual lecture of the ten year endowment made possible by the Friends and Colleagues of Gail Goldsmith and Wyeth.

The MEFACOOG Board approved grants in 2007 for several important initiatives of the College. The ACOOG Historian Committee is producing an educational DVD and CD-ROM about the History of the ACOOG. The National Student Society of the ACOOG has met for the first time in St. Louis at the ACOOG Fall Conference. The Osteopathic Manipulative Medicine Guidelines for Osteopathic OB/GYN Residencies in CD/ROM format is in production. These projects would not be possible without the support of you, the donors. Thank you for your continuing support.

FINANCIAL REVIEW

STATEMENT OF ACTIVITIES

Year Ended December 31, 2006

<table>
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<td>Support Services</td>
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| Other Income (Expenses) | $33,813 |
| Change in Net Assets   | $23,057 |
| Net Assets, Beginning of Year | $602,428 |
| Net Assets, End of Year      | $625,485 |

STATEMENT OF FINANCIAL POSITION

Year Ended December 31, 2006

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<td>Unconditional Promises to Give</td>
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<tr>
<td>Total Assets</td>
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<table>
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<th>Liabilities and Net Assets</th>
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<td>Accounts Payable</td>
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<td>Total Liabilities</td>
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<tr>
<td>Net Assets</td>
<td>$625,485</td>
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<tr>
<td>Total Liabilities and Net Assets</td>
<td>$653,105</td>
</tr>
</tbody>
</table>
The primary indication for treatment of POP is for symptomatic relief. For women experiencing mild symptoms, conservative treatments are often adequate. There are several options such as pelvic floor exercises, biofeedback, and pessaries. However, significant POP often necessitates surgical correction, as the more conservative methods are unsuccessful or unsatisfactory to the patient. Commonly used procedures have been anterior and posterior colporrhaphy, hysterectomy, uterosacral vault suspension, sacrospinus fixation and sacral colpopexy, among others. More recently, biologic and synthetic mesh materials have been used in vaginal procedures. Briefly, the Prolift™ procedure employs a polypropylene mesh placed via a vaginal extraperitoneal colpopexy (VEC) in either the anterior or posterior compartment, or both. Figure 1 illustrates the delivery system and anterior portion of mesh. The purpose of this study was to determine the efficacy and perioperative outcomes for the Prolift™ procedure with six month median follow-up.

**Materials and Methods**

This is a large, multi-center, retrospective study including 350 patients, each of whom underwent the Prolift™ procedure between February 2005 and May 2006. The procedure involves placement of a synthetic polypropylene mesh graft via a VEC in the anterior or posterior compartment, or both. The mesh is held in place by tension-free extension arms that run through the obturator and/or ischiorectal spaces. These arms are delivered via a cannula and suture retrieval system. Pre-operative assessment involved collecting a relevant history, including a wide range of symptoms and duration of these symptoms, as well as pregnancy and menstrual history and any past treatments. Voiding diaries were also completed by patients prior to their office visit. A targeted physical exam was done on each patient at her initial visit, including POPQ staging, neuro-sensory exam and uroflowmetry when indicated. Pre-operative urodynamics were also used when indicated.

Data were collected by chart reviews of all patients undergoing the procedure during the time period indicated above.
Outcome measurements included: peri-operative data (operative time, estimated blood loss (EBL), type of anesthesia), intra-operative complications and post-operative complications (mesh erosions, post-implant pain recurrence of prolapse). Recurrence was defined as Stage 2 or greater prolapse at the three month or greater follow-up visit.

### Results

Patient demographics were as follows [mean (+SD)]: age 65 (+11.7), parity 2.8 (+1.3) and BMI 28.6 (+5.4). The mean pre-operative POPQ stage was 2.65 and mean point C was -1.7 (+4.4). 178 of the VEC procedures were anterior, 81 were posterior and 90 were total (anterior and posterior). 264 had concomitant mid-urethral slings placed. 293 (83%) were completed under regional (epidural) anesthesia. Additional surgical procedures performed at the time of the Prolift™ as indicated included: enterocoele repair (24), perineorrhaphy (76), rectoceles repair (63), hysterectomy (7) and uterosacral vault suspension (2). Mean operative time was 102.8 minutes (+35.8), and mean EBL was 83.4ml (+52.2).

