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USER COMPLIANCE OF A NEW HYDROPHILIC COATED MALE CATHETER

Hypothesis/aim of studyIntroduction & objectives
Clean intermittent catheterization (CIC) is the standard treatment for patients who are unable to empty their bladder. It is a therapy with few contraindications but compliance could sometimes be an issue. Optimized compliance appears to be obtained by giving the patient a free and adapted choice (1) why patients' catheter preferences is essential (2,3). The primary objective of this study was to investigate perception of and compliance to a newly developed hydrophilic coated catheter available for male patients who practice CIC, i.e. LoFric Origo®.
Secondary objectives included collection of epidemiological data of a broad male population, practicing CIC for different reasons, for a greater understanding of preferences, needs and opinions by users. This information will form the foundation for continued product development to ensure catheters that meet user requirements and that could potentially reduce complications related to CIC.

Study design, materials and methods
A non-interventional study design was used and patients from the 19 participating European hospitals (2 in Switzerland, 3 in Belgium, 2 in the Netherlands, 4 in Norway, 4 in France and 4 in the UK) who were using the new catheter were asked to participate. Two questionnaires were filled out; one describing background data, and if applicable performance of CIC. A second questionnaire was filled out in their home-setting eight weeks later evaluating features of the new catheter.

Results
A total of 416 patients were eligible for the study (179 routinely disposable catheter users and 237 de novo catheter users). Background data from the first questionnaire was obtained from all patients. The response rate for the second questionnaire was 88%, i.e. 365 patients. The three most common reasons for CIC were bladder outlet obstruction such as prostate hyperplasia (28%), bladder dysfunction such as underactive/overactive bladder (27%) and spinal cord injury (18%). Patients evaluating the new catheter (n = 365) showed a general satisfaction rate of 81% and 72% were still using it at the end of the study. The remaining 28% had discontinued their use due to no persistent need to catheterize (6%), therapy switch (2%), a catheter switch (19%) or other reasons (1%). Specific features of the new catheter were evaluated and it was perceived as hygienic due to the insertion grip by 85% and the foldable feature was deemed as important by 67%. A total of 85% of the patients would recommend the new catheter to a friend and 77% would like to continue using it. When comparing the results reported from previous catheter use and the new catheter similar values were reported for satisfaction (79% previous vs. 81% new catheter), ease of use at insertion (78% previous vs. 83% new catheter) and withdrawal properties (92% vs.92%). Patients evaluating LoFric Origo consisted of a majority of new users still coping with illness and/or learning the therapy while the group who reported previous catheter use was experienced CIC users.

Interpretation of results
Although it is recognized that not one single catheter option would suit every patient, the general compliance to and satisfaction of the new catheter was high and it seems to be a useful addition among hydrophilic coated catheters. Patients acknowledged the use of the hygienic insertion grip that could facilitate non-touch catheterization and 81% found it easy to use.

Concluding message
The results confirm previous reports that describe patient preferred catheter features to be convenience (e.g. portability and ready to use), ease of use and hygienic factors and that these may increase compliance to the therapy and potentially decrease complications.

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Disclosures
Funding: LoFric Origo®(Wellspect HealthCare, DENTSPLY IH AB, Sweden **Clinical Trial:** Yes **Registration Number:** Clinicaltrials.gov identifier = NCT01796587 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Commissie Medische Ethiek Van Se Universitaire ziekenHuizen Kuleuven, Leuven, Belgium Commission cantonale valasanne d'ethique médicale, Sion, Switzerland Ethikkommission des Kantons Luzern, Luzern, Switzerland Commissie Mensgebonden Onderzoek, Nijmegen, Netherlands Toetsingscommissie Patiëntgebonden onderzoek, Gorinchem, Netherlands Regionale komiteer for medisinsk og helsefaglig forskningsetikk, Oslo, Norway NRES Committee London – City & East, Bristol, UK (No approval required) **Helsinki:** Yes **Informed Consent:** Yes