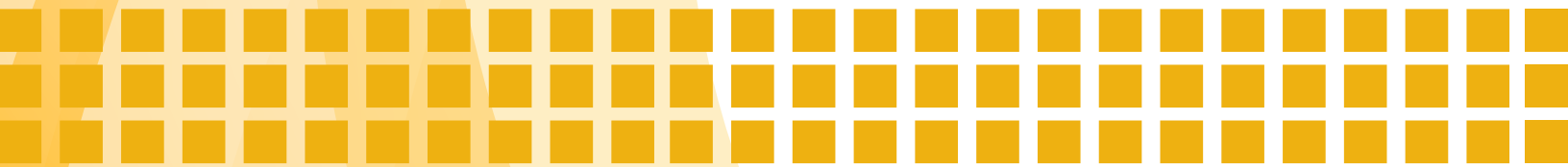


UROLIFT®

BPH Relief. In Sight.™



UroLift® System
Clinical Results

Overview

The UroLift® Prostatic Urethral Lift is a minimally invasive procedure proven to treat lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). It relieves prostate obstruction and opens the urethra directly by retracting the obstructing prostatic lobes without cutting, heating or removing prostatic tissue. By avoiding these means of prostatic injury, treatment with the UroLift System has been shown to offer rapid and durable improvement in symptoms with low morbidity.¹⁶

Because the safety and efficacy of UroLift system treatment has been rigorously studied in multiple randomized and open label studies, the European Association of Urology (EAU) has rated the clinical evidence supporting the UroLift Prostatic Urethral Lift (PUL) as Level 1A in its Guidelines.¹ Similarly, the UK National Institute for Health and Care Excellence (NICE) has concluded that PUL is clinically effective, cost effective compared to TURP (transurethral resection of the prostate), and should be offered in the UK National Health System (NHS).^{2,3} The American Urological Association (AUA) has issued a public position supporting access to and adoption of PUL, in lieu of guidelines that issue only every 6 to 7 years.⁴

The efficacy of the UroLift System has been demonstrated in numerous studies,^{5,6,7} including a randomized double-blinded study conducted primarily in the US,^{8,10,12,16} a randomized comparison to transurethral resection of the prostate (TURP),¹¹ a randomized crossover study,¹⁴ a European retrospective registry¹⁷ and open label studies conducted in the USA, UK, Germany, Netherlands, Spain, Italy, France and Australia.^{13, 18-26} Improvement in LUTS, as seen through reduction in IPSS (International Prostate Symptom Score), has been consistent across the various studies, showing rapid relief within two weeks across all studies and sustained effect through four years [Figure 1]. Over 950 patient-years of data have been presented in peer-reviewed publications to date.

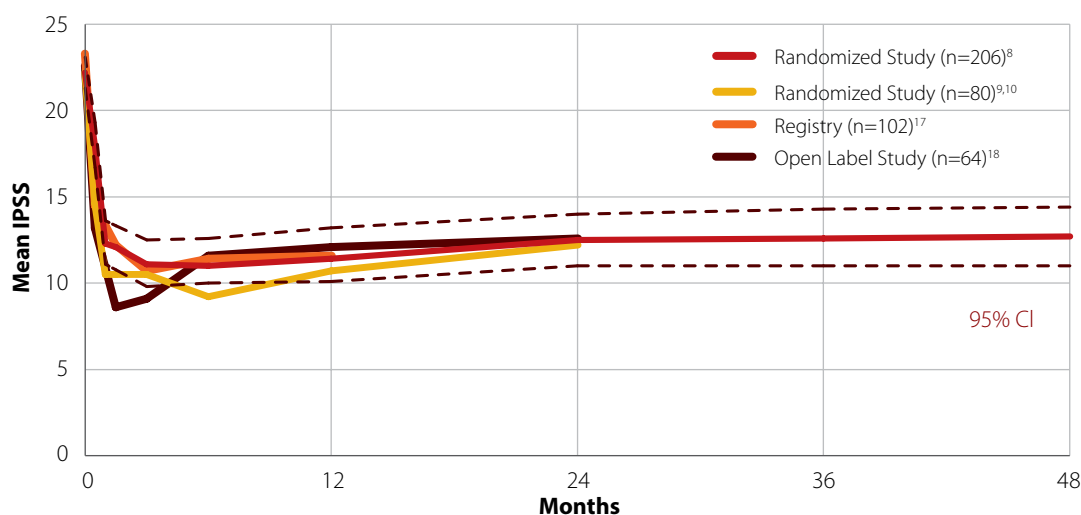


Figure 1: International Prostate Symptom Score (IPSS) improvement as a result of UroLift System treatment in four major studies.

In addition to improving LUTS, the UroLift System has demonstrated significant improvement in peak urinary flow rate (Qmax) improving 4.3 mL/sec by 3 months and sustained to 4 years, $p < 0.001$.⁸ Quality of life also improved significantly, with the IPSS QOL and BPH Impact Index maintaining 52% and 54% improvements, respectively at 4 years, $p < 0.001$.⁸ Retreatment rates remain low for a BPH procedure, with 5%-6.5% retreatment at 1 year rising approximately 2%-3% per year to 13.6% by 4 years.^{8,10,12,16} This retreatment rate is on the order of more invasive surgery and far less than that reported for other minimally invasive procedures.^{8,10} Over the first postoperative year, no additional surgical intervention has been required for complications typically associated with other BPH procedures, such as bladder neck contracture, transfusion, or stress incontinence. These 1 year complication-related reoperation rates have been reported as high as 14% to 25% for TURP, the standard surgery for BPH.²⁷⁻³¹