Intraoperative complications included 9 (2.6%) cystotomies, 1 (0.3%) urethral obstruction and 1 (0.3%) pelvic hematoma. Nearly all patients were discharged post-operative day one. Catheters were removed on post-operative day one in 298 patients with the remaining removed between post-operative days 2 and 14 (mean 1.7 days). Vaginal packing was placed for an average of 1.1 days.

Median follow-up was 6.0 months, ranging from 0.5 to 14 months. Post-operative findings included: de novo overactive bladder (OAB) in 14 (4%), de novo stress urinary incontinence (SUI) in 8 (2.3%), post-operative voiding dysfunction in 12 (3.4%), constipation in 31 (8.9%) and dyspareunia in 22 (6.3%). Mesh exposure was seen in 4 (1.1%) patients, all treated with office resection and/or vaginal estrogen. Table 1 summarizes intra- and postoperative complications.

Post-operative POPQ evaluation revealed a 90.6% cure rate. Most recurrences were seen in patients who underwent a single-compartment VEC with recurrence in the opposite compartment. Of the 33 recurrences, 11 underwent subsequent surgical correction.

### Conclusion

Based on these short-term results, the Prolift™ procedure is a safe procedure for the treatment of moderate to severe POP. There are low complication and excellent cure rates.

Dyspareunia and vaginal pain are a concern for the use of Prolift™ in young, sexually active women. Long-term follow-up is needed to further evaluate the duration of cure for this procedure.

<table>
<thead>
<tr>
<th>Post-Operative Complications and Findings</th>
<th># Patients</th>
<th>% Patients</th>
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</thead>
<tbody>
<tr>
<td>Prolapse Recurrence (≥ Stage 2)</td>
<td>33</td>
<td>9.4</td>
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<tr>
<td>Opposite Compartment</td>
<td>17</td>
<td>52</td>
</tr>
<tr>
<td>Same Compartment</td>
<td>9</td>
<td>27</td>
</tr>
<tr>
<td>Apical prolapse only</td>
<td>7</td>
<td>21</td>
</tr>
<tr>
<td>Perineal Wound Separation</td>
<td>1</td>
<td>0.3</td>
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<tr>
<td>Vaginal Mesh Exposure</td>
<td>4</td>
<td>1.2</td>
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<tr>
<td>Constipation</td>
<td>31</td>
<td>8.9</td>
</tr>
<tr>
<td>Pre-operative</td>
<td>85</td>
<td>24.3</td>
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<tr>
<td>Voiding Dysfunction</td>
<td>12</td>
<td>3.4</td>
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<tr>
<td>de Novo OAB</td>
<td>14</td>
<td>4</td>
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<tr>
<td>de Novo SUI</td>
<td>8</td>
<td>2.3</td>
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<tr>
<td>Dyspareunia</td>
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<tr>
<td>Mild - Moderate</td>
<td>16</td>
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<tr>
<td>Severe (Preventing Intercourse)</td>
<td>6</td>
<td>1.7</td>
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<tr>
<td>Median follow-up</td>
<td>6.0</td>
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</table>

Table 1. Summary of Intra-Operative and Post-Operative Complications.
OBJECTIVE

The goal of this study is to evaluate the efficacy of the On-Q Painbuster for postoperative pain control in patients undergoing a laparoscopic assisted vaginal hysterectomy.

