Spiral Multidetector Computerized Tomography Evaluation of Adjustable Continence Therapy Implants

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Purpose: ProACT™ is an adjustable continence therapy implant for post-prostatectomy incontinence. We evaluated the exact device location in clinical success and failed implant cases using spiral multidetector computerized tomography.

Materials and Methods: We evaluated 18 consecutive patients postoperatively using pelvic spiral multidetector computerized tomography. Of the patients 11 (61%) were dry or improved and 7 (39%) had not improved despite multiple balloon adjustments. Thin pelvic collimated scans with bone algorithm were obtained, completed by multiplanar reformatting and a volume rendering technique. The computerized tomography technique is described.

Results: Multidetector computerized tomography showed device sites compared to local anatomical structures. In 64% of dry or improved patients the devices were above the urogenital diaphragm and adjacent to the urethral wall (the correct position) while in the remaining 36% of cured patients only 1 device was positioned correctly. Of nonimproved patients 86% had balloons that were not adjacent to the urethra. The scout view did not show malpositioning in any of these cases. Only multiplanar reformatting with the volume rendering technique revealed misplacement.

Conclusions: Multidetector computerized tomography data shows that a poor outcome in most failed cases results from poor device positioning. In a few failed cases an unsuccessful result is probably caused by excessive tissue sclerosis. To our knowledge we report for the first time how continence can be determined by the action of only 1 device.

Key Words: urethra; prostatectomy; prostheses and implants; urinary incontinence; tomography, spiral computed

Abbreviations and Acronyms

3D = 3-dimensional
AP = anteroposterior
CT = computerized tomography
MDCT = multidetector CT
MPR = multiplanar reformatting
PGI-S = Patient Global Impression of Severity questionnaire score
US = ultrasound
VLPP = Valsalva leak point pressure
VRT = volume rendering technique

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THE ProACT adjustable continence therapy device for post-prostatectomy incontinence was commercialized in Europe in 2002, although it was used in clinical studies since 1999, and has been clinically reported since then.[1–4] The device is a minimally invasive treatment that can be postoperatively adjusted as required. The characteristic of being adaptable to the individual clinical condition presupposes, theoretically at least, that it must be effective in all cases.

At our institution we have been evaluating outcomes in patients implanted with ProACT since 2000. While therapy was effective in most cases, in a number of failures no immediately obvious cause was detected by conventional x-ray. We supposed that incorrect device positioning or tissue quality determined failure. The literature describes optimal device placement in females based on cadaver laboratory results or magnetic

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resonance scanning[5,6] but to our knowledge this has not yet been reported in males.

Between 2004 and 2006 we performed this study to determine the exact location of ProACT devices using spiral MDCT. We believe that this 3D study may well be an innovative investigational approach, providing clear in vivo information on the anatomical location of the devices and allowing early identification of the cause of implant failure. This more timely intervention enables earlier evaluation of alternative treatment options, ensuring that the patient would be dry or improved as soon as possible.

MATERIALS AND METHODS

A total of 162 male patients were implanted with the ProACT device from May 2000 to January 2009. By the commencement of this study in 2004 we had successfully overcome the learning curve of this procedure and performed more than 50 implantations. Informed consent was obtained for pelvic spiral CT from a small cohort of 18 consecutive patients. Since we were unsure of the information that this type of invasive scanning would provide, a limited number of patients were included regardless of clinical outcome. All 18 patients had undergone adjustments to attain optimum continence. At the time of the study mean followup was 18 months (range 3 to 30). Mean balloon volume was 4 cc (range 2 to 7) and patients underwent a mean of 3 adjustments (range 1 to 6) before study.

In all 18 patients the ProACT was implanted secondary to urodynamic stress incontinence after prostatic surgery. All patients reported failed rehabilitation methods, including pelvic floor training and electrostimulation. Of the men 12 (67%) had undergone radical prostatectomy and 6 (33%) had undergone transurethral prostatectomy for benign prostatic hyperplasia. Four men (57%) were treated previously for urethral stenosis or bladder neck sclerosis,

