

The LoFric® Catheter: Overview of Clinical Studies

The LoFric® catheter is the most well-documented catheter for intermittent catheterization available today. Below are summaries of a selection of these clinical studies. Please contact Astra Tech at 1-877-4-LOFRIC (877-456-3742) to request study reprints.

Long-Term Study Results: LoFric® vs. Conventional Catheters

Clean Intermittent Catheterization in Spinal Cord Injury Patients: Long-Term Follow-up of a Hydrophilic Low Friction Technique, Waller, Jonsson, Norlen, Sullivan, *Journal of Urology*, February 1995

Numerous long-term follow-up studies in patients on clean intermittent catheterization using conventional PVC catheters have reported patients experiencing urethral complications including urethral strictures and false passages. One 12-year follow-up study reported a dramatic increase in the incidence of such complications in patients performing CIC for more than five years.

This retrospective study was conducted to investigate whether use of the LoFric® catheter helped reduce the incidence of catheterization-related urethral complications, particularly in the long-term. The study included 30 patients using the LoFric® catheter that had been followed by the hospital for more than five years. The mean follow-up period was seven years. Patients were subject to urological evaluation every year or every second year and, in between, were recommended to submit urine every second month for cultures.

No new urethral trauma occurred in any of the 30 patients after starting CIC on LoFric®. No surgeries were required, and no incidents of false passages, meatitis or meatal stenosis were detected. Two patients experienced epididymitis. **In four patients who had signs of strictures at the outset of the study from previous use of an indwelling catheter, these signs subsided once CIC using LoFric® was initiated. In addition, 12 patients (40%) maintained sterile urine during the entire follow-up period.**

Incidence of Urinary Tract Infections: LoFric vs. Conventional Catheters

A Prospective Randomized Trial of the LoFric Hydrophilic Coated Catheter Versus Conventional Plastic Catheter for Clean Intermittent Catheterization, Vapnek, Maynard, Kim, *Journal of Urology*, March 2003

The objectives of this one-year study were to compare the incidence of urinary tract infections, as well as the degree of hematuria, experienced by patients using the LoFric® catheter vs. patients using conventional plastic catheters. Forty-nine adult male patients who had all previously been using conventional catheters completed the study. Follow-up with urinalysis was conducted every three months.

While the incidence of urinary tract infections was not significantly different between the two groups at either the beginning or end of the study, **the group of patients using the LoFric® catheter experienced a statistically significant decrease in UTIs during the study period.** At the outset of the study, the group randomized to LoFric® had a UTI incidence of .45 per patient per month. By the end of the study, UTI incidence in this group was .13 UTIs per month. The group using conventional catheters did not see a significant decrease in infection incidence.

Furthermore, the group of patients using the LoFric® catheter experienced a significantly lower rate of hematuria throughout the study period than the group using conventional plastic catheters.

Incidence of Urethral Inflammation and Hematuria: LoFric® vs. Conventional Catheters

Urethral Cytology in Spinal Cord Injury Patients Performing Intermittent Catheterisation, Vaidyanathan, Soni, Dundas, Drishnan, *Paraplegia* (32) 1994

This study used cytology to compare urethral inflammation and bacteria colonization in the urethras of patients

using the LoFric® catheter vs. patients using conventional PVC catheters with gel. A total of 31 patients, 14 using a conventional catheter and 17 using the LoFric® catheter, were included in the study. The group of patients using LoFric® had catheterized for an average of 151 days, whereas the patients in the conventional catheter group had only catheterized for an average of 24 days.

While 9 out of 14 (64%) patients using a conventional catheter were detected with urethral inflammation, only 1 out of 17 (6%) patients using the LoFric® catheter was detected to have urethral inflammation.

The authors compared the ratio in the urethral tissue samples of neutrophil polymorphs to epithelial cells. The mean ratio was 66% for the group using ordinary catheters as compared with just .04% in the LoFric® group, **indicating that the amount of inflammation experienced by patients using the ordinary catheter was greater, with statistical significance, than that experienced by patients using LoFric®**

Urethral cytology also revealed a significantly greater number of bacteria in the group of patients using conventional catheters. These results occurred even though the LoFric® group had been catheterizing for six times as long, on average, than the group using conventional catheters. Furthermore, the number of bacteria seems to be correlated with the degree of inflammation.

Clean Intermittent Catheterization in Boys Using the LoFric® Catheter,

Sutherland, Kogan, Baskin, and Mevorach, Department of Urology, UCSF, San Francisco, *Journal of Urology*, December 1996

A total of 33 boys experienced in performing clean intermittent catheterization were randomized to either the LoFric® catheter or the leading PVC catheter for a period of 8 weeks. All subjects were evaluated by weekly urinalysis and questionnaires to compare the incidence of hematuria and bacteriuria.

The study found less hematuria, with statistical significance, in patients using the LoFric® catheter. In addition, fewer episodes of bacteriuria were seen with the LoFric® group.

Comparison of Urethral Trauma, Catheter Removal Friction: LoFric® vs. Hydrophilic Catheters without Sodium Chloride Coating

The Importance of Osmolality in Hydrophilic Urethral Catheters: A Crossover Study, Waller, Telander, Sullivan, *Spinal Cord* (35) 1997

LoFric® is the only hydrophilic catheter on the market with sodium chloride as a component of its coating to raise the osmolality of the catheter to a physiological level. The purpose of raising the level of osmolality is to prevent migration of the water layer into the urethral wall once the catheter has been inserted. This study was conducted to examine the difference in removal friction and incidence of the catheter sticking inside the urethra in patients using the LoFric® catheter vs. a hydrophilic catheter not coated with sodium chloride. The other hydrophilic catheter studied is coated with urea and PVP, and is available on the U.S. market.