INTRODUCTION

Adequate postoperative pain control is a challenge that every surgeon faces. Inadequate control of postoperative pain may delay overall recovery. The On-Q Painbuster device is an FDA approved disposable elastomeric infusion pump designed to deliver local anesthetic directly to the surgical site for up to three days to relieve postoperative pain. A capillary flow-restricting orifice located at the end of the tubing and the positive pressure system of the elastomeric infusion pump maintains a consistent flow rate. Patented “soaker catheter” technology ensures uniform distribution and full coverage of the surgical site. The pump delivers a continuous infusion through two infusion ports at a rate of 2ml/hr/catheter. The most frequently used anesthetic is 0.5% bupivacaine.

MATERIALS AND METHODS

Twenty patients undergoing laparoscopic assisted vaginal hysterectomy were recruited for this prospective, observational study. All patients received the On-Q Painbuster. All patients received Demerol 100mg with Vistaril 50mg IM while in the hospital. Patients were discharged with Vicodin or Tylenol #3. All patients were sent written questionnaires regarding their post-operative pain control. Pain control was measured subjectively. The narcotic usage was measured by the patient’s medical record and the written questionnaire. This study was approved by the Kettering Medical Center Network – IRB (IRB#: 06-029).

CATHETER PLACEMENT

The On-Q PainBuster is the only type of pain pump used in this study, specifically, the PM025. The pump holds 270cc of 0.5% bupivacaine, which is delivered at a rate of 4ml/hour. Two 8-inch T needles were placed intraabdominally above the pubic bone (Figures 1, 2, 3). The needles were placed through the peritoneum at the level of the suture lines bilaterally (through the pedicle of the infundibulopelvic or tubo-ovarian ligament; Figures 4, 5). The catheters were threaded through the guide leaving the distal tips between the peritoneum and vaginal mucosa. The distal 2cm remained in the vaginal vault. A bolus of 5cc of 0.5% bupivacaine was infused into both catheters. The tubing was secured to the patient’s abdomen with a Tegaderm dressing. At the completion of the surgery, the On-Q PainBuster pump was attached to the proximal portion of the catheters. The pump device was placed in a pouch around the patient’s waist.

RESULTS

Twenty patients received the On-Q Painbuster. All pumps remained in place for 3 days and were removed by the patient at home; no adverse effects were experienced. Nine patients were discharged within 6 hours of their surgery. Eleven patients remained in the hospital for less than 24 hours (Table 1). All patients received 0 to 3 doses of Demerol 100mg with Vistaril 50mg IM; 75% used 2 or fewer injections (Table 2). Patients used 2 to 9 tablets of Vicodin or Tylenol #3, while in the hospital. Patients used 0 to 30 tablets of oral narcotics at home. All patients reported adequate pain control at home. None of the patients required nausea medication. All patients ambulated within 2 to 9 hours after surgery. One patient was back to her normal activity in 1 week; 4 were back to normal activity in 2 weeks; all were back to normal activity within 6 weeks.

(NOTE: Catheter placement has since been changed. The distal tips of the catheters now are placed in the cul de sac of the pelvis without ever entering the vagina, see Figure 6.)

Submitted by Lynn Powers, DO, OB/GYN Resident

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CONCLUSION

The results suggest that the On-Q Painbuster is an acceptable method for adequate postoperative pain control in patients undergoing laparoscopic assisted vaginal hysterectomy.

REFERENCES

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Abstract Objective: This study was undertaken to assess the apparent efficacy of the NovaSure™ ablation after the procedure in women with dysmenorrhea and menorrhagia secondary to dysfunctional uterine bleeding (DUB).

Study design: A descriptive study using feedback from subjects both prior and after NovaSure™ ablation. A total of 99 women who had undergone NovaSure™ ablation in the past two years for DUB responded. An eleven-question survey was used to assess quality of life prior to and after ablation.

Results: Median and mean age of the patients was 41.8 and 42 years, respectively, ranging from 28 to 62 years. Seventy-eight percent of the patients reported hypomenorrhea. Successful bleeding reduction was achieved in ninety-five percent of patients using the NovaSure™ GEA device. With a mean follow-up of 1.31 years, hysterectomy was avoided in eighty-nine percent of patients. Patient satisfaction rates are extremely high in those who have undergone the procedure.

