The world’s most well documented catheter

Documentation summary
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Why is documentation of urinary catheters so important?

- Serious clinical documentation is an insurance of the catheter's safety
- Many users lack a sense of feeling and therefore can not rely on pain as a warning system
- Catheters must be suitable for lifelong therapy, because it often takes years before any complications become evident
- Greater friction – greater risk for injury

Since catheterisation is often a lifelong therapy we must make sure that the catheters really are suitable for long-term therapy. Staying healthy and avoiding infections are very important. For someone who uses a catheter 3–5 times a day, it can mean the difference between falling ill or staying healthy.

The greater the friction between the catheter and the urinary tract, the greater the risk that catheterisation will cause injury and bleeding. Several studies show that injuries usually become visible only after some years of catheter use. As users often lack a sense of feeling, pain can not always be relied upon to serve as a warning system for damage or injury. For a user, clinical documentation is an insurance that the catheter will not end up creating urethral damage.

Documentation summaries

In this folder you will find a selection of short summaries of clinical articles published on the subjects Clean Intermittent Catheterisation and Clean Intermittent Dilatation. Most of these articles concern LoFric, but we have also included a few studies of plain PVC catheters. This is to provide you with information that demonstrates the significant difference between LoFric and PVC catheters.

The purpose of this summary is to serve as a guide on all LoFric documentation and the interested reader is recommended to read the complete articles. To order reprints of the complete articles, please contact your local Astra Tech representative or the headquarter of Astra Tech.
LoFric is the world’s most well documented catheter

Not all catheters are the same
A common myth is that all catheters that have been approved by a healthcare system are of equal quality and that their health effects during long-term use are well documented. In reality, however, this approval often means that they simply meet the minimum standards. Every catheterisation causes strain on the urethra. Each small injury by itself is not particularly significant, but over time these individual injuries add up. In the long term, this can mean the difference between falling ill or staying healthy.

More than 25 years of experience
LoFric has been on the market for over 25 years and is by far the market’s most well documented urinary catheter. The studies in this summary prove how well LoFric works, both in short and long-term use. LoFric is the only hydrophilic catheter that can display documented reduced long-term risk of complications.

Astra Tech invented the hydrophilic catheter and we are still the world leaders in hydrophilic catheters for Clean Intermittent Catheterisation (CIC). With access to the combined resources of Astra Tech and AstraZeneca, we are committed to remain the leaders in this field. We were active partners in the development of CIC therapy. Astra Tech developed LoFric in close co-operation with users, researchers and healthcare professionals, and we were pioneers in establishing CIC as a therapy in many parts of the world.

The only catheter in the world with Urotonic™ Surface Technology
All LoFric catheters have a unique surface layer. It is based on Urotonic Surface Technology – a patented process that makes the catheter isotonic to urine. In plain English, this means that the salt concentration of the catheter’s surface is the same as in urine and thus is adapted for the urethra. The clever part of this technology is that water remains around the catheter tube, ensuring minimal friction between the catheter and the urethra during the entire catheterisation process. Not only when the catheter is inserted but, just as importantly, also when it is withdrawn.

The salt concentration in your urine is higher than in the rest of your body. If you do not compensate for this, the catheter tends to cause high friction and is therefore difficult to withdraw. A catheter that lacks Urotonic Surface Technology risks drying out while it is inserted, which also leads to greater friction when you withdraw it. And greater friction means a significantly increased risk of injuries and infections in the urinary tract.
Clinical relevance of Intermittent Self Catheterisation

1. Clean intermittent catheterization – A valuable treatment regimen?

Author: Bakke A
Institution: Department of Gen. Surgery, Section of Urology, Haukeland Hospital, University of Bergen, Norway
Presented: International Medical Society of Paraplegia, Annual Scientific meeting, Oslo, Norway, June 26-28, 1986

Objective: To assess complications amongst CIC patients.
Methods: During 1982–1985, 57 patients were placed on CIC. In this study the patients were followed for a mean observation time of 12 months, on numbers of urinary track infections and bacteruria.
No of patients: 57, both males and females.
Result: This group of patients had a median 2 clinical infections and 4 bacteruria a year.
Conclusion: CIC have been a good form of treatment for those patients who could manage to carry on.

Highlights:

“CIC have been a good form of treatment for those patients who could manage to carry on.”
Long-term study of Intermittent Self Catheterisation

1. Clean intermittent self-catheterization – A 12 year follow-up

Author: Wyndaele JJ, Maes D
Institution: Department of Urology, University Hospital Ghent, Ghent, Belgium
Presented: Journal of Urology 1990; 143(May): 906-908

Objective: Retrospective study on 75 patients on CIC long-term effects and complications.
Methods: Every 1 to 2 years blood tests, urograms and urodynamic studies were done. All patients had regular follow-up with urological evaluations at least two times a year.
No of patients: 75, both males and females, mean CIC 7 years.
Result: 19 patients had bilateral hydronephrosis at start but only 5 had minor dilatation after CIC. Vesicorenal reflux: A total of 20 patients had reflux before CIC and 5 of them disappeared after CIC. 62 % remain dry for at least 4 h after CIC. Complications occurred in up to 20 % of the patients (urethral complications, bladder calculus, pyelonephritis and epididymitis).
Discussion: Long time CIC provide good clinical results in this patient group, in most cases kidney dilatation will be relived or improved.
Astra Tech comment: This is not a study on LoFric but on CIC.