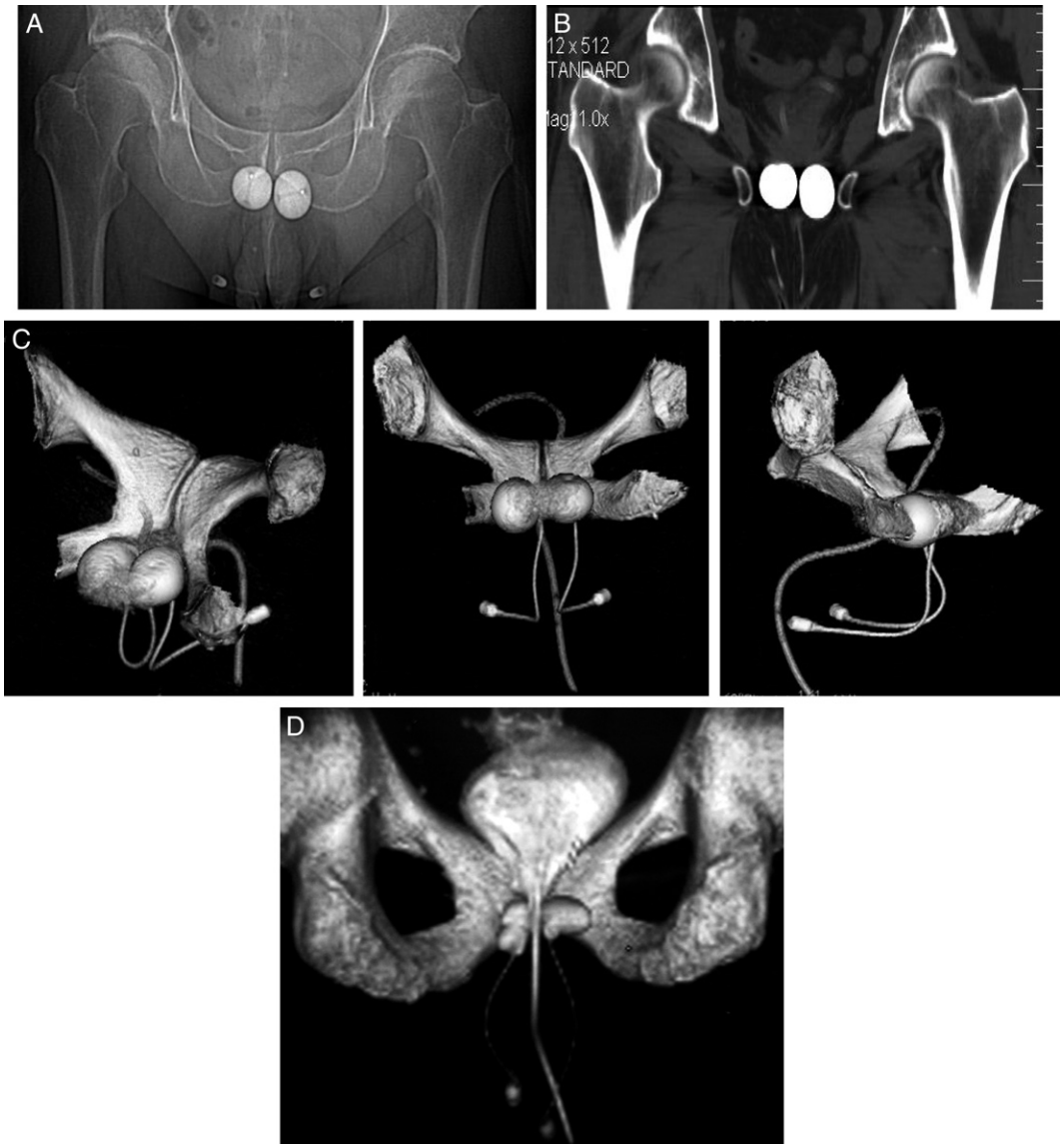

Figure 1. AP scout view (*A*), coronal MPR (*B*) and VRT (*C* and *D*) show good balloon positioning in patients after radical prostatectomy

or with radiotherapy. Implantation was done an average of 24 months (range 12 to 38) after prostatic surgery. Implantation was performed using fluoroscopic guidance, as described by Hübner and Shlarp.[7] Mean patient age at implantation was 68 years (range 58 to 78). Patient continence was evaluated at baseline using daily pad count, 24-hour pad test for an average of 3 days, VLPP and PGI-S.[8] Of the patients 12 (66.6%) had severe, 4 (22.2%) had moderate and 2 (11.1%) had mild incontinence. Continence was graded according to 4 criteria, including severe—daily pad count greater than 4, 24-hour pad test greater than 250 gm daily, VLPP less than 50 cm H_2O and PGI-S 4, moderate—daily pad count 2 to 4, 24-hour pad test 50 to less than 250 gm, VLPP 50 to greater than 100 cm H_2O and PGI-S 3, and mild—daily pad count 1 to 2, 24-hour pad test less than 50 gm, VLPP greater than 100 cm H_2O or negative and PGI-S 2.