Conclusion: Relatively short term results demonstrate that the NovaSure™ system is a safe and effective alternative to hysterectomy for treatment of women with menorrhagia secondary to DUB.

Menorrhagia has been defined as prolonged or excessive uterine bleeding that occurs at regular intervals. The average woman loses about 35 mL of blood during menstruation. Hallberg et al., measured the critical blood loss as 80 mL, which is most commonly used as the cutoff for excessive bleeding. Studies have shown that only 40% of women who present with complaints of clots and heavy bleeding actually qualify for menorrhagia. Due to the subjectivity of menorrhagia as a complaint, the main aim of treatment has to be improved quality of life.

We have yet to find a clear mechanism that explains the symptom of heavy menstrual bleeding in women without pelvic pathology or systemic disorder. Menstrual problems are among the most common reasons for specialist referral and account for a third of gynecological outpatient workload. Due to technology and better nutrition, earlier onset of menarche and increased life expectancy are a reality. We also now possess the ability to regulate fertility while women spend less time breastfeeding than perhaps ever before. All of these factors contribute to the fact that women experience ten times more menstrual cycles in their lifetime than their predecessors a century ago.

Hysterectomy is currently the most popular treatment method for women with menorrhagia. Hysterectomy is the second most frequently performed surgical procedure, after cesarean section, for women of reproductive age in the United States. Approximately 600,000 hysterectomies will be performed this year in the United States. Despite its effectiveness, hysterectomy has a number of serious drawbacks. Morbidity, mortality, late postoperative complication rates, including the need to re-operate are very costly both figuratively and literally.

Ablation of the endometrium is both less invasive and less aggressive in comparison to a hysterectomy. The MISTLETOE study has shown endometrial ablation to be a safe procedure. A follow-up study of 10,686 women who had undergone endometrial resection or ablation found a complication rate of 1.25–4.58%. Lower mortality and morbidity rates and significantly lower procedure costs are causing this method to become increasingly more popular among the gynecologic community worldwide.

The NovaSure™ GEA disposable ablation device consists of a conformable, bipolar, gold-plated, porous, fabric mesh, mounted on an expandable metal frame. Integral to the hand-held device is the Intrauterine Measuring System (IMD) used to determine uterine cavity width (cornua-to-cornua distance). The unique geometry of the electrode allows for a controlled depth of ablation. It is characterized by a more shallow depth of myometrial penetration (2 mm) at the cornua and lower uterine segment, and a deeper (5 mm) ablation in the mid-body of the uterus. The NovaSure™ GEA device can treat uteri with sounding lengths up to 12 cm. During insertion into the uterine cavity, the ablation electrode is housed in a protective sheath (similar to an IUD) with an outside diameter (OD) of 7.2-mm. During electrode deployment the sheath is withdrawn into the endocervical canal, allowing for full and proper intrauterine deployment of the fan-shaped bipolar electrode. During the ablation procedure, a protective sheath occupies the full length of the cervical canal, assuring an effective protection of the endocervix from thermal injury.

The NovaSure™ GEA Controller contains a constant power output generator with a maximum power delivery of 180 watts. Measurement of uterine cavity length (determined during sounding and cervical dilation), and width (measured by the GEA device at the time of device deployment), are key-entered into the controller, which automatically calculates the unique power output...
required to assure an optimal, confluent endo-myometrial ablation. Throughout the short procedure, the depth of ablation is continuously controlled by monitoring tissue impedance (resistance). Vaporization of the endometrial layer is a low impedance process owing to a high concentration of conductive liquid (saline) present in the endometrial tissue. As a result, the endometrial tissue is not slowly ablated, but vaporized instead. The vaporization front is continuously moving deeper and closer to the edge of the myometrium. Once the ablation process reaches the myometrial layer, the content of the saline becomes significantly lower. Tissue impedance (resistance) rises rapidly during myometrial tissue desiccation process and reaches 50 Ohms which is equivalent to the impedance of the ablated superficial myometrium. This signal’s the NovaSure™ generator to automatically terminate the ablation process. This automatic feedback mechanism is a key aspect of the NovaSure™ GEA technology and differentiates it from other global ablation technologies. With the NovaSure™ GEA, the ablation process is based, not on temperature and time, but on specific, well-analyzed physical characteristics (electrical conductivity) of tissues that are continuously changing during the ablation process. This approach allows for an effective ablation independently of the endometrial layer thickness. Treatment time, basically, equates to the length of time that is necessary to vaporize an endometrial layer of a certain thickness. The ablation procedure usually is longer in patients with thick endometrium (100-120 seconds) and is shorter in patients with thin endometrium (30-100 seconds). This unique approach allows for a well-controlled, tailored, consistent and rapid ablation process.

