Asian Journal of Andrology (2015) 17, 225–229

www.asiaandro.com; www.ajandrology.com

Open Access

EXPERIENCE AND HISTORY

Sexual Function

Early history of inflatable penile prosthesis surgery: a view from someone who was there

David F Mobley

Asian Journal of Andrology (2015) **17**, 225–229; doi: 10.4103/1008-682X.140962; published online: 18 November 2014

The publication of the use of an inflatable penile prosthesis (IPP) in 1973 by Dr. FB Scott. changed the world of treatment options for erectile dysfunction (ED). Much has been written since then about techniques, improvements, management of difficult cases, complications and their management, and mechanical and device changes over time. Few reports, if any, are available in the medical literature regarding the early development, surgical techniques, and controversies surrounding its introduction to the world's urological community. This article is, for the most part, the observations of one who was "there" in the early and mid-1970's and was a witness to the history of this remarkable marvel of creativity, engineering, design, and to the personalities involved.

INTRODUCTION

This publication came about almost by accident. In May, 2014, I was in the Orlando airport waiting for my Houston flight after the American Urological Association annual meeting, and ran into Professor Run Wang, of the University of Texas and the M.D. Anderson Cancer Center, who is president-elect of the Sexual Medicine Society of North America, and an accomplished prosthetic surgeon. I have known him professionally in Houston for a number of years. We began chatting and reminiscing about the "old days" in the penile implant arena. He knew I had been doing prosthetic surgery for almost 40 years. During this encounter, he introduced me to Ms. Danqing Ren, Science Editor, *Asian Journal of Andrology*. Subsequent to this encounter, I received E-mails from both of them asking if I would be interested in writing an article for the Journal relating my experiences at Baylor College of Medicine (BCM) and my time with Dr. F Scott. the father of the IPP back in the 70's. I happily took on this project.

It has been 41 years since the first publication of the inflatable penile implant, and 23 years since the death of its inventor and hence some of the details may be "fuzzy." I make an effort to distinguish from what I know for sure, to what I've heard from others, and I will even relate some of the "rumors." A lot was going on. It was fun being there. These were heady times for all the involved parties. A few of the residents and a few of Dr. Scott's fellow colleagues felt this was going to be game changing development in the management of ED, but many who were there did not seem to appreciate how big this was likely to be for a condition called "impotence" and at a time when 95% of men were felt to have a psychological etiology.[1]

For me, it began in 1967 when I was considering my specialty future in medicine. I was still in medical school, but nearing the last year. I had decided urology was for me. I knew I wanted to stay in the South, with a residency in a well-respected institution. I had the opportunity to spend an elective with Dr. Milton Goldman, who was trained at BCM. He encouraged me to apply at BCM in Houston, and he put in a good word for me, which helped immensely. Back then there was no matching program for residency and no postgraduate year-1 (PGY-1), PGY-2 etc.; only internship and residency. I did my "rotating internship" in Memphis, then on to Houston to do the required year of general surgery, prior to urology. I spent that year in the surgery department of the famed Dr. Michael E DeBakey. I had decided long before college that I wanted to serve my country in the military in some fashion. During medical school, I decided that I would spend 2 years in the United States Air Force, and I decided to do this between surgery and urology. This tour of duty was completed in August 1973.

During my surgical year at BCM, I spent 3 months on the urology service and saw the very early days of the development of the IPP. I was fascinated by the work Dr. F Brantley Scott. was doing, not only with the IPP, but also the artificial urinary sphincter (AUS), and I was anxious to get back to Baylor Urology.

Dr. F BRANTLEY SCOTT AND INFLATABLE PENILE PROSTHESIS DEVELOPMENT

To enjoy some insights about the early days of the IPP, a little biographical sketch of the great Brantley Scott is in order. I don't throw around the word "great" loosely. The F. stood for Frank, but he was Brantley to all who knew him. He encouraged the residents to call him Brantley as opposed to "Dr. Scott." Something many of our attending did not do, instead requesting a more formal relationship. I will refer to Dr. Scott in this report as Brantley, not to be overly familiar, but because I think he would have wanted me to do that.

Born in 1930 in Prescott Texas, Brantley was a real Texan. He wore cowboy boots, big belt buckles, often a cowboy hat, and he had a key chain with a spur on it. He attended The University of Texas in Austin, or as it is known in Texas, "The University." His medical education was obtained at Yale University, but he wasted no time getting back to Texas. He was an imposing man in every way; big in stature and big in personality, big in brilliance, with immense self-confidence, and with a big captivating voice to accompany this (**Figure 1**).