The achievable treatment results with the UroLift System are considerably greater than that offered by medical therapy both with respect to alleviation of suffering and symptoms (primary treatment aim) and with respect to disobstruction (improvement in urinary flow) [Figure 2]. While TURP and laser therapies offer, on average, 3 to 4 points greater IPSS reduction, these points come at a cost of several significant potential complications. One striking advantage of the UroLift System treatment compared to all other conservative and operative therapy procedures is preservation of sexual function.^{15,20,32-41}

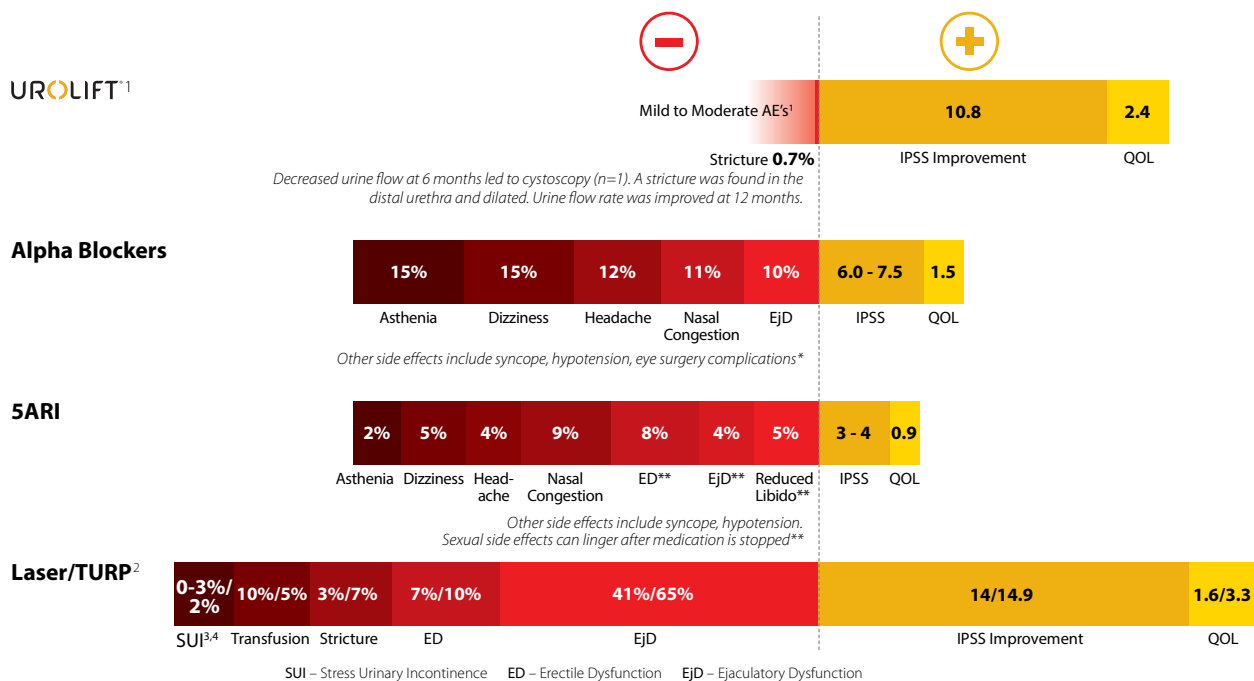


Figure 2: Safety and effectiveness results in the first year of BPH treatment options.

Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.¹

1. L.I.F.T. IDE Study. Roehrborn. J Urology 2013; 2. AUA BPH Guidelines 2003, 2010; 3. Naspro, Eur Urol 2009; 4. Montorsi, J Urol 2008

*Bell et. Al. **Irwig & Kolukila JSM, 2001 <http://www.ncbi.nlm.nih.gov/pubmed/21418145>

The UroLift System treatment has consistently demonstrated an excellent safety profile. Bleeding is much less than TURP, with a 0% transfusion rate to date for UroLift vs. 5%-7% for TURP. Required postoperative catheterization has been shown to be 20%-32% (compared to standard protocol for nearly all TURP patients) with a mean catheter duration of 0.9 days (compared to 1-5 days for TURP).^{19-21,27-31} Other important advantages are the ability to offer UroLift system treatment using only local anesthesia, as well as a patient’s rapid return to work and preoperative activity.^{13,14,16} Patients on average missed only 3 days work, including procedure day, and returned to preoperative activity levels by 6 days.¹³ This compares favorably to several weeks of recovery associated with TURP, laser, and other BPH procedures.²⁷⁻³¹

Adverse effects of UroLift System treatment are predominantly mild to moderate transurethral side effects (e.g. dysuria, hematuria, pelvic discomfort, urgency) that typically resolve within two to four weeks. Within the first postoperative year, there has been no incidence of transfusion, bladder neck contracture, or stress incontinence reported in any study of the UroLift System.⁸⁻²⁶ These are common complications of both TURP and laser treatments.²⁷⁻³¹

Finally, an important and unique feature of treatment with the UroLift System is the preservation of sexual function. In each of the published studies, including the large randomized study, there has been 0% incidence of sustained anejaculation/ retrograde ejaculation. This compares favorably to the 40%-80% rates published for TURP and laser, as well as the 10% to 28% rates published for alpha-blockers.²⁷⁻³¹ Erectile function has been preserved, again with no incidence of sustained erectile dysfunction (ED), compared to the widely published 10% rate associated with TURP and laser.²⁷⁻³¹ McVary et al. demonstrated that, while erectile function was maintained for men entering the study with no or mild ED, erectile function actually improved for men that had entered the study with severe ED.¹⁵

In summary, clinical results from multiple high quality studies demonstrate that treatment with the UroLift System offers rapid and significant improvement in lower urinary tract symptoms and flow through a less invasive procedure that uniquely preserves sexual function and avoids complications typically associated with other BPH procedures. Symptom, flow and quality of life improvements are durable to at least 4 years.

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