An important component, unique to the NovaSure™ GEA, is a vacuum pump, contained within the RF Controller. This pump provides continuous suction during the procedure, thus allowing for the removal of steam, blood and other by-products of ablation from the cavity. As opposed to balloon ablation technologies, in which pressure distends the uterine cavity, the NovaSure™ GEA system’s use of constant vacuum assures intimate contact between the ablation electrode and the endometrium.

Another valuable aspect of the NovaSure™ GEA system is its portability and lightweight, allowing the system to be easily stored in an office cabinet.

**SAFETY FEATURES**

A Cavity Integrity Assessment System (Perforation Detection System) is another integral part of the NovaSure™ GEA System. This automatic safety feature assists the physician in the timely detection of a uterine perforation, and prevents energy delivery in such cases. The Cavity Integrity Assessment System utilizes the same technology employed by conventional hysteroflators, in which there is an inverse relationship between flow rate and pressure. CO2 is delivered into the uterine cavity at a safe flow rate (max 100 c.c/min) and pressure (max 100 mm Hg). The goal is to generate and maintain an intrauterine pressure of 50 mm Hg for a period of 4 seconds. The pressure of 50 mm Hg was chosen in order to avoid false positive results due to leakage of CO2 through the Fallopian tubes (cracking pressure of the Fallopian tube is 75-80 mm Hg). Once the controller determines that this pressure is maintained, thus confirming uterine wall integrity, it signals the generator to proceed with the ablation process.

**MATERIALS AND METHODS**

After devising the methods, the Institutional Review Board at Saint Anthony Hospital was informed of the proposed study. The decision was made that a chart review and descriptive study would only require patient consent and not official approval through the IRB. Subjects were identified from past procedure logs of three different private OB/GYNs in the South Oklahoma City area. A total of two hundred and sixty-eight women were identified who had undergone endometrial ablation with the NovaSure™ device during 2004-2006 for menorrhagia secondary to DUB. An outcome questionnaire was mailed to each of these subjects using a mailing address from the billing office. A form letter was attached to the questionnaire. The letter informed the subject of the identity of the observer and described the nature of the study. It also asked for permission to use their information in a confidential study for medical purposes. A total of one hundred and four responses were received. Five of the questionnaires did not have subject identification and were not included in the results. The remaining ninety-nine responses were reviewed along with their history and pathology results from the patient chart. The names of the subjects were coded numerically for the purpose of patient confidentiality. The results of each questionnaire were placed into Microsoft Excel™ for database storage and analysis. A T-test was conducted using SPSS 14™.

The great majority of subjects had failed conservative therapy. A hysteroscopy and endometrial curettage was performed in addition to the NovaSure™ GEA on each case. The date of the procedure performance was not correlated to a particular menstrual cycle day. Some of the subjects underwent ablation while actively bleeding. All the procedures were performed in an outpatient surgery setting.