Brantley was adored by all those who had the opportunity to know, and especially those fortunate enough, myself included, to work

Institute for Academic Medicine, Houston Texas, 18300 Katy Fwy, Ste 325, Houston, TX 77094, USA. Correspondence: Dr. DF Mobley (Mobleyresearch@gmail.com)

Figure 1: Photo of Dr. Scott circa 1975. Courtesy American Medical Systems, Inc.

directly with him. All the residents loved him, but although they loved and revered the man, many during my era were not taken with all this prosthetic work. To my knowledge, I was the first graduate resident of Baylor to go out into the community setting and do implant surgery. Many of the residents thought this gadgetry was going nowhere, and they were interested in transurethral prostatectomies, cancer surgery and the like. Some of the faculty felt this was all gadgetry with no future, and would die due to the difficulty of the surgery and the large number complications and revisions that were fairly common in the early days.

Brantley's spacious office in St. Lukes Episcopal Hospital was in the basement and always bustling with energy and happy people. He had a robust urodynamics lab and staff, and he had a special interest in evaluating bladder dysfunction. He knew and understood bladder function/dysfunction as well as anyone in his era. He was always learning more as impressive data was constantly generated in his laboratory. He also had his own micro laboratory. Patients came to see him from all around the world. Physicians visited him from many foreign countries. He had a very impressive guest book. Many urologists arrived in hopes of being able to observe the famous Dr. Scott in the operating suite. He was always kind, outgoing, and gracious to these guests. It was really quite impossible to accommodate all the physicians who wished for an audience with Brantley.

Among these early implanters were future giants of the implant world. Included were such figures as the late Dr. William Furlow of the Mayo Clinic, the inventor of the Furlow Inserter, still in use today, Dr. John Mulcahy from Indiana University, who revolutionized techniques of salvage surgery, and Dr. Steven Wilson of The University of Arkansas who has published so much on techniques to manage the "difficult implant." These are but a few luminaries who benefitted from Brantley's early work. It was very interesting to me at the time that although surgeons from around the country and the world were taking the IPP baton and running with it, almost no one in Houston was interested in this world of prosthetic surgery in the early days.

Brantley was considered a renaissance man by all who knew him. He was a physician, a scientist, an author, an artist, a sculptor, a rancher, a jewelry maker, a pilot, an airplane-builder, a medical device developer, a musician, an entrepreneur, and a scholar. He was a thoughtful innovator with the capability of reasoning out any surgical problem in the field of urology. We residents often said that if we could think of one- or two-ways to handle a challenging surgical problem, Brantley could think of six or more possible options. Once in private practice, many of his former residents, myself included, would call for his advice in a challenging medical or surgical case, and he always took the time to help out. When I left Baylor to go out into the Houston community to do prosthetic work, there was some resistance in my local area to allowing this kind of surgery in a community hospital. I was one of the first, if not the first, to do this surgery outside the medical center. It was often labeled experimental or worse. Brantley came to my defense, and all the resistance to do prosthetic surgery dissolved.

Brantley is of course, known worldwide for his impact on urologic prosthetic surgery, and is probably best known for the IPP which in the early days, and for many years to follow, was even referred to as the Scott prosthesis. Despite the massive fame of the IPP, Brantley devoted a tremendous amount of his energies into development and improvement of the AUS, which preceded the IPP. Although I never heard him say so directly, I really think his real love was first the AUS above the IPP.

The IPP was an engineering off-shoot of the AUS. Working with biomedical engineer, Dr. Gerald Timm, and with team members at American Medical Systems (AMS), Inc., they had the idea that if they could develop an inflatable cuff as in the AUS, already successful, then the same engineering technology could be used to develop penile cylinders that could be inflated and deflated. Now I must say here, that this is how the story was promoted for its concept, development and inception. I don't know if this is precisely true, but at least conceptually, I think it is. AMS, founded in 1972 by the collaboration of Robert Buuck, Gerald Timm (PhD, engineer), William Bradley, M.D. (Neurologist) and Dr. Scott, was then a small biomedical engineering company in Minnetonka, MN. This team worked closely, and their first IPP publication in 1973 changed the urology world forever.[2] The article was published just as I was returning to Baylor from my tour as a physician in the Air Force.