Highlights:

“Long time CIC provide good clinical results...”
2. Clean intermittent catheterization from the acute period in spinal cord injury patients. Long term evaluation of urethral and genital tolerance

Author: Perrouin-Verbe B, Labat JJ, Richard I, Mauduyt de la Greve I, Buzelin JM, Mathe JF
Institution: Department of Rehabilitation, Department of Urology, Hospital St Jacques, CHR Nantes Cedex, France.
Presented: Paraplegia 1995;33: 619–624

Objective: Triple objectives to evaluate the overall rate of complications of CIC, indications of long term CIC and also to study 2 groups (CIC 2 years and CIC >5 years). Why discontinuance? Why acceptance?

No of patients: 159, both females and males.
Methods: Retrospective patients on SCI from 1980-1988. Overall rate of infections, lithiasis, damage of the upper urinary tract and urethral tolerance were evaluated. Reasons for discontinuance, choice of voiding model, dependency of assistance. Persistence of incontinence. Patients used PVC with lubricant, in many cases reused for a week or longer.
Result: Acceptance: only 8 patients stopped CIC after having practiced CIC for at least 2 years. All of them dysynergic with remaining incontinence. The group who had done CIC >5 years were 89% continent. Tetraplegic patients discontinued more than paraplegic patients due to dependency of assistance.
UTI: 60% cytobacteriological infection, 28% with a lower UTI. Urethral stricture: 5.3% to 19% depending on the number of years on CIC. For patients who used CIC for >5 years the rate of epididymitis was 28.5%!
Discussion: Many patients choose to continue CIC for a long time, the reason for that is thought to be improved degree of continence, another factor is the ability to autonomy. The type of catheters used seems to be important concerning complications in the long run. Use of low friction catheters might decrease urethroprostatic infections and epididymitis.
Astra Tech comment: Lower levels of complications are seen in longterm studies with LoFric.

Highlights:
“The type of catheters used seems to be important concerning complications in the long run.”
3. Clean intermittent catheterization in spinal cord injury patients: Long-term follow-up of a hydrophilic low friction technique

**Author:** Waller L, Jonsson O, Norlén L, Sullivan L  
**Institution:** Spinal Injuries Unit, Department of Neurosurgery, Department of Urology, Sahlgrenska University Hospital and Östra University Hospital, Gothenburg, Sweden  
**Presented:** Journal of Urology 1995; 153: 345-348

**Objective:** 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.

**Method:** 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 who 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 of patients:** 30, both females and males.

**Result:** No new urethral trauma occurred in any of the 30 patients after starting CIC on LoFric. No surgery was required, and no incidents of false passages, meatalitis or meatal stenosis were detected. Two patients experienced epidydimitis. 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.

**Discussion:** The use of LoFric seems to decrease the urinary tract infection rates, compared to what has been reported in other studies when catheters with lubricating jelly were used.

**Highlights:**

“It seems reasonable and is indicated by our study that the hydrophilic catheter (LoFric) regimen has a preventive effect on urethral traumatic complications and that it can facilitate the healing of minor epithelial damage as reported by Bakke et al.”

“Progression towards strictures after early urethral trauma seems to be preventable by the use of this catheter (LoFric).”
4. Physical predictors of infection in patients treated with clean intermittent catheterization: a prospective 7-year study

Author: Bakke A, Digranes A, Höisaeter PÅ
Institution: Department of Surgery, Section of Urology and Department of Microbiology and Immunology, The Gade Institute, Haukeland Hospital, Bergen, Norway
Presented: British Journal of Urology 1997;79: 85–90

Objective: To study urinary tract complications in patients treated using long-term CIC, and to evaluate the physical factors which might be implicated in these complications.

Methods: Prospective follow-up study of out-patients. The same group of patients attended a one year follow up study 1988, and was now contacted again by letter and asked to participate in the study. Most patient (91%) used the low-friction LoFric catheter. Questionnaire was sent out and urine samples were also collected. UTI and other problems related to CIC were recorded. <2 indicated no or only minor infections, >4 indicated more frequent or more serious problems.

No of patients: 302, both females and men.

Result: Questionnaire -65% had no symptoms of clinical Urinary Tract Infections (UTI), 35% had some signs of clinical UTI. None of the patients had been hospitalized. 76% of patients reporting UTI used antibiotics and 15% used antibiotics in patients without sign of UTI. Patients who reported infections had a mean catheterization volume of 432 ml, against 353 ml in those not reporting infection (p=0.009). Bacteriuria was found in 61% of the evaluable samples. The frequency of catheterization correlated to bacteriuria -< 3/day more bacteriuria than >5/day.

Discussion: Patients who had clinical UTI in the first study and kept their catheterization volume low, had fewer infection problems 7 years later. By using low-friction catheters you minimize the risk for urethral complications. After a mean follow up of 8.8 years there were no urethral strictures or epididymitis.

Highlights:

“Increasing the frequency of catheterisation is important in reducing episodes of bacteriuria, and it may be connected with the ‘wash-out’ effect.”
5. Impaired Renal Function in Newly Spinal Cord Injured Patients Improves in the Chronic State – Effect of Clean Intermittent Catheterization?