Patient quality of life (QOL) evaluation was perceived as the optimal assessment of success following this procedure due to the disabling nature of menorrhagia/dysmenorrhea. Using a customized questionnaire based on a menorrhagia study in Canada, eleven questions were used to assess outcomes of the procedure. The subject selects one of five possible responses to each question on this self-administered instrument. Each response is scored one to five, with a higher score meaning a worse outcome. Categories evaluated post-ablation included pelvic pain, menstrual bleeding, fatigue, sexual health and personal sense of health. The total score provides a variety of clinically meaningful efficacy outcome data in addition to subjective QOL improvement. The results of this evaluation were used to demonstrate whether an improvement in QOL score occurs after the NovaSure™ procedure.

(Continued on Page 16)
Results

Median and mean age of the patients was 41.8 and 42 years, respectively, ranging from 28 to 62 years. Ninety-six percent of the subjects were parous at the time of the procedure. The average parity was 2.09 and the median was 2. Mean follow-up time at the time of syllabus deadline was 479 days (1.31 years). Due to the fact that the mean age is 42 years, an assumption can be made that most subjects were premenopausal. However, no follicle-stimulating hormone (FSH) levels were examined during the chart review, to assure their premenopausal status (FSH < 40 u/L).

The most common method of contraception at time of NovaSure™ was tubal ligation prior to NovaSure™, with fifty percent of subjects reporting this method. Remaining methods included vasectomy (29%), other (16%) and tubal ligation at time of NovaSure™ (5%).

A scoring system was devised using questions from the survey. With a possible score out of 5 for each of the questions, results were calculated. A higher number for each response was defined as a worse outcome. Scores of pelvic pain/dysmenorrhea and menstrual bleeding before and after procedure were assessed based on subject responses.

The mean score for pelvic pain/dysmenorrhea before procedure was 3.68 (median 4.0). Thirty-five percent of subjects responding as “quite a bit” of pain prior to the procedure (Figure 1). Mean score for pelvic pain/dysmenorrhea after procedure was 1.48 (median 1.0). Seventy-three percent of subjects felt their pain was “much better” post-procedure. A successful pelvic pain/dysmenorrhea reduction was defined as a subject response describing pain post-procedure as “much better” or “a little better.” Eighty-eight percent of patients achieved this amount of pain relief using the NovaSure™ GEA device (Figure 2).

A mean score for bleeding before procedure was 4.48 (median 5.0). Sixty-three percent of subjects described their menstrual bleeding prior to the procedure as “a lot” (Figure 3). A mean score for bleeding after procedure was 1.19 (median 1.0). Successful bleeding reduction was defined as a subject response describing menstrual bleeding post-procedure as “much better” or “a little better.” This reduction was achieved in ninety-five percent of patients using the NovaSure GEA device (Figure 4). Hypomenorrhea was defined as no more than “spotting” with menses. This result was found in seventy-eight percent of subjects at follow-up. This figure is less than the eighty-eight percent Gallinat quotes at 12 months follow-up.

Subjects were asked to respond with their perceived level of fatigue after the procedure (Figure 5). According to Hallberg, sixty-seven percent of women with menorrhagia will develop iron-deficiency anemia. Fifty percent of subjects responded as feeling “less tired” post-ablation. These findings correlate with the anemic percentages mentioned earlier. Forty-six percent (46/99) stated that they felt “about the same.” Four percent (4/99) of respondents that they felt “more tired” post-ablation.

Evaluation of sexual health was also performed (Figure 6). Subjects were asked about their sexual health after the NovaSure™ GEA. Sixty-three percent (62/99) retorted “no difference” in their sexual health post-ablation. Twenty-two percent (22/99) of subjects stated sexual health to be “improved” post-ablation. Six percent (6/99) described their sexual health as “worse.” Nine percent (9/99) responded “Not applicable.”
During the follow-up period, eleven hysterectomies were performed. One patient presented with endometrial curettage findings of focal complex endometrial hyperplasia after ablation, which resulted in hysterectomy. Ten hysterectomies were performed for failure, with deep adenomyosis and leiomyomata diagnosed on four specimens. With a mean of 1.31 years, hysterectomy was avoided in eighty-nine percent of patients.