Brantley worked at a time when surgeons of his fame could charge pretty much whatever they chose for their work. Some surgery was covered by insurance, some were not. Despite his worldwide fame, and the heavy demand for his services, his fees were always very fair and reasonable, and from what I knew about surgical fees back then, his charges for surgery were often much less than the charges of his lesser-known colleagues. He was not out to gouge anyone. He didn't make a big deal out of this, he just did not charge excessive fees for his services. He did operate on some very wealthy patients, and if they were willing to donate to Baylor or to his research, that was a different matter, but it was not associated with surgical fees. He did generate largess for The Texas Medical Center and Baylor from appreciative patients and philanthropists.

No Brantley story could be told without acknowledging his wonderful sense of humor. He was the consummate speaker and could mesmerize any audience. He had a collection of several thousand humorous slides to add levity to all his presentations. His sense of humor was always just around the corner even in the midst of a long, trying and difficult procedure. This always helped things to go smoothly and kept the overall cooperation and teamwork in the operating room at the high level needed.

Finally, he was a family man. When I knew Brantley, he was married to his second wife, Karolyn, a wonderful lady who loved and doted on Brantley. They had a wonderful marriage, and together they would have residents and their wives (all our urology residents were male then) over to their home from time to time for barbeque, dinner, etc., He had five children, four girls, and one son. He spoke lovingly of all of them often. He cherished his time with his family, and ultimately he retired as a fairly young man to spend more family time, something that had been difficult for him I'm sure, during his years of great fame and demand.

ON TO THE EARLY DAYS OF INFLATABLE PENILE PROSTHESIS SURGERY

Nowadays the work-up for IPP surgery, for most experienced surgeons, is pretty simple and usually straightforward. The usual

candidate is a man who failed, or could not use, PDE-5 therapy, and either failed other conservative therapies or is not interested in such therapies as penile injections or vacuum devices. Counseling the patient, making him aware of the nature of the surgery, and his expectations and risks, and if he agrees, surgery is scheduled and done. In some cases, a more extensive work-up may be involved. The surgery is nearly always done as an out-patient, or with a short overnight observation in the hospital. Recovery is usually uneventful; complications, infections and revisions are uncommon.[3]

Back in the 70's at Baylor it was quite a different world for penile implant patient selection, evaluation and subsequent surgery. I think Brantley felt as though he was under close scrutiny and peer pressure and that his surgical activities were being closely watched. I have no personal knowledge as to whether the initial penile implant surgery had the blessing on an Investigational Review Board as we would do today with something so new, untested, and revolutionary. Because it was new and truly revolutionary, everything was done by "the book". To a large extent, Brantley and his team wrote "the book" and created the guidelines on evaluation of the patients requesting implant surgery. They went about this with a careful scientific approach. There was no lack of patients wanting his services, but he only performed surgery after a quite extensive and exhaustive work-up. Along with the usual history and physical, Brantley worked very closely with Baylor's psychiatry department and especially with Dr. Ismet Karacan, in designing protocols and diagnostic tools. Patients underwent psychological assessment with various tools such as the Minnesota Multiphasic Personality Inventory. Most patients spent 2–3 nights in a sleep lab where nocturnal penile tumescence was quantitated including measurements of other sleep parameters.

Prior to this work, it was pretty much assumed that morning sleep erections were due to a full bladder. Baylor's sleep lab showed that nocturnal erections were related to rapid-eye movement, or the deepest phase of sleep, not to a full bladder.[4] If the potential implant patient made it through all this, he would interview with Brantley, and surgery could be arranged. But the patient had to be willing to go through this evaluation before being considered for surgery. This was his protocol at that time.

The first implants were very different from what we use today, and the surgery itself was very different as well. Brantley was opening up a new frontier of surgery and techniques were developed very carefully, and thoughtfully, but sometimes out of immediate necessity, techniques were created and improvised in the O.R. Brantley was very cognizant that if his prosthetic surgery resulted in too many complications, infections, failures or re-operations, the future of these accomplishments could be doomed. He stressed precision in his surgery. The preoperative preparation included the patient entering the hospital the night before surgery. Urine cultures were obtained prior to surgery to confirm that the urine was sterile. Upon arrival in the O.R. holding area, the shave preparation was done. Intravenous antibiotics were administered in the holding area. At this time shave preps for many surgical procedures were done the night before the operation, but not for IPP or AUS surgery. The shave was done in the O.R. to minimize any skin damage or contamination. The prep in the O.R. was a full 10 min of povidone-iodine. By the clock. Full 10 min. The surgeon and the assistants, residents, nurses, had extensive hand washing with povidone-iodine, then another coat of iodine was sprayed onto the hands of the surgeons and assistants and allowed to dry before the hands were inserted into the surgical gloves. He asked everyone to completely cover all hair. Brantley had a beard, and so he wore a full face cap to prevent any hair from inadvertently falling into the wound. Brantley did all the surgery himself. Residents were there to watch, learn, and to hold retractors, not to do the case. He said, "these patients are paying for Brantley Scott to do the surgery, and he will do the surgery". As residents of course, we wanted to do the case, but this was not allowed. Observers from all over the world were common in the O.R. and Brantley was a gracious teacher.