At imaging 11 patients (61%) were dry (0 or 1 safety pad) or improved (greater than 50% decrease in daily pad use and pad test result with a Patient Global Impression of Improvement Score of 1 or 2)[8] and 7 (39%) had no improvement (less than a 50% decrease in daily pad use and pad test result with a Patient Global Impression of Improvement Score of 3 or 4) despite multiple balloon adjustments. In this nonimproved group 1 patient had undergone urethrotomy, 1 had undergone prior bladder neck incision for sclerosis and 2 had received radiotherapy.

CT Technique

The patient was placed supine. A 10 Ch Nélaton catheter was used to evidence the urethral tract. The bladder was filled with 400 mgl/ml/40 ml nonionic contrast medium to determine the spatial relationship of the devices with the bladder neck. Thin pelvic collimated scans (spiral scan 0.8 seconds, 2.5 mm thick, 1.25 mm scan interval and speed 3.75 mm per rotation) with the standard algorithm of acquisition and reconstruction bone algorithm were evaluated and completed by MPR and VRT.[9–12] Scan time was between 35 and 40 seconds, and radiation exposure was 400 to 500 mGy/cm. This pelvic examination includes visualization of the pubic symphysis, the urological prosthesis and the urethra along its entire length. MPR allows visualization along the principal axis of the anatomical structures that run perpendicular or oblique to the CT axial plane, choosing from the coronal, sagittal or oblique view. VRT allows creation of a 3D image due to dedicated software. All scout views were considered as if they were digital x-rays, similar to conventional x-ray of the pelvis, along the 2 orthogonal projections. Scout view data were compared to MPR data and applied to patient clinical data. Device morphology and position were considered, particularly volume and site symmetry, and the spatial relationship between the devices and bone structures (pubis and ischiopubic branches), urethra, bladder neck and prostate. The definition of correct device positioning was based on previously published, suggested parameters,[1,7] ie the retropubic site, under the bladder neck or around the prostate apex, above the urogenital diaphragm, adjacent to the urethra wall, and when possible symmetrical and lateral to the urethra at the 3 and 9 o'clock positions.

RESULTS

MDCT clearly revealed the site of the devices in relation to the urethra, bladder neck, pubis and pelvis. MPR, VRT and scout views concurred in the 7 of 11 dry or improved patients (64%), showing that the devices were placed paraurethrally at the bladder neck in patients after radical prostatectomy or adjacent to the residual prostatic tissue and in all above the urogenital diaphragm (figs. 1 and 2). In 2 of the remaining 4 of 11 dry or improved patients scout views raised the suspicion of malpositioning of only 1 device while images seemed normal in the other 2 of 4. In those 2 cases conventional x-ray was inadequate. In contrast, MPR and especially VRT images clarified that 1 device had not been correctly positioned in all 4 of 11 patients. This means that in these 4 cases the bulking effect achieved was based on 1 correctly placed balloon only (fig. 3).

In 6 of 7 patients (86%) considered not cured the devices had migrated distal below the pelvic floor. The scout view identified evident malpositioning in only 3 of the 7 cases. The other 4 cases seemed normal on scout view. In 3 of the 4 cases that seemed

