

CASE STUDY

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

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ABSTRACT: An abbreviated case study of 4 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: 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 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 3 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)

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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 4 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 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 STUDY RESULT CONCLUSION:

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 in adequate 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.