With all these precautions, infections were, fortunately, uncommon. Brantley was ahead of his time believing that postoperative antibiotics should be very limited, a day or two at most. He told me that he really felt that once the incision was closed, antibiotics were of no benefit. At the time, that was somewhat revolutionary thinking. Although infections were uncommon, device failures, malfunctions, leaks were common, and IPP revisions were far more common than today. As a side note, this was different than with the AUS where infections and erosions were more common in the early days, because there was no deactivation mechanism on the pump until much later.

With regards to the infection issue, Brantley really felt these cases should be done in a laminar flow room, but these rooms, unfortunately, were reserved for the orthopedic, especially hip cases at St. Lukes. I was personally fortunate to be able to use a laminar flow room at my hospital after I left my residency, and he thought I was very fortunate to have this luxury.

Since he could not use the laminar flow room, he invented his own, which he called the surgical isolation bubble system (SIBS). It was quite clever and very easy to use. It was like a baby's incubator, only bigger, with air flow from the head of the patient through the bubble and out the foot end of the bubble. Once available, I too used the SIBS (**Figure 2**).

It turned out this laminar-flow approach did not appreciably reduce infections, and it is no longer used. He did this inventive work with a company he was instrumental in developing, Lone Star Surgical, now Cooper Surgical. Many of you know he also developed a wonderful self-retaining retractor system. It was known as the Scott retractor and for many of us, it is still the Scott retractor, but it is now known as the Lone Star Retractor, still used extensively. The IPP surgical procedure and the device itself were quite different. We had no sutures on the distal end of the cylinders to pull through the corpora, no rear-tips, no kink-proof tubing, no refined pump mechanism, and no quick-connectors. Initially, there were two pumps, one on each side of the scrotum. The reservoir was round and flat and consisted of two pieces of silicone glued together. With this early design, reservoir leaks, rare today, were commonplace. The tubing was not kink-proof, and great care was made to route the tubing so no kink would occur in the system (**Figure 3**).

There was not a choice between infrapubic and penoscrotal devices. There was only one approach surgically. A relatively long vertical incision from symphysis to umbilicus was carried down to the fascia. A long corporotomy was made to ease the difficulty of inserting the cylinders. To dilate the corpora, Brantley used his own "Scott's Potts" (his invention) and Hegar dilators. The exit tubing from the cylinders was deep in the posterior corpora, and so unless a separate hole was made in the very proximal corporal body for the exit tubing, the tubing would rest against the posterior aspect of the cylinders, often causing a cylinder leak and a revision.

The cylinders were a whole different story. We had no sutures through the distal end to push through with either a Furlow inserter or a dilate, measure, and insert (DMI). Neither had been invented. The DMI or dilamesinsert

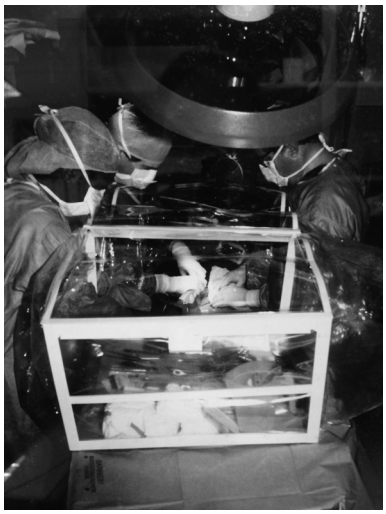

Figure 2: Dr. Mobley and his surgical team using the surgical isolation bubble system circa 1982.