**Author:** Pettersson-Hammerstad K, Jonsson O, Berrum Svennung I, Karlsson A-K  
**Institution:** Spinal Injury Unit, Sahlgrenska University Hospital and Department of Surgery and Institute of Neuroscience and Physiology Sahlgrenska Academy, University of Göteborg, Sweden  
**Presented:** J Urol 2008;180: 187-191

**Objective:** We investigated renal function in spinal cord injured subjects in relation to the level and completeness of injury and bladder emptying regimen in the acute and chronic stages.  
**Methods:** A retrospective chart review was performed of 169 spinal cord injured subjects treated at the Spinal Cord Injury Unit, Sahlgrenska Hospital between 1985 and 2002. Renal function based on glomerular filtration rate was evaluated by chromium-ethylene-diamine-tetra-acetic acid clearance 3 to 4 months after injury and at follow up 3 to 5 years after injury.  
**No of patients:** 169 spinal cord injured males and females.  
**Results:** The glomerular filtration rate was lower than expected in the first investigation in the whole group (82% of the expected value). When divided according to level of lesion the figure was lower in the cervical (81%) and thoracic (88%) levels of the lesion and in the American Spinal Injury Association A group compared to the American Spinal Injury Association B-E group. In the second investigation we found a significant improvement in the whole group of 6%. When dividing the group according to bladder emptying regimen we found that in the group that emptied the bladder by clean intermittent catheterization glomerular filtration rate improved significantly (7%).  
**Conclusion:** Spinal cord injury affects renal function and has a deteriorating effect on glomerular filtration rate. The reduction is seen on the cervical and thoracic levels of injury and in complete injuries. Renal function improves with time after injury and improvement is seen most clearly in the group that uses clean intermittent catheterization as a bladder emptying method.

**Highlights:**

“Renal function improves with time after injury and improvement is seen most clearly in the group that uses clean intermittent catheterization as a bladder emptying method.”
Objective: Acute urinary retention (AUR) is a painful subacute emergency that is frequently seen in the general practice of urology. Urethral catheterization to drain the bladder can usually be performed successfully, safely, and with minimal discomfort using standard balloon retention catheters. In a small percentage of cases, however, abnormal urethral anatomy precludes passage of catheters of any size. In these situations, the urologist has a variety of more invasive and complex tools available for draining the bladder. With the introduction of hydrophilic catheters and their prominent use in children receiving intermittent catheterization, we have developed a protocol extrapolating our knowledge in children to the older male in AUR in whom a traditional catheter could not be placed.

Methods: A total of 44 men in AUR in whom placement of a traditional catheter had failed were recruited into our study in an attempt to avoid more invasive bedside maneuvers or surgical intervention. A hydrophilic catheter that had been modified to allow the throughput of a wire was used to attempt bladder catheterization.

Results: Of the 44 men, 34 (72%) had successful placement of the hydrophilic catheter, relieving their discomfort and AUR. Of the 34 successful catheterizations, 30 (88%) resulted in successful placement of an indwelling Council catheter after removal of the hydrophilic catheter. Long-term drainage was accomplished in 30 (68%) of the 44 men in whom initial catheter placement for AUR had failed.

Conclusions: We propose that the hydrophilic catheter should be a part of the urologist’s armamentarium whenever treating men with AUR.

"We propose that the hydrophilic catheter should be a part of the urologist’s armamentarium whenever treating men with AUR."
Urinary tract infection/bacteriuria, difference between LoFric and PVC

1. Bacteriuria in patients treated with clean intermittent catheterization

**Author:** Bakke A, Digranes A  
**Institution:** Department of Gen. Surgery, Section of Urology, Haukeland Hospital, University of Bergen, Norway  
**Presented:** Scand J Infect Dis 1991; 23: 577-582

**Objective:** To assess the occurrence of bacteriuria in all patients using CIC in a defined population.  
**Methods:** Nearly all adult outpatients practicing CIC in Norway were asked to take part in a 1-year follow-up study concerning physical and psychological complications to CIC. Clinical examination and laboratory analyses performed every 3 months during 1 year.  
**No of patients:** 407, both males and females, 96% used LoFric.  
**Result:** During the study 1413 urine samples were cultured. Bacteriuria was found in 50% of the samples, but there was no difference found between males and females. Notable is that 86% of the patients had no clinical signs of Urinary Tract Infections.  
**Discussion:** In the present study few had signs of clinical infections. Antibiotics should be used sparingly in the management of these patients.

**Highlights:**

“Increasing the frequency of catheterisation is important in reducing episodes of bacteriuria… and it may be connected with the ‘wash-out’ effect.”

“It also supports the recommendations to minimize the use of antibiotics in patients treated with CIC and having a frequency of >4 catheterizations per day, thereby ensuring that the mean volume of catheterization is kept to <400 mL in adults.”

2. Efficacy and safety of clean intermittent catheterization in adults

**Author:** Hellström P, Tammela T, Lukkarinen O, Kontturi M  
**Institution:** Division of Urology, Oulu University Central Hospital, Oulu, Finland  
**Presented:** European Urology 1991; 20: 117-121

**Objective:** To assess safety, effect and complications in CIC.  
**Methods:** Prospective study to assess the efficacy and safety of CIC. The primarily indications for CIC was injury to the innervation of the bladder or weakening of contractility for other reasons. Patients were examined twice a year by renal ultra-sonography, midstream urine analyses and creatinine determinations. Follow-up mean time was 40 months.
**No of patients:** 41, both males and females.

