

CASE STUDY

Clinical Evaluation of male patients who suffer from Urinary Incontinence and the use of the URINCare® Bladder Management System for an extended period of time

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ABSTRACT: A total of 9 male patients were studied with varying degrees and complications of Urinary Incontinence (UI). The patients were prescribed the GEN II URINCare® Bladder Management System to reduce the adverse events that they were suffering from with their current UI methods.

INTRODUCTION: The study focuses on male patients who suffer from Urinary Incontinence either as a primary diagnosis or side effect of another complication such as: Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis (MS), Prostate Cancer, Neurogenic Bladder, etc. The age of the patients range from 54 years to 91 years old and each patient has suffered from UI from 1 to 20+ years. Patients are both ambulatory and non-ambulatory. Other methods of treating their UI were condom catheters, Foley Catheter, medications, pads, diapers, penile clamps, etc. These methods have proven to be uncomfortable and unsuccessful in managing their UI for extended amounts of time; which has lead to other complications such as penile erosion, decubitus ulcers, skin macerations, urinary tract infections, etc, prompting the physicians to prescribe the GEN II URINCare® Bladder Management System.

RESULTS:

Case 1 is an ambulatory 78 year old male who suffers from UI as a complication of MS. Patient suffers numerous issues aside from MS such as hematuria, enuresis, UTIs, colon cancer, etc. Patient has tried numerous medications for UI with little tolerance to them because of the side effects. He has also used condom catheters with no success due to his limited capabilities from MS. The patient had been prescribed the URINCare® System as a last resort in managing his UI that he has suffered from for 20+ years. The patient wears the System 16+ hours a day without complications, leakage, skin breakdown, irritation or UTIs.

Case 2 is a semi-ambulatory 72 year old male who suffers from Urinary Incontinence due to Prostate Cancer. The patient's medical history includes a radical prostatectomy and a subsequent salvage radiation therapy for

cancer of the prostate. This had left the patient suffering from incontinence and retention. The patient suffered from urinary retention and had a Foley Catheter in place to manage the retention. He then had an outpatient procedure performed for an incision/resection of the bladder neck. The surgery was successful in treating the urinary retention, but left the patient with permanent incontinence. The patient tried to temporarily manage his UI with condom catheters and pads/diapers, but had little success due to skin breakdown and severe penile irritation. The patient's urologist prescribed the GEN II URINCare® Bladder Management System to keep all moisture away from the patient's skin and keep him dry at all times. The patient currently wears the System from 8-14 hours per day to reduce the likelihood of reoccurring skin breakdown and keep him comfortable.

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Case 3 is an ambulatory 71 year old male who suffers from UI as a result of Prostate Cancer. The patient has had major scarring issues in the prostatic urethra after receiving radiotherapy. He also suffered from a bladder outlet obstruction as well as a hypotonic detrusor, which led him to intermittent catheterizing himself. He then completely calcified his prostatic and was no longer able to catheterize, leading to a suprapubic tube being placed in February 2012. The patient also has a Cystoscopy litholopaxy which has left him leaking profusely, despite the suprapubic tube. The patient needed a non-invasive means to manage his incontinence that didn't add to the reoccurring medical conditions that he suffers from currently. The patient was prescribed the GEN II URINCare® Bladder Management System in March of 2012 and wears the System for both day and nighttime use to minimize his complications of UI.

Case 4 is a 70 year old non-ambulatory male who was prescribed the GEN II URINCare® Bladder Management System to manage the complications from UI due to Prostate Cancer. The patient also suffered from severe back pain, which led to him receiving a steroid injection in his lower spine. He developed a staph infection which destroyed his 8th and 9th vertebra leaving the surgeon no other choice but to perform surgery which included a steel rod and 6 screws. Because of this, the patient was left paralyzed in his lower extremities. The patient's physicians agree that they cannot perform additional surgery to help him manage his incontinence or have any type of invasive method due to the staph infection in his bloodstream, which clings to foreign matter. The patient has tried condom catheters as a non-invasive method of UI treatment, which caused skin breakdown and ulcers to develop. Due to the patient's other medical conditions,

any infection is a life threatening issue. The GEN II URINCare® Bladder Management System is the only System that the patient can wear for 24 hours that keep the integrity of his skin intact and the patient out of the intensive care unit.

Case 5 is a semi-ambulatory 91 year old male suffering from UI due to Ureter Cancer. The patient underwent a left nephroureterectomy to remove the cancer tumor(s). The patient also suffers from diabetic peripheral neuropathy, which contributes to the complications of his UI. He has suffered from reoccurring UTIs (before using the GEN II URINCare® Bladder Management System) which are a severe consequence to diabetic neuropathy, being that poor blood flow causes risks for developing ulcers leading to infection, amputation, and even death. The patient cannot use an invasive device due to his diabetic neuropathy or a non-invasive device (such as a condom catheter or penile clamp) that could lead to skin breakdown and infections. The patient wears the GEN II URINCare® System 24 hours a day to remove all moisture and keep him dry to reduce infections. The patient has not suffered from another UTI since being on the System, reducing significant hospitalization costs and patient stress.