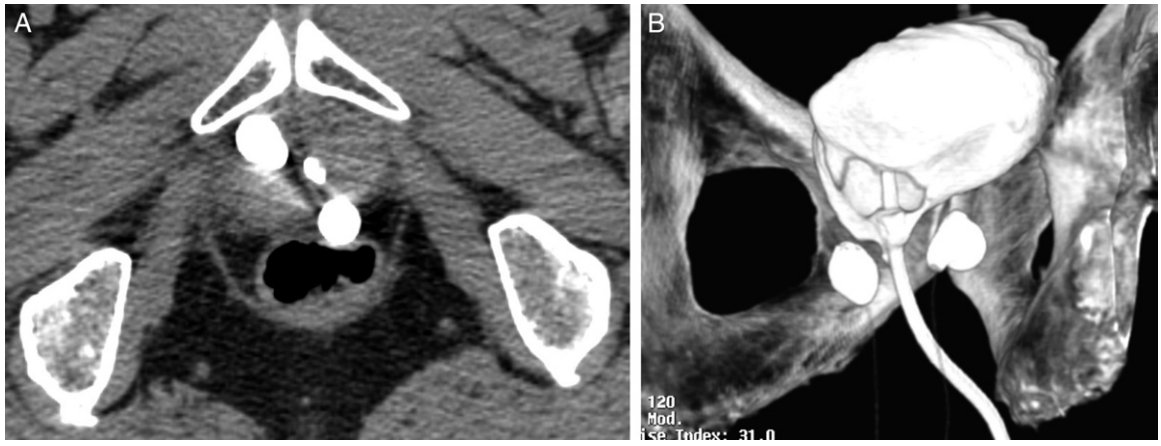

Figure 2. Oblique view (*A*) and 3D VRT (*B*) reveal spatial relationship between devices and residual prostatic tissue

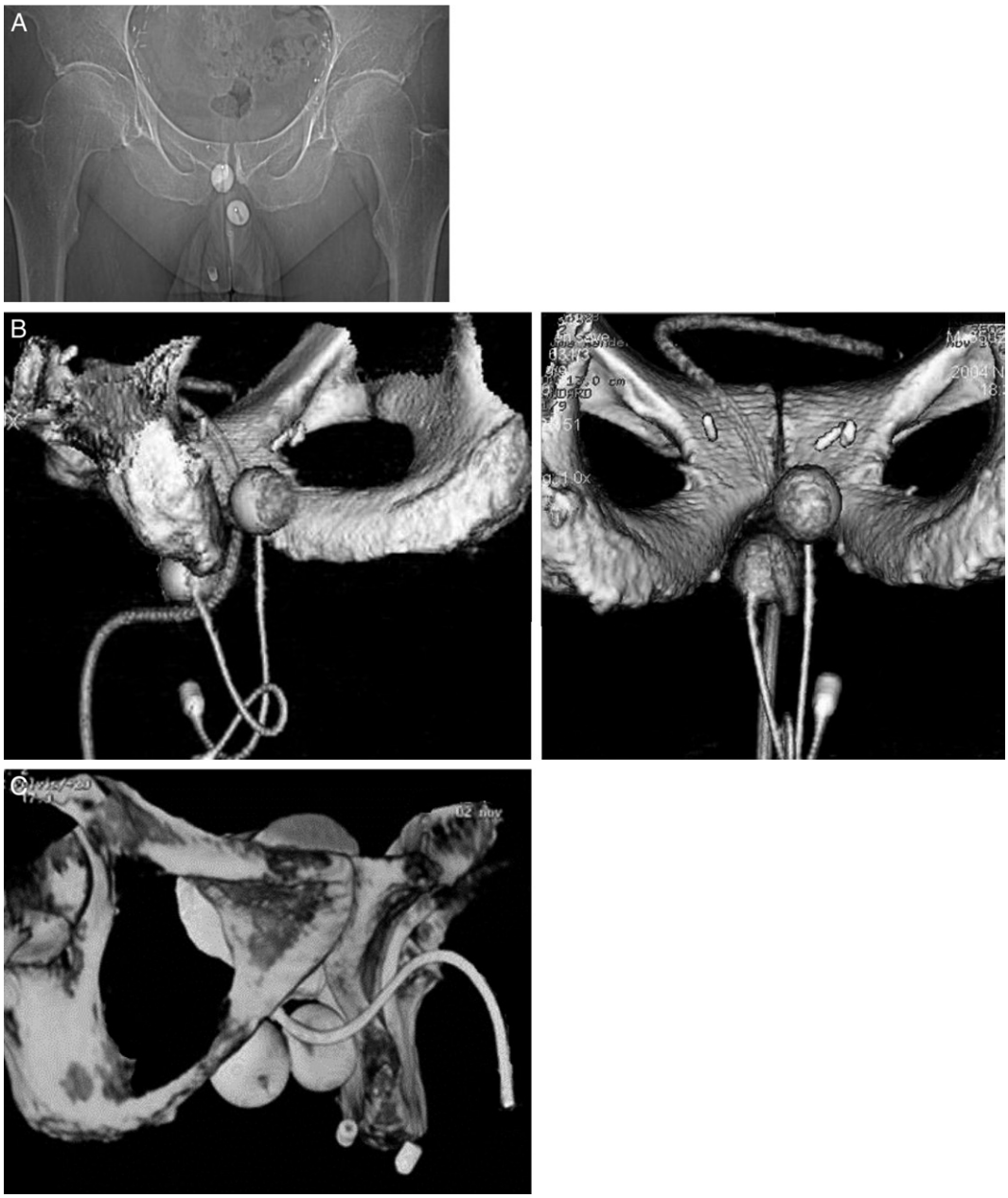

Figure 3. AP scout view (*A*) shows poor left balloon position. VRT (*B*) confirms urethral course and bulking effect depending on only right balloon. Only left balloon is effective (*C*).