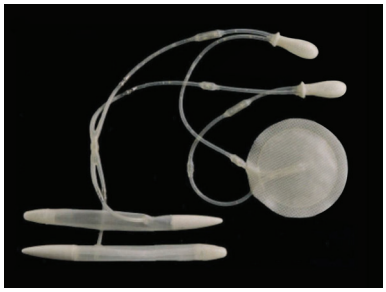

Figure 3: American Medical Systems (AMS), Inc., inflatable penile prosthesis circa 1970. Printed with permission from AMS.

was Brantley's invention, and both these instruments are used today.

Cylinder insertion was a challenge. It was inserted into a bath of absolute alcohol and acetone, kept very cold with dry ice. The cylinder filled with saline was dipped into this very cold concoction, which quickly froze the saline in the cylinder, making what we nicknamed a "popsicle". Then we tried to stuff the frozen cylinders into the proximal and distal ends of the corporal bodies. The freezing effect subsided very quickly, so speed was of the essence. If we missed it on the first pass, back to the freezing bath, and then repeat the process, sometimes several times. Contrast medium was used in the system to make it radiopaque. One can laugh at this today comparing how easy it is to insert the cylinders with the sutures on the distal end.

Eventually, we got the cylinders into place, and the corporotomy was closed. Now, the reason for the large incision: the tubing was not kink-proof, so in order to avoid kinks in the system the tubing was passed through the inguinal canal on one side, across the abdomen above the fascia, to the opposite inguinal canal and down into the scrotum for pump placement. The tubing was all secured with rubber-shod mosquito hemostats during the procedure. These rubber-shods were called "newborns" because they were newly made for each procedure. He had some other pet names for various instruments. We did not have the easy connectors we have today. They were metal and had to be secured very carefully with silk sutures. Not too tight to cut the tubing, and not too loose to fail to secure it. The early devices required multiple connectors, not one. During the procedure dual antibiotic spray, usually kanamycin and bacitracin, "bug juice" was used liberally. Closure was done in a similar fashion as we do today.

Postoperative care was interesting and challenging, for the patient, and for the resident on Brantley's service. Brantley was concerned about moving fluid in the device early, and the patient left the O.R. with partial inflation. Most patients remained in the hospital for the better part of a week. This would be almost unheard of today in US, but it is still the practice in many countries. During this week-long stay, it was the residents' job to go by and cycle the device a couple times a day. Yes, there was swelling, and pain and the patient did not like this regimen and neither was this a favorite task of the resident. It didn't take more than a couple years of experience to figure out that this was not really necessary. Eventually this "cycling" of the device was abandoned.

DEAR ABBY EVENT AND THE IMPACT ON INFLATABLE PENILE PROSTHESIS

After the publication in Urology in 1973, the IPP became well-known to the urological community but not yet to the world. This all changed in March 1975 and became quite a local controversy. In November 1974 a 40 years old school teacher had written to Abigail Van Buren, popular syndicated columnist, "Dear Abby", about her husband's impotence. Dear Abby's response, in essence, was to accept no sex, or get an annulment. In March 1975 Brantley's response to Dear Abby, (and to the world as she had a large following) was to inform her about his IPP procedure here in Houston at St. Lukes. As the story goes, and I have every reason to believe this is reasonably accurate, the powers that be, at both Baylor and St. Lukes were not happy that he had written this letter without "permission". Now-a-days, with the professional solicitation and advertising that we see, this seems pretty mild, but it created a huge controversy in the Houston medical community in 1975. All parties settled their differences, but it was a very big issue at a time. After the Dear Abby publication, not only urologists, but millions of men all over the world knew Dr. Brantley Scott, and thousands from everywhere sought his care. A storage room in his basement office contained about 30,000 letters at one time. There was no way he could operate on even a fraction of those seeking his care. Dear Abby herself opined again in 1984 on the benefits of the Scott prosthesis and of Dr. Scott himself.

By this time, he had all the surgical procedures he could handle in a lifetime. A letter today to a newspaper columnist wouldn't create a ripple on any medical organization's radar screen. Brantley was way ahead of the times and understood the power of the media and self-promotion. He did it ethically and was able to endure the criticism of the academic community knowing full well he did not do anything wrong.

The world was his oyster. He was sought after as guest professor, lecturer and with all the professional perks and adulation that go with greatness and fame. During my last couple years at Baylor, Brantley would often do 20 or so implants in 1 week, along with some AUS cases. He might then take some vacation time to pursue his other interests, especially flying and family. When he came back to town, refreshed, another large group of patients had been worked-up and were ready to have surgery. This was a routine in the heady days working with Brantley Scott.