**Result:** 75% continued with CIC. 5 men were suffering from hydro-nephrosis and renal insufficiency when started CIC; 4 of them were completely resolved and 1 had deteriorated. 26 patients were incontinent before CIC and this decreased or ceased completely in 8 cases. Bacteriuria was common but only 4 patients had repeated UTI.

**Discussion:** The high incidence of bacteriuria might be because some of the patients did not preform CIC often enough, making them susceptible to infections. The self-lubricating hydrophilic disposable catheters may have helped to reduce urethral complications.

**Highlights:**

“The self-lubricating hydrophilic disposable catheter may have helped to reduce urthral complications.”

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### 3. Physical complications in patients treated with clean intermittent catheterization

**Author:** Bakke A, Vollset SE, Höisaeter PÅ, Irgens LM  
**Institution:** Department of Gen. Surgery, Section of Urology, Haukeland Hospital, University of Bergen, Norway  
**Presented:** Scand J Urol Nephrol 1993; 27: 55-61

**Objective:** Prospective study to assess complications in patients treated with CIC.

**Methods:** Follow-up period for 12 months. Every 3 months examination of urine analyses (bacteria/blood), general condition and radiological examination (urography u-sound).

**No of patients:** 302, both males and females.

**Result:** Clinical symptoms of Urinary Tract Infections (UTI) and bacteriuria was between 20-25%, 2.6% had bladder stones, 1 epididymitis and 2 strictures. 93% had normal s-creatinin and in 75% radiology examinations were normal. The main complication attributable to CIC was bleeding in connection with catheterization and UTI. Tendency to bleeding was more frequent with low age, female sex and high clinical infection score. Lower infection score was found in patients using only LoFric compared to those using plain PVC catheters.

**Conclusions:** Patients on CIC have some, but mostly minor, complications. CIC is beneficial in most patients.

**Discussion:** It is an interesting observation that the group of patients not using LoFric, but who used plain PVC, had the highest clinical infection score. Significantly lower infection score was found in LoFric CIC group compared to PVC!

**Highlights:**

“A lower infection score was found in the patients using only low-friction catheters (LoFric) compared to those using plain PVC catheters (p<0.05).”
4. Urethral cytology in spinal cord injury patients performing intermittent catheterization

Author: Vaidyanathan S, Soni B M, Krishnan K R, Dundas S.
Institution: Mersey Regional Spinal Injuries Centre, Southport, Southport General Infirmary, Southport, United Kingdom.

Objective: 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.

Methods: 14 using a conventional catheter and 17 using the LoFric catheter, were included in the study. A group of 11 patients on long term indwelling catheter was also 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.

No of patients: A total of 31 patients (+ 11 indwelling patients).

Result: 9 out of 14 (64%) patients using a conventional catheter were detected with urethral inflammation, but only 1 out of 17 (6%) patients using the LoFric catheter. Highest amount of inflammation was seen, as expected, in the indwelling catheter group. Urethral cytology revealed a percentage ratio of polymorphs to epithelial cells of 66 in PVC catheter group and only 0.04 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. Furthermore it also revealed a significantly greater number of bacteria in the PVC group compared to LoFric. These results occurred even though the LoFric group had been catheterizing for six times as long, on average, than the group using conventional catheters. The number of bacteria seems to be correlated with the degree of inflammation.

Conclusion: The use of LoFric catheter for intermittent catheterization was associated with significantly lesser degree of urethral inflammatory response when compared to the use of a PVC catheter.

Highlights:

“In conclusion, use of a LoFric catheter for intermittent catheterization was associated with significantly lesser degree of urethral inflammatory response when compared to the use of a PVC catheter.”

“…significantly greater numbers of bacteria were seen in those practicing intermittent catheterization with a PVC catheter as compared to those using a LoFric catheter.”
5. A Prospective randomized trial of the LoFric hydrophilic-coated catheter versus conventional plastic catheter for clean intermittent catheterization.

**Author:** Jonathan M. Vapnek, Frederick M. Maynard, Jiensup Kim.
**Institution:** Departments of Urology and Rehabilitation Medicine, Mt. Sinai School of Medicine, MetroHealth Medical Center, Loma Linda University Medical Center and Department of Clinical Research, Astra Tech AB.
**Presented:** The Journal of Urology 2003;169: 994-998.

**Objective:** The objectives of this one-year study were to compare the incidence of urinary tract infections, as well as the degree of pyuria, hematuria, experienced by patients using the LoFric catheter vs. patients using conventional plastic catheters.
**No of patients:** 62 male.
**Methods:** Forty-nine adult male patients who had all previously been using conventional catheters completed the study. Follow-up with urine analysis and physical examinations was conducted every three months.
**Result:** 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.
**Conclusions:** Patients using the hydrophilic coated catheter have a significant decrease in the degree of microhematuria as well as a significant decrease in the rate of urinary tract infections compared with those using standard plastic catheters. Patients who experience difficulty with CIC and those who with a high rate of UTI may benefit from using the hydrophilic-coated catheter on a regular basis.