normal on conventional x-ray only MDCT revealed migration into the superficial perineum (fig. 4). In contrast, in 1 of 4 cases MDCT and scout views agreed and showed that the balloons were in the correct endopelvic position close to the urethral wall. In our opinion balloons in this patient did not provide a bulking effect, probably as a result of sclerosis secondary to scarring after radiotherapy. In this case MDCT demonstrated homogeneous tissue of hypodensity at the level of the implant, which suggested sclerosis (fig. 5).

Nonresponsive cases with incorrect positioning of 1 or 2 devices were reimplanted. Time from explantation to reimplantation was based on migration severity. Reimplantation was done rapidly after removal at the same intervention when the devices had migrated into the perineum and, thus, were quite a distance from the endopelvic urethra. Device removal was followed by reimplantation 4 weeks later when the devices were positioned above the urogenital diaphragm. Delayed time to reimplantation enabled the cavity left by the original device to close and the new balloon to be positioned in a new space.

Five of 7 reimplanted patients became dry or improved and remained so at last followup. Another 2 reimplanted patients, including 1 treated with pre-

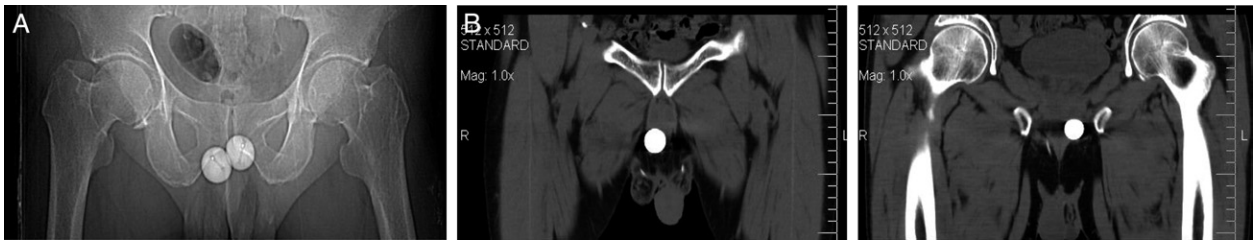

Figure 4. AP scout view (*A*) shows apparently normal position of devices but coronal MPR (*B*) reveals poorly positioned right balloon.

vious radiotherapy and 1 with previously treated bladder neck sclerosis, did not improve after 4 adjustments, although the balloons were apparently positioned correctly on further CT. In these cases failure was probably likely due to poorly compromised sclerotic tissue, which we now consider a relative contraindication to reimplantation.[13] These cases were explanted and successfully implanted with an artificial sphincter.

DISCUSSION

We considered diverse radiographic methods to study device positioning postoperatively in collaboration with our radiological colleagues. Magnetic resonance imaging shows the maximum anatomical detail but overall it is technically complex, costly and time consuming, and requires radiological expertise. In our experience urethrography is invasive with limited sufficient radiographic evidence to clarify the relationship between the device and the urethra and, thus, suggest a therapeutic plan in failed therapy cases. In our experience perineal US only proved useful to confirm device migration into the perineum and did not clearly show the relationship between the balloons and the urethra. In contrast, Gregori et al described biplanar transrectal US,[14,15] which is probably the most valuable ultrasound technique, allowing us to observe the relationship between the devices, the urethra and the bladder neck intraoperatively as well as postoperatively. This was only recently described and at the time of our study we did not have access to this technique. Ultrasound visualization can be unfortunately decreased or impaired by metal clips, a not uncommon condition in patients after prostatectomy.

In clinical practice the devices are commonly evaluated by conventional x-ray. When done in AP and laterolateral orthogonal projection, it reveals spatial relationships between the devices and the bony structures so that only gross dislocation or deflated balloons can be seen. In the absence of radiological abnormalities continence would be attempted only by progressive filling of the devices up to the maximum 8 ml volume allowed.

Other than patients with irradiation etc, it is not easy to predict at an early stage which will not have a successful outcome despite adjustment. We evaluated our patients at an early stage with MDCT. MDCT reveals any incorrect device positioning even when conventional x-rays show correct positioning. Thus, MDCT enables accurate placement of a new implant on 1 side or bilaterally as required.