I left Baylor in 1977 to go into private practice in Houston. Dr. Carlton, chief at Baylor, encouraged me to remain on the faculty as I had done quite a bit of research and publication during residency, and he thought I should continue in that vein. However, I was enamored of prosthetic urology and was anxious to give it a go on my own. Colleagues told me they thought there was no future in this endeavor and that even if there were a future for this type of surgery, I could not successfully do prosthetic urology in the same town as Dr. Brantley Scott But, in his usual way; he encouraged me and supported me in this endeavor. To this day, I greatly enjoy prosthetic urology and in knowing and affiliating with so many of the urologists in the "prosthetic community". Having been an early adaptor, I have been afforded many opportunities to teach this surgery to American urologists, as well as urologists in various countries around the world. It remains a joy to be part of all this.

Although not really part of the early days of prosthetic surgery, a few things to tie together loose ends: rumor has it that Brantley owned some stock early on in the infancy of AMS which was probably not worth much, until AMS was purchased by Pfizer in 1985. With his ownership position, it is said that he became quite wealthy overnight. I hope this is true. He deserved it. However embellished the tale might be, its currency shows some validity. AMS was eventually bought by E.M. Warburg, Pincus and Co. LLC, and is today part of Endo International. In this paper, I purposely have not discussed other companies that have come and gone in the implant business as they are not part of the early story involving Brantley, St. Lukes and BCM, where so much of the history occurred. To my knowledge, the only other company in the U.S. presently making an inflatable IPP is Coloplast, formerly Mentor Corporation. I have personally enjoyed long and enjoyable relationships with both companies.

Brantley did not work a lot after the Pfizer purchase and eventually retired to spend most of his time outside Austin, Texas with his family, golfing, pursuing his myriad nonmedical interests, especially flying.

THE DAY THE MUSIC DIED

About a year or so before his death Brantley was giving a talk to a large gathering of urologists in Houston. A urology colleague in Houston, Dr. Walter Wolf, and his wife, had died fairly recently in a plane crash, a Beechcraft Bonanza, while trying to land in very inclement weather. In his presentation, mesmerizing as always, Brantley described what he thought happened to Dr. Wolf's plane. The weather, the visibility, the winds, the physics, etc., Brantley was a talented and highly experienced pilot and his explanation was very interesting to all of us. We had lost a revered colleague, and all of us had wondered, why? In this talk, he also spoke about the plane he was building, and that he too had had a close call, an almost fatal crash. He explained the physics of all this to us. Very interesting stuff, but as he was describing his close call, I turned to my good friend, Dr. Neil Baum, now a well-known and prominent urologist and prosthetic surgeon in New Orleans and said to him "I'm afraid Brantley is going to die in that experimental plane of his".

Within less than a year, as in the song "American Pie" by Don McLean in 1971, in which he sings of "the day the music died" about the 1959 plane crash that killed Buddy Holly, Richie Valens and "The Big Bopper", the music died for so many of us who knew and revered Brantley Scott. The music stopped the day that his Quest-Air plane stalled about 150 feet off the ground. He was practicing in preparation for the Oshkosh air show. The great Dr. Brantley Scott died on impact near San Marcos, Texas on July 27, 1991, and the world lost a giant of urology.

His legacy lives on. He is remembered very fondly by everyone who knew him. He left behind a family who loved him. The American Urological Association has the Dr. F Brantley Scott award each year. His name is all over the buildings at AMS, and hundreds if not thousands of urologists are grateful for his teaching and innovations, as well as hundreds of thousands of men and women around the world who have benefitted from his two greatest surgical contributions; the artificial sphincter and the inflatable penile implant.

ACKNOWLEDGMENTS

The author wishes to acknowledge the valuable assistance of Dr. Run Wang in editing of this paper.

COMPETING INTERESTS

The author declares no competing interests.

REFERENCES

1 Masters WH, Johnson VE. Human Sexual Inadequacy. Boston: Little Brown; 1970. p. 185.
2 Scott FB, Bradley WE, Timm GW. Management of erectile impotence. Use of implantable inflatable prosthesis. *Urology* 1973; 2: 80–2.
3 Mulcahy JJ. Current approach to the treatment of penile implant infections. *Ther Adv Urol* 2010; 2: 69–75.
4 Karacan I, Hursch CJ, Williams RL, Thornby JI. Some characteristics of nocturnal penile tumescence in young adults. *JAMA Psychiatry* 1972; 26: 351–6.