**Highlights:**

“Use of the hydrophilic coated catheter by patients on intermittent self- catheterization is associated with less hematuria and a significant decrease in the incidence of urinary tract infections.”

“…patients reported high degrees of satisfaction with the hydrophilic coated catheter and many continued to use them after the conclusion of the study.”
Friction measurement and epithelial damage

1. Effect of catheterization and surface osmolarity on urethral epithelium, an experimental study on dogs

**Author:** Sullivan L, Carlsten U, Bowald S, Nilsson A  
**Institution:** Spinal Injuries Unit, Department of Neurosurgery, Sahlgrenska University Hospital, Gothenburg, Sweden  
**Presented:** International Medical Society of Paraplegia, Annual Scientific meeting, Stoke Mandeville Hospital, United Kingdom, May 13-16, 1987

**Objective:** Assess the complications with LoFric with or without salt coating and conventional catheter.  
**Methods:** Randomized dogs in 3 groups. The dogs were CIC 5 times per day for 35 days. The catheter was left in the urethra for 60 sec. The urethra was examined macro- and microscopically to find degree of damage and ulcerations.  
**Result:** No clear differences were seen after LoFric with or without salt. Conventional catheter showed ulcerations, marked oedema and petechial bleeding.
2. Clean intermittent catheterization in boys using the LoFric catheter

**Author:** Sutherland RS, Kogan BA, Baskin LS, Mevorach RA  
**Institution:** Department of Urology, University of California School of Medicine, San Francisco, California  
**Presented:** The Journal of Urology 1996;156: 2041–2043

**Objective:** Hypothesis was that in boys hydrophilic catheter would be associated with less urethral abrasion and improved comfort.  
**Methods:** 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.  
**No of patients:** 33 boys.  
**Result:** Significantly fewer episodes of microscopic hematuria occurred in the LoFric group than in the PVC catheter group. There were also fewer episodes of bacteriuria in the LoFric group but the difference was not statistically significant. 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.  
**Conclusion:** In boys the LoFric catheter appears to cause less trauma. Satisfaction is higher with the LoFric device and for selected patients it has significant advantages. The hydrophilic LoFric catheter is safe and effective for intermittent catheterization in boys.

**Highlights:**

“The LoFric catheter was associated with less microscopic hematuria than the Mentor (PVC) catheter, which was used with standard gel lubricant.”

“In boys the LoFric catheter appears to cause less trauma.”

3. The importance of osmolality in hydrophilic urethral catheters: a crossover study

**Author:** Waller L, Telander M, Sullivan L  
**Institution:** Spinal Injuries Unit, Department of Neurosurgery, Sahlgrenska Hospital, Göteborg, Sweden  
**Presented:** Spinal Cord 1997;35: 229–233

**Objective:** 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.
Methods: 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. 

No of patients: 14 males.

Result: 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 80 mOsm/kg for the other hydrophilic catheter.

Discussion: The outer layer should possess the same osmolality as the urine which passes the urethral epithelium when the bladder is emptied.

“Our own experience during the early stages of development of the LoFric catheter and the results of this present study indicates the importance of osmolality of the outer layer of hydrophilic catheters.”
4. The importance of osmolality for intermittent catheterization of the urethra

**Author:** Lundgren J, Bengtsson O, Israëlsson A, Jönsson A-C, Lindh A-S, Utas J

**Institution:** Astra Hässle, Mölndal, Sweden and Astra Tech, Mölndal, Sweden.

**Presented:** Spinal Cord 2000;38: 45–50

**Objective:** 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. Secondarily, 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.

**Methods:** 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.

**No of patients:** 15 rabbits.

**Result:** 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.

**Conclusion:** To minimize the risk of urethral trauma, high osmolality catheters are recommended, especially when the catheterization times are a few minutes of duration or more. There is no difference in urethral trauma between catheters with or without eyes.

**Highlights:**

“It may be concluded that the osmolality is one important factor... when comparing different hydrophilic catheters, in regards to removal friction and urethral trauma.”

“...it is suggested that there is no difference in urethral trauma between catheters with or without eyes.”
Patients satisfaction and clinical background of patients

1. Assessment of the polyvinyl pyrrolidone coated catheter

**Author:** Capper V, Deane AM, Hindmarsh JR  
**Institution:** Institute of Urology, London, United Kingdom  
**Presented:** International Continence Society, Fourteenth Annual Meeting, September 13-15, 1984

**Objective:** To assess how comfortable a PVP coated catheter is.  
**Methods:** Patients requiring catheterization due to examination either for urodynamic studies (n=21), residual volume (n=56) or self-catheterization (n=23).  
**No of patients:** 100 consecutive patients, both males and females.  
**Result:** All patients with previous experience from catheterization (n=20) found the test catheter more comfortable than conventional technique.  
**Conclusion:** We conclude that this catheter has a major advantage, over conventional catheters with added lubricants, of improved patient comfort during catheterizations.  
**Astra Tech comments:** This is an early study on LoFric before “salted LoFric” (Urotonic Surface Technology) was developed. Clinical trials is an important way too improve our products.

**Highlights:**

“This catheter has a major advantage, over conventional catheters with added lubricants.”