The study was a crossover study including 14 male spinal cord injury patients. Each subject was catheterized for 10 days with one type of catheter and then crossed over to the other catheter for 10 days. In total, 526 removal friction measurements were performed using an electronic dynamometer. All catheterizations were performed by the same experienced nurse.

Removal friction force levels were 55% lower, a statistically significant difference, with the LoFric® catheter. In addition, the nurse was asked to subjectively assess the incidence of the catheter sticking to the urethra upon removal. Sticking was observed 42 times in nine patients using the hydrophilic catheter without sodium chloride coating. Sticking was thought to occur three times in two patients using the LoFric® catheter.

The authors noted a strong inverse correlation between osmolality and removal friction. Osmolality measurements, taken in two different laboratories, were 900 and 950 mOsm/kg for LoFric® and 15 and 80mOsm/kg for the other hydrophilic catheter.

The Importance of Osmolality for Intermittent Catheterization of the Urethra, Lundgren, Bengtsson, Israelsson, Jonsson, Lindh and Utas, *Spinal Cord* (38) 2000

Because LoFric® is the only hydrophilic catheter for CIC with sodium chloride in its coating, the authors of this study sought to determine whether the sodium chloride indeed makes a difference in removal friction of hydrophilic catheters. Using a light microscope, the authors also compared the degree of urethral trauma experienced by the subjects. Secondly, because some catheter manufacturers offer polished drainage eyes, the authors undertook to determine whether drainage eyes make a difference in removal friction or tissue trauma.

The authors conducted a histology study in rabbits comparing the difference in removal friction forces between a first generation LoFric® catheter without sodium chloride in the coating and a present generation LoFric® catheter with sodium chloride coating. Each subject was catheterized one time and then euthanized so urethral tissue could be examined.

Friction measured upon removal of the hydrophilic catheter without sodium chloride coating was greater, with statistical significance, than friction measured to remove the present generation LoFric® catheter.

In addition, epithelial cell damage was found to be statistically significantly less with the present generation LoFric® catheter than with the hydrophilic catheter without sodium chloride coating.

The presence of drainage eyes was not found to make any significant difference in removal friction or epithelial cell damage.

Patient Satisfaction Studies: LoFric® vs. Conventional Catheters

Patient Satisfaction and the LoFric Catheter for Clean Intermittent Catheterization, Diokno, Mitchell, Nash, Kimbrough, *Journal of Urology*, February 1995

This study was conducted to assess patient satisfaction with the LoFric® catheter on the attributes of convenience, ease of handling, and comfort. All patients used the LoFric® catheter for a period of one month. The study population consisted of 25 patients with prior experience performing CIC and 16 patients just starting a CIC regimen.

Experienced patients were asked to rate both their previous catheter and the LoFric® catheter in terms of convenience, ease of handling, comfort and overall opinion at the outset of the study and again after using LoFric® for one month. Patients new to CIC were asked to perform the same ratings at the end of the one month period.

All patients just starting on CIC gave the LoFric® catheter very favorable ratings on all four attributes and all wished to continue using it following the study.

Patients experienced in CIC gave the LoFric® catheter higher scores, with statistical significance, than their previous catheter on the attributes of convenience, comfort, and overall opinion. Ease of handling was also rated higher for LoFric®, but without statistical significance. **Eighty-one percent of the experienced patients wished to continue using the LoFric® catheter rather than their previous catheter following the study.**

Clean Intermittent Catheterization in Boys Using the LoFric® Catheter, Sutherland, Kogan, Baskin, and Mevorach, Department of Urology, UCSF, San Francisco, *Journal of Urology*, December 1996

A total of 33 boys experienced in performing clean intermittent catheterization were randomized to either the LoFric® catheter or the leading PVC catheter for a period of 8 weeks. All subjects were evaluated by weekly urinalysis and questionnaires to compare the incidence of hematuria and bacteriuria. **In addition, patients were asked both at the outset and conclusion of the study to rate the LoFric® catheter and their previous catheter on the attributes of convenience, ease of handling, comfort of insertion, and overall opinion.**

The group using the LoFric® catheter gave it significantly higher scores for convenience and insertion comfort than they gave to their previous catheter. Thirteen out of sixteen (81%) in the LoFric® group wished to continue using LoFric® rather than returning to their previous catheter following the study.

LoFric® for Use in Dilation of Strictures

Long-term Results of Intermittent Low-Friction Self-Catheterization in Patients with Recurrent Urethral Strictures, Harris, Beckingham, Lemberger and Lawrence, *British Journal of Urology* (1994) 74

Direct vision internal urethrotomy is one of the most popular treatments for urethral strictures. There is, however, an unacceptably high recurrence rate of 25-50%. In this study, 101 patients used the LoFric® catheter for dilation after an initial urethrotomy had been performed. Patients were instructed to dilate twice a week for one month and once a week thereafter. Patients were randomized to continue dilation for a period of either six months or 3 years to investigate the significance of the duration of the treatment.

The recurrence rate in the group that stopped dilation after six months was 40%, which is in the same range as reported for urethrotomy alone, while patients that stopped dilation after 1-3 years (some patients stopped earlier than instructed) had a recurrence rate of only 14%. All stricture recurrences occurred within two years of stopping dilation. A group of nine patients chose to continue dilating after the three-year study period was over. *At the time this study was published, no recurrences had been seen in that group and those patients had all maintained satisfactory flow rates.*