A cervical dilatation and uterine curettage was performed with each procedure reviewed. Pathology findings from the endometrial specimens were analyzed (Figure 7). Benign secretary endometrium was most prevalent (34.1%). Study population incidence of endometrial hyperplasia was found to be seven percent, which is in accordance with incidence of ~5% by Archer et al.1 Endometrial polyps were found in eleven percent of the specimens collected.

Patient satisfaction was evaluated post-procedure as well. Overall, eighty-nine percent of subjects responded that they “felt better” after the procedure (Figure 8). Subjects were asked whether they would recommend NovaSure™ GEA to a friend. Seventy-nine percent responded they would “definitely recommend.” Eleven percent responded “probably recommend.” Seven percent responded “not sure.” Three percent of subjects “definitely would not recommend” the NovaSure GEA to a friend (Figure 9).

**Discussion**

Clinical outcomes from this study appear somewhat similar to others when evaluating the success of NovaSure™ GEA. Cooper et al. found a successful bleeding reduction in ninety percent at one year after ablation with the NovaSure™ device.12 One concern is that this study may be limited by a short follow-up period. However, Gallinat found that there is no difference in success rates when comparing 6, 12, and 36 month follow-up.10 If that is the case, then a mean follow-up of 1.31 years should be sufficient to evaluate outcomes. Another possible limitation to this study is sampling bias. Those who responded may have done so because the procedure results in a good outcome. Just the same, those who chose not to respond may have done so because the procedure did not result in a good outcome.

Patient satisfaction following NovaSure™ GEA was extremely high. Ninety percent of subjects would either “definitely” or “probably recommend” the procedure to a friend. This response is very similar to the ninety-two percent satisfaction found by Abbott et al. in 2002.10 Fatigue appears to be improved after an endometrial ablation using the NovaSure™ device. No doubt this finding is related to a reduction in menstrual blood loss, thus improving hemoglobin concentrations. A woman’s sexual health is influenced by many factors. While twenty-two percent did state their sexual health as being “improved,” the majority of subjects responded that the NovaSure™ GEA made “no difference” in their sexual health. Overall, data from this study should continue to propagate NovaSure™ GEA as a safe and effective alternative to hysterectomy for menorrhagia secondary to DUB.

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MEFACOOG welcomes the newest Corporate Partnership Council member, Duramed Pharmaceuticals, Inc., a division of Barr Laboratories. Duramed has joined at the Platinum level. The following information was provided by the company to educate our membership. We want to recognize the educational grant that assists MEFACOOG in accomplishing its mission.

Our thanks to these companies for their valuable assistance in partnering with the MEFACOOG to foster continuing improvements in women’s healthcare. Corporate Partnership Council of the Medical Education Foundation of the American College of Osteopathic Obstetricians and Gynecologists Mission Statement

The mission of the CPC of the MEFACOOG is to enhance and improve the quality of women’s healthcare through collaborative partnerships. We will accomplish our mission by:

1. Education of:
   - Physicians
   - Residents and other related
   - Healthcare professionals
2. Increasing industry awareness of the uniquely osteopathic educational model
3. Improving industry access to physicians and the patients they serve
4. Collaboratively identifying, developing and implementing educational programs in women’s healthcare and thereby,
5. Improving the lives of women through education

The current members of the Corporate Partnership Council (CPC) are:

**Platinum $25,000+**
- Ortho-Women’s Health & Urology – George Roberts
- Wyeth Pharmaceuticals – Mark Barbee
- Bayer HealthCare Pharmaceuticals – Tom LiVecchi
- Matria Healthcare – John Miller
- Organon, Inc. – Aimee DeBlasis
- Eli Lilly and Company – Sharron Stewart
- Pfizer, Inc
- Duramed Pharmaceuticals, Inc. – Amy Neimann

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A receipt will follow by the U.S. Mail. Thank you for assisting the MEFACOOG in accomplishing its mission and to foster continuing in women’s healthcare.