2. Clinical background of patients treated with clean intermittent catheterization in Norway

**Author:** Bakke A, Brun OH, Höisaeter PÅ  
**Institution:** Department of Surgery, Section of Urology, Haukeland Hospital, University of Bergen, Norway  
**Presented:** Scand J Urol Nephrol 1992; 26: 211-217

**Objective:** To assess the clinical background of all adults patients using CIC outside hospital in Norway.  
**Methods:** All urologists, several neurologists and gynaecologists, as well as physicians working in rehabilitation hospitals in Norway were asked to notify all patients already on CIC or about to start CIC. Physical and psychological complications were followed-up for 1 year. The patients were classified by a neuro-urological index and disability score. Most patients (95,8%) used LoFric.  
**No of patients:** 407, both males and females.  
**Result:** 5 diagnosis groups. 1) 106 patients with lesions in medulla spinalis above conus area. 2) 141 patients with affections of conus and peripheral nerves. 3) 136 patients with detrusor myopathy or non-neurogenic bladder. 4) 19 patients with infravesical obstruction with normal detrusor. 5) 5 with suprapontine affection.
Conclusion: This study shows that a great variety of bladder dysfunctions can be successfully treated with CIC. It also shows that CIC was used in all age groups and equally in both sexes. CIC could be performed even by highly disabled persons.

Highlights:

“This study shows that a great variety of bladder dysfunctions can be successfully treated with CIC. CIC could be performed even by highly disabled persons.”

3. Patient satisfaction and the LoFric catheter for clean intermittent catheterization

Author: Diokno A C, Mitchell B A, Nash A J, Kimbrough J A
Institution: Department of Urology, William Beaumont Hospital, Royal Oak, Michigan

Objective: This study was conducted to assess patient satisfaction with the LoFric catheter on the attributes of convenience, ease of handling, and comfort.

Methods: 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.

No of patients: 41, both males and females.

Result: 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.

Discussion: Eighty-one percent of the experienced patients wished to continue using the LoFric catheter rather than their previous catheter following the study. It appears that most patients will be satisfied with the disposable catheter and will prefer it as an alternative to a plastic catheter with lubrication applied by the patient.

Highlights:

“After trying the disposable catheter (LoFric) 81% gave it a more favorable general opinion score than they did the old catheter and stated that they would use the new catheter (LoFric) if given a chance.”
4. Comparative study of the degree of satisfaction of patients on intermittent catheterisation using LoFric and Polyvinyl chloride (PVC) catheters.

Author: P. López Pereira, M.J. Martínez Urrutia, L. Lobato, S. Rivas, E. Jaureguizar Monereo
Institution: Children’s Urology Unit, La Paz University Hospital, Madrid (Spain)
Presented: Actas Urológicas Españolas 2001; Volumen XXV - num 10

Objective: To determine whether this type of catheter (LoFric) involves a higher degree of satisfaction than the use of ordinary PVC catheters.
Methods: Prospective study on spina bifida patients with previous experience with PVC catheter. The patients were provided with LoFric catheters for a period of 2 months. By questionnaire they were asked the degree of satisfaction and comfort (anonymously).
No of patients: 40, both boys and girls.
Result: Eighty-six percent found LoFric easy to learn to use. 51% who reported some kind of discomfort when removing the conventional catheter, 72% of them said it was eliminated with the new catheter. The LoFric catheter was favored by 70% because it reduced the discomfort compared to conventional PVC catheter.
Conclusions: The use of LoFric catheter could be justified in patients who report discomfort with conventional catheters. It can also be recommended in patients with artificial sphincter, bladder augmentation and Mitrofanoff procedure.
Discussion: In this study we found that LoFric increased the degree of comfort and satisfaction for most patients, decreasing or eliminating discomfort when the catheter is removed or inserted.

Highlights:

“In our study we found that in general the LoFric catheter increased the degree of comfort and satisfaction for most patients, decreasing or eliminating altogether the feeling of discomfort when the catheter is removed or inserted.”
5. A Novel Product for Intermittent Catheterisation: Its Impact on Compliance with Daily Life - International Multicentre Study

**Author:** Bjerklund Johansen T, Hultling C, Madersbacher H, Del Popolo G, Amarenco G, for the LoFric Primo Study Group
**Presented:** European Urology 2007;52: 213–220

**Objectives:** This study was undertaken to evaluate patient openness to changing and satisfaction with catheters used in intermittent catheterisation (IC) for urinary retention from neurogenic bladder dysfunction, and to compare patient response to conventional catheters and a novel packaged hydrophilic catheter: LoFric Primo.

**Methods:** Of 409 patients recruited, 378 (283 males, 95 females; mean age: 43.5 yr) completed a 12-d trial of the novel catheter. The diagnoses were spinal cord lesion in 65.6%, multiple sclerosis in 9.6%, spina bifida in 2.3%, and other neurologic conditions in 22.5%; the mean duration of IC was 4.6 yr. Patients evaluated their current catheter at recruitment and the novel catheter after the 2-wk trial by questionnaire. Patient satisfaction was expressed on a Visual Analogue Scale for seven topics covering use and general satisfaction.