Case 6 is an ambulatory 84 year old male who has suffered from UI for 8 years as a result of Prostate Cancer. The patient has had an Artificial Urinary Sphincter (AUS) inserted twice. The first AUS failed; the second was infected and had to be removed due to erosion. He then managed his incontinence by having a Foley Catheter inserted, but had erosion of the distal urethra, causing it to be removed. The patient then was brought to the hospital to have a Suprapubic Cystostomy

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placed. The patient still had continually leakage of urine despite the Suprapubic Cystostomy with reoccurring UTIs which he managed with condom catheters. The patient suffered from impaired tissue integrity due to the moisture between the skin from the condom catheters, prompting the physician to prescribe the GEN II URINCare® Bladder Management System. The patient has had no reports of skin breakdown, UTIs or infections since using the System for 12-16 hours a day.

Case 7 is an 83 year old active, ambulatory male with progressive UI as a complication of Prostate Cancer. The patient has difficulty using a condom catheter due to the length of his penis; the adhesive also leaves the patient with skin irritation and soreness. He cannot use an indwelling catheter due to having reoccurring UTIs. The numerous medications prescribed, such as: Vesicare, Flomax and Sactura were unsuccessful in helping the patient manage his UI and complications of it. Since being prescribed the GEN II URINCare® Bladder Management System, the patient has had no adverse events and has been able to wear the System 24 hours a day with no UTIs, skin breakdown or irritation.

Case 8 is a 54 year old quadriplegic male with severe UI due to Cerebral Palsy, causing a Neurogenic bladder. The patient has 24 hour caregivers who manage his care surrounding his numerous medical conditions. The patient's caregivers have tried to manage his UI with Texas catheters and diapers, both which led to the patient having skin breakdown and decubitus ulcers on his left buttocks. To keep the patient in some semblance of good health, his caregivers attempted to manage his UI with a Foley catheter, which led to reoccurring UTIs causing numerous hospitalizations with

exorbitant costs and patient stress. The physician had prescribed the GEN II URINCare® Bladder Management System to reduce complications that the patient was had suffered from with other methods of managing his incontinence. When using the System, the patient has experienced none of the previous complications he had with other methods. When the patient does use the System (depending on his medical situation at the time), the patient wears the System 24 hours a day to maintain the integrity of his skin and reduce the likelihood of reoccurring UTIs.

Case 9 is an 85 year old semi-ambulatory male with limited activity. He suffers from UI and complications of it due to Parkinson's disease. He has a severe allergy to adhesive tapes, so he cannot use any method of managing his incontinence with such materials and cannot self catheterize himself due to his Parkinson's. He has also tried to manage his UI with diapers, pads, and condom catheters; all which led to him suffering from skin breakdown and sensitivity. The patient also suffers from reoccurring UTIs. He was prescribed the GEN II URINCare® Bladder Management System in November of 2011. Since the use of the System, he wears the System 18 hours a day. The patient has not suffered from UTIs or skin breakdown. Due to the patient having an insurance issue on coverage, the patient has had to stop using the System until an appeal is overturned. This has led the patient back to experiencing severe UTIs and hospitalization, ending up in the Intensive Care Unit. His physicians felt that it would be best to place the patient in a Skilled Nursing Facility until his medical condition improves. To date, the patient still resides in the SNF.

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Since the introduction of the URINCare® Bladder Management System in 2009, it has been prescribed to over 500 patients; including civilian patients and our United States Veterans. The System has been extremely successful in maintaining skin integrity due to reduced moisture against the skin, decreasing the likelihood of Urinary Tract Infections and hospitalizations due to Urinary Incontinence and its complications. The System has been prescribed for various medical conditions with the intention of keeping the user dry at all times, whether they suffer from permanent incontinence or incontinence as a complication of a Neurogenic condition, muscular disorder; or the inability to safely get to a bathroom facility. The patients in the case study wear the URINCare® System for a minimum of 8 hours with a maximum of 24 hours a day with no adverse events or complications while using the System. The patients have found the System to be comfortable to wear under their everyday clothing, giving them the independence and quality of life that they have been missing with other methods of managing Urinary Incontinence.

The GEN II URINCare® Systems' patented ability to automatically route the urine completely away from the patient's skin, represents the technological breakthrough that was needed for patients suffering from UI. The caustic nature of urine, especially when in contact with skin, has been well demonstrated and as such for chronic use, condom catheters for males and protective and limited absorptive undergarments for females continue to represent inadequate and higher risk options for patients. The GEN II URINCare® Bladder Management System provides the necessary paradigm shift that is imperative for those patients especially in need, having failed other available options, largely as a result of their inadequacy for efficient urinary collection and isolation away from the patient.