

CASE STUDY

Clinical Evaluation of 32 Year Old Patient with Multiple Complications of UI and the use of the GEN II URINCare® Bladder Management System

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ABSTRACT - Patient is a 32 year old male who suffers from severe and chronic impairments, including cerebral palsy, schizophrenia and epilepsy with a global and overall severe mental impairment status. He first sought treatment for incontinence and recurrent urinary tract infections approximately 5 years ago. The complications lead to the patient and his physician looking for a viable solution to aid in the reduction in the complications that the patient was suffering from. The GEN II URINCare® Bladder Management System was prescribed and led to fewer complications and hospitalizations.

INTRODUCTION

A board-certified general and urologic surgeon, performed and / or ordered numerous investigations to identify the source of the patient's problems, including a CT scan that showed anatomic changes of the bladder suggesting significant neurologic deterioration and dysfunction impacting its function. Subsequently, urodynamic studies were performed to better determine patient's specific impairment of function with respect to the urinary system's normal role of urine storage and elimination. These studies demonstrated that patient's bladder contracted involuntarily and also in an uncoordinated fashion with the external sphincter - a condition with potential severe complications including renal failure. Given the degree and severity of impairment to normal bladder function for both storage and elimination, the patient's physician/surgeon determined the medically appropriate course of action for the patient, given his medical condition and prognosis was to provide chronic drainage by way of an indwelling catheter placed suprapubically, which was done surgically on November 7, 2007.

Over the ensuing four years, the patient went on to suffer recurrent and increasingly complicated urinary tract infections due to numerous different and also increasingly antibiotic resistant bacteria. These infections required numerous trips to the emergency room for urinary sepsis, and included multiple hospitalizations so that the patient could receive intravenous antibiotics. These infections continued to recur despite multiple catheter changes, irrigations with saline and Renacidin, along with multiple courses of antibiotics. The patient's physician determined in 2011 that the continued presence of the suprapubic catheter or "foreign body" in the patient's bladder would likely result in urosepsis and possible septic shock. To exacerbate the situation further, the catheter began to regularly obstruct due to urinary sediment resulting to urine leakage.

After the numerous complications, including hospitalizations, that the patient experienced with the suprapubic, indwelling catheter between 2007 and 2011, and in an attempt to keep the patient in some semblance of relative health, the patient's physician determined that the suprapubic catheter should be removed, and a sphincterotomy and transurethral prostatectomy would be performed to create a freely draining bladder. To be clear, after this surgery, the patient would be permanently incontinent as the sphincterotomy would eliminate his ability to retain urine in his bladder. After the surgery, the patient would pass urine almost continuously under low pressure, which would then be collected externally using a condom catheter (a passive, external urine collection system). While the patient had attempted

management of his urinary impairment with a condom catheter prior to placement of the indwelling, suprapubic catheter with unsatisfactory results, the patient's physician professional opinion was that it was worth another trial in order to avoid the only other option, which was major surgery involving urinary diversion using an intestinal segment. Removing the suprapubic catheter would also eliminate the source of the patient's recurrent and complicated urinary tract infections and hospitalizations.

The patient had a sphincterotomy and prostatectomy in September 2011, when the patient began using condom catheters. He also attempted to use the Bioderm catheter system, which is similar to the condom catheter as it is an entirely external, although passive

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male urine collection system. Neither system successfully kept the patient dry; he suffered additional urinary tract infections and local penile skin erosion requiring multiple visits to numerous medical facilities.

Given the permanent incontinent status of the patient after his sphincterotomy and prostatectomy in September 2011, the complete lack of satisfactory results with other options (condom catheters and indwelling catheters), the severe risk of decubiti, local complications and dependence on other caregivers that would almost certainly result if the patient had to rely

on adult diapers to address his condition, The patient's physician prescribed the GEN II URINCare® System for him in November 2011. The GEN II URINCare® System involves a sensor activated control device connected to a medical grade polyurethane male cup and a reusable collection chamber. When the sensor detects urine in the cup, the control device immediately evacuates the cup into the attached collection chamber. Since there is no indwelling catheter involved, and because the cup/sensor system actively and immediately evacuates the cup of all urine, there is a greatly decreased risk of urinary tract infection, skin irritation, decubiti and leakage.

RESULTS

Since using the GEN II URINCare® System, the patient has suffered a significant reduction in urinary tract complications over his seven plus months of use, as well as some overall health and functional status improvements. The patient's physician reports that the patient is highly satisfied with the system. In the patient's physician's expert opinion, the GEN II URINCare® System's ability to entirely route urine away from the skin, thereby avoiding prolonged irritation, provides an excellent option for the most complex patients who have failed all other methods for safe urinary elimination. In his opinion, while adult diapers are felt to be another method for this collection, long-term use almost always results in skin breakdown and decubiti, almost guaranteeing reoccurring trips to a medical facility and / or hospital, and they generally fail to provide reliable and safe extracorporeal urinary collection. The physician's opinion is that the GEN II URINCare® System has demonstrated its ability to reduce complications such as urinary tract infection and decubiti in long-term incontinent patients, and is without question less expensive than repeated visits to the emergency room and multiple three to ten day hospitalizations to treat severe, antibiotic resistant infections.

THE GEN II URINCare® BLADDER MANAGEMENT SYSTEM

The URINCare® System was initially created for the Active Duty Military pilots as a safe and effective way to empty their bladders in-flight. With the growing number of civilians suffering from UI, Omni Medical Systems saw the opportunity to apply and modify the technology in order to better serve patients given the large void that exists for available solutions for patients in need of more reliable and safe urinary collection. As such, the development of the URINCare® Incontinence Management System¹ ensued with its introduction to the public in 2007 to address this specific need.

The GEN II URINCare® Systems' patented ability to entirely route the urine completely away from the patient's skin represent the very paradigm shift

necessary 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 females¹ 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.

¹The GEN II URINCare® Bladder Management System for men is available while the URINCare® Bladder Management System for women is currently in testing¹