**No of patients:** 409 males and females.

**Results:** Of the 378 patients, 55.2% were happy to continue with the novel device, which was 74% of patients using standard polyvinyl chloride (PVC) catheters and 36% of those using prelubricated PVC (p = 0.04). No individual patient factors were found to be significant in catheter choice. For the whole study population “ability to comply with daily life activities” was maintained with the novel product despite handling and general satisfaction being found more troublesome.

**Conclusions:** The main finding was that more than 50% of the patients wished to continue with the novel catheter and reported increased satisfaction regarding introduction of the catheter, handling, time spent, perception of IC, general satisfaction, and ability to cope with daily life.

**Highlights:**

“… more than 50% of the patients wished to continue with the novel catheter and reported increased satisfaction regarding introduction of the catheter, handling, time spent, perception of IC, general satisfaction, and ability to cope with daily life.”
Strictures


Author: Zambon J-V, Delaere KPJ
Institution: Department of Urology, De Wever Hospital, Heerlen, The Netherlands
Presented: EAU meeting, Amsterdam, Netherlands, June, 1990

Objective: To assess if ISC can maintain post-operative urethral patency.
Methods: Two days after optical urethrotomy ILSC was performed twice daily and later once a week. Patient follow up period was median 8,5 months.
No of patients: 15 males.
Result: Well-tolerated and urinary flow rates remained acceptable in all patients.
Conclusion: Simple, safe and effective method to maintain urinary flow and to prevent strictures. Good patient compliance, without serious complications.

Highlights:

“Intermittent Low-Friction (LoFric) Self Catheterization is a simple, safe and effective method in the prevention of recurrent urethral strictures with good patients-compliance and without serious complications.”

2. Intermittent self-catheterization (ISC) for urethral strictures

Author: Lawrence WT, Iacovou J
Institution: Urology Department, Nottingham City Hospital, Nottingham, United Kingdom
Presented: AUA, Toronto, Canada, April, 1991

Objective: To assess if Intermittent Self Catherization can maintain post-operative urethral patency.
Methods: All patients performed ISC weekly with LoFric for 6 months after optical urethrotomy. Group 1 continued ISC after 6 months and group 2 stopped ISC after 6 months. Follow up period was 3–4 years.
No of patients: 59 males.
Result: All (21) in group 1 had good flow rates and 8 of 24 in group 2 had new strictures that needed further surgery. Fourteen patients were lost to follow-up.
Conclusion: ISC was easy to teach to an elderly population and prevented further surgery.
Discussion: 9 patients died of unrelated causes during the study and it would have been unfortunate if they had undergone expensive operative treatment.
3. Treatment of recurrent urethral strictures using Clean Intermittent Self-Catheterization (CISC)

Author: Robertson GSM, Everitt N, Lamprecht JR, Brett M, Flynn JT
Institution: Area Urological Service, Leicester General Hospital, Leicester, United Kingdom

Objective: To assess if Clean Intermittent Self Catheterization can prevent recurrent strictures.
Methods: Patients with at least one recurrent urethral stricture were taught and told how to CISC twice a week for 4 weeks and then weekly for a further 5 months. Flow rate was measured.
No of patients: 64 males, 1 female.
Result: 56 patients were satisfied with CISC. There were 9 episodes of recurrent strictures and 11 episodes of urinary tract infections.
Conclusion: Clean Intermittent Self Catheterization can prevent hospitalization and further surgery. 86% of patients found the method “very satisfactory”.

Highlights:
“A total of 86% of the patients found the method very satisfying.”

4. Treatment of recurrent urethral stricture by internal urethrotomy and intermittent self-catheterization: a controlled study of a new therapy

Author: Bødker A, Ostri P, Rye-Andersen J, Edvardsen L, Struckmann J
Institution: Departments of Urology T, D and H, Glostrup Hospital, Rigshospitalet, Gentofte Hospital and Department of Surgery K, Fredriksberg Hospital, Copenhagen, Denmark

Objective: To assess the course after termination of Clean Intermittent Self-Catheterization.
Methods: Men with recurrent urethral strictures who had previously been treated with internal urethrotomy were randomized to either a treatment group with CIC for three months or an observation group. Follow-up for 12 months with flow rate. Patients were examined after 2, 4, 6 ,12 months.
No of patients: 61 males.
Result: 26 of 28 patients in the treatment group completed CIC. No complication, no hematuria or UTI. No new strictures during the treatment with CIC. However, the results were not significantly different between the treatment and control groups at study end; 78% had recurrence in the treatment group vs. 82% in control group.
Conclusion: Since no patients had clinical signs of stricture during CIC, we conclude that CIC should be continued for a long duration, possibly permanently, after a internal urethrotomy.
5. Prevention of urethral stricture recurrence using clean intermittent self-catheterization

Institution: Departments of Urology, Aalborg Hospital and *Hvidovre Hospital, Denmark

Objective: To investigate the effect of CIC LoFric Charrière 16 or 18 on prevention of urethral strictures after internal urethrotomy.

Methods: Randomly selected controlled study CIC weekly for 1 year following Sachse’s operation for urethral stricture. Objective examination for strictures every 2 months after op. Study duration 1 year (24–45 months).