It is important to verify before each adjustment that there has been clinically significant improvement, in this case a progressive decrease in urine leakage. It makes no sense to continue with adjustment if there is not even minimal improvement. Devices well positioned near the urethral wall and in the presence of soft tissue generally appear to work effectively from the time of the first adjust-

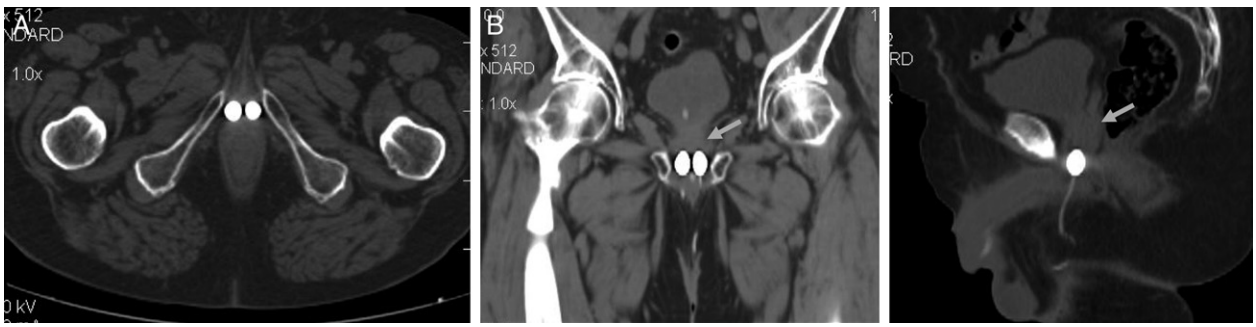

Figure 5. MPR shows normal device position (*A*) but homogeneous area of hypodense tissue (arrow) at implant level, suggesting sclerosis (*B*).

ment while successive refinements ultimately increase clinical efficacy and patient satisfaction. If no initial clinical benefit is achieved at a 4 cc volume, then the devices are not close enough to the urethral wall (poorly positioned or migrated) or the urethral wall is sclerosed and the tissue is compromised. In this case it is difficult to achieve a satisfactory result even with a maximum filling limit of 8 cc and a decision may be made to consider revision.

Followup in patients implanted with ProACT starts with the first 1-month assessment at the outpatient department with a clinical visit and interview to achieve an objective/subjective evaluation. When the patient is dry and satisfied, only routine evaluations are done. However, when there has been some improvement but the patient is not fully satisfied, the balloons are adjusted until the optimal continence target is attained. When a patient presents at visit 3 (3 adjustments at monthly intervals or a total volume of 4 ml) with no improvement, we believe that it is necessary to investigate device position with a first line radiological technique such as conventional x-ray or US. When the devices appear in an apparently good position, MDCT may be indicated to better determine device positioning while minimizing the risk of false-negative findings. When the balloons are seen to be in a reasonably good position, further adjustment may be attempted to achieve the bulking effect. In cases of clear balloon malpositioning on MDCT reimplantation is considered.

MDCT is rapid (about 35 to 40 seconds) and well accepted by patients. Most of our reimplanted patients became dry or improved. In patients who did not improve despite apparently optimal balloon positioning this was probably due to severely scarred or noncompliant tissue. In these cases we explanted the balloons, followed by successful artificial urinary sphincter implantation. MDCT is an expensive technique but the cost is decreased if we consider the savings achieved by avoiding multiple, useless adjustments, which are also costly.

CONCLUSIONS

ProACT devices did not create the desired bulking effect when they were not placed adjacent to the urethral wall, and when they were placed in sclerotic tissue where there was no evidence of urethral compression by the devices. Multiple balloon adjustments in these circumstances would have been to no avail, causing frustration for urologist and patient.

Our study shows that conventional x-ray does not always sufficiently reveal the exact position of the implant. Thus, it is not adequate in all patients to find the cause of failure. In contrast, MDCT identifies the relationship between the devices and the urethra with excellent spatial resolution and possible 3D evaluation. To our knowledge we report for the first time how continence can be achieved by the action of only 1 device. These data led us to adopt MDCT in select cases for earlier diagnosis when there is no improvement to minimize the possibility of unnecessary adjustments. Instead we perform select explantation and reimplantation to attain a dry, satisfied patient as rapidly as possible.

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