No of patients: 55 (31 CIC 24 control), only males.
Result: Within the first year 4 patients on CIC and 15 patients in the control group developed urethral strictures (P<0.01). 2 years after completion of treatment 6 pat on CIC insisted on continuing CIC. None of the 6 patients developed strictures during observation period (24–45 months). All CIC patients were able to perform CIC with no related complications.

Conclusion: Weekly CIC is a simple method of reducing the frequency of urethral stricture recurrence after internal urethrotomy.

Discussion: CIC following operation for strictures may reduce costs by preventing operation for recurrent stricture.


Author: Harriss D R, Beckingham I J, Lemberger R J, Lawrence W T
Institution: Department of Urology, City Hospital Trust, Nottingham and Department of Urology, Eastbourne District General Hospital, Eastbourne, United Kingdom
Presented: British Journal of Urology 1994; 74: 790-792
Objective: To ascertain the duration of intermittent low-friction self-catheterization (ILSC) required to cause stricture stabilization.

Methods: 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 three years to investigate the significance of the duration of the treatment.

No of patients: 101 males.

Result: 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 ceasing dilation. A group of ten patients chose to continue dilating after the three-year study period was over.

Conclusion: The results indicate that ILSC is safe and effective in preventing stricture recurrence in the long-term. The recurrence rate of strictures was significantly lower when ILSC was continued for more than 12 months compared with ILSC that was stopped at 6 months.

Discussion: In the group of ten patients who chose to continue dilating after the three-year study period was over, none developed a stricture recurrence. These patients may have discovered the only sure method of preventing a recurrent stricture.

Highlights:

“In the group of ten patients who chose to continue dilating after the three-year study period was over, none developed a stricture recurrence.”

7. Intermittent self-dilatation after internal urethrotomy for primary urethral strictures: A case control study

Author: Lauritzen, M¹, Greis, G², Sandberg, A³, Wedren, H⁴, Öjeby, G⁵, Henningsohn, L⁶

Institution: ¹Department of Urology, Karolinska University Hospital in Huddinge, Stockholm, Sweden, ²Department of Surgery, County Hospital Gävle, Gävle, Sweden, ³Department of Surgery, County Hospital Blekinge, Karlskrona, Sweden, ⁴Department of Urology, Uppsala University Hospital, Uppsala, Sweden, ⁵Department of Surgery, County Hospital Bollnäs, Bollnäs, Sweden, ⁶Division of Urology, Institution for Clinical Science, Intervention and Technology, Karolinska Institutet, Stockholm, Sweden


Objective: To retrospectively evaluate the effects of intermittent self-dilatation (ISD) on the natural course of urethral strictures after an internal urethrotomy.

Methods: A retrospective case control analysis of all males who had undergone a first time internal urethrotomy due to a urethral stricture in 1998-2000 at 15 urological departments in Sweden. Demographic data including stricture localization, stricture aetiology and reoperation dates, as well as postoperative indwelling catheter and antibiotic treatment,
were collected from the medical records. Factors concerning the ISD were also gathered: postoperative starting time, dilatation catheter size, dilatation frequency and time for retreatment. All patients’ medical records were followed for 3-6 years until 2003.  

**No of patients:** Out of 217 included patients 162 were treated with internal urethrotomy only and 55 with internal urethrotomy followed by postoperative ISD.  

**Results:** The median time until recurrence (surgical reoperation) was 732 days in the ISD group and 167 days in the non-ISD group (p<0.0001). The frequency of recurrence after internal urethrotomy was 9% (5/55) in the ISD group and 31% in the non-ISD group (51/162) during the observational follow-up period (p=0.0007). There was a higher risk of recurrence among those with a traumatic aetiology (39/104) compared with those with unknown aetiology (14/89) (p=0.0005). Patients with a postoperative catheter had a lower risk of recurrence (40/172) than those without one (16/45) (p=0.01).  

**Conclusions:** Postoperative ISD of a urethral stricture, primarily treated by internal urethrotomy, significantly reduces the stricture recurrence rate as well as delaying the time until recurrence.  

**Highlights:**  

“Postoperative ISD of a urethral stricture, primarily treated by internal urethrotomy, significantly reduces the stricture recurrence rate.”
Post-operative retention

Post-operative urine retention
(Postoperative Retention of Urine)

**Author:** Skovdal J, Hoffmann E, Jensen P, Petersen JK  
**Institution:** Department of Surgery, Central Hospital, Naestved, Denmark  
**Presented:** Ugeskr for Laeger1988; 150/48: 2976-2978

**Objective:** To assess the incidence of Postoperative retention of Urine (PU) in patients undergoing surgery, and to obtain empirical grounds for the treatment of PU by clean intermittent catheterization.

**Methods:** Consecutive surgical patients over 15 years of age. PU definition was failing spontaneous micturation for more than 4 hours after induction of anesthesia.

**No of patients:** 25, both males and females.

**Result:** Totally 15 patients needed at least one CIC (1-4).

**Conclusion:** In this study the incidence of PU was 60%. We conclude that a fixed regiment with CIC every four hour at the latest, is an adequate treatment for PU.

**Highlights:**

“The results of intermittent catheterization in selected patient groups have been satisfactory: the number of UTI declined and the use of polyvinyl-pyrrolidone catheter LoFric offered the patients good comfort.”

“We conclude that a fixed regiment with CIC every four hour at the latest… is an adequate treatment for PU.”
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