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Pemberton P[1], Brooks A[2], Eriksen C M[3], Frost S[3], Graham S[4], Greenman L[5], Hannigan H[4], Looms D[3], Moran S[6], Ollerhead D[7], Shaw J[8], Williams D[6]
1. Warrington PCT, 2. Canterbury and Coastal PCT, 3. Coloplast A/S, 4. Solihull PCT, 5. Halifax PCT, 6. North Liverpool PCT, 7. Bebington and West Wirral PCT, 8. Rugby PCT

A COMPARATIVE STUDY OF TWO TYPES OF URINARY SHEATH: A RANDOMISED, PROSPECTIVE, CROSSOVER CLINICAL STUDY

Hypothesis / aims of study
To compare the new Conveen Optima urinary sheath with the established Clear Advantage urinary sheath with regard to patient satisfaction and preference. The primary endpoint was urinary sheath product preference, and secondary endpoints were handling, application, comfort, leakage and skin reactions.

Study design, materials and methods
This randomised, prospective, open, crossover study at seven centres in the UK included males at least 18 years of age and using at least one one-piece urinary sheath a day. Exclusion criteria were mental health problems and participation in other clinical studies. Each participant tested 10 urinary sheaths of each product Conveen Optima (Coloplast A/S, Denmark) and Clear Advantage (Mentor, U.S.A.). Participants were randomised according to a block randomisation list.

In order to calculate a 95% confidence interval for the expected preference for each product of 50% and an estimated error of 15% the number of subjects needed was 43, thus, it was planned to include 50 patients to compensate for dropouts.

Data regarding demographics and nurse/helper evaluation was reported descriptively. 95% confidence intervals were calculated for the product preference results. Secondary parameters were analysed using the Wilcoxon test and the Sign test where appropriate (SPSS version 11.5 for Windows) with a significance level of 5%.

Results
Of the 53 men included in the study, 44 fulfilled the evaluability criteria and were included in the analyses.

Eighty-one percent of the participants reported having a preference and of these 67% (95% confidence interval 52% to 82%) preferred the Conveen Optima urinary sheath, whereas 33% (95% confidence interval 18% to 48%) preferred the Clear Advantage urinary sheath.

The participants found both the opening and the removal of the sheath from the individual packaging significantly easier for Conveen Optima than for Clear Advantage. Fewer participants experienced wrinkles or bubbles when applying the Conveen Optima urinary sheath and more patients felt safe immediately after application of the Conveen Optima urinary sheath. The participants of the study felt that the Conveen Optima urinary sheath was more comfortable to wear. In addition, more participants found that the drainage from the sheath into the urine bag was satisfactory and that the individual packaging of the Conveen Optima urinary sheath enabled them to easily carry it around with them. Furthermore, significantly more participants found both connection and subsequent disconnection of the sheath from the urine bag easier with the Conveen Optima product. These results are summarised in Table 1.

Participants rated their feeling of security significantly higher on an eleven-point scale (0=very insecure, 10=very secure) when using the Conveen Optima urinary sheath (P=0.029, Wilcoxon test). Where nurses applied the urinary sheaths, more nurses found the Conveen Optima urinary sheath easy to apply when wearing gloves. With regard to all the other questions asked, there was no statistically significant difference between the Conveen Optima and the Clear Advantage urinary sheaths.

Interpretation of results
This study shows that the Conveen Optima urinary sheath provides a higher feeling of security. Furthermore, the Conveen Optima sheath was found to be easier to handle and apply in some of the aspects studied and importantly, it was found to be at least as user-friendly as the Clear Advantage sheath in all the other aspects studied.

With regard to the primary endpoint of product preference, the study showed that 67% preferred the Conveen Optima urinary sheath over Clear Advantage, which was previously shown to perform significantly better than other self-adhesive urinary sheaths on the UK market at that time [1]. 60% of the participants were already using the Clear Advantage urinary sheath before entering the study and must therefore be expected to favour Clear Advantage. It is interesting to note that such a large proportion preferred the Conveen Optima urinary sheath. This large preference may be due to the improved feeling of security, the improved comfort and improved packaging of the product.

Concluding message
This is one of the first randomised clinical trials aimed at providing evidence for healthcare professionals in order to assist them and their patients in making informed choices concerning a urinary sheath product. The study shows that the newly developed Conveen Optima urinary sheath provides a higher feeling of security than the well-established product, Clear Advantage. Furthermore, Conveen Optima was found to be easier to handle and apply as well as more comfortable to wear. Finally, the overall product preference for Conveen Optima was 67%, indicating that it is more acceptable than the well-established product.

Table 1. Issues were stated as questions and answered on the following scale: 1 strongly disagree; 2 disagree; 3 neither agree or disagree; 4 agree; 5 strongly agree. The differences between the products were all statistically significant at 5% (Wilcoxon test).

Parameter	**Issues**	**Clear Advantage**	**Conveen Optima**	***P* value**
Application	Ease of opening individual packaging	3.30	4.32	<0.001
	Ease of removal from individual packaging	3.66	4.39	<0.001
	No wrinkles/bubbles on sheath when applied	3.57	3.86	0.036
	Confidence when wearing the sheath	3.36	3.69	0.043
Overall wear	Comfortable to wear	3.79	4.02	0.018
	Drainage of urine into bag during use	3.89	4.14	0.033
Connection to urine bag	Ease of connecting sheath to urine bag	3.80	4.14	0.018
	Ease of disconnection of urine bag from sheath	3.82	4.32	<0.001
Packaging	Ease of carrying sheath around	3.21	4.30	<0.001

References
1. BJU Int (2001), 87: 367-372.

FUNDING: Study funded by Coloplast A/S, Denmark
DISCLOSURES: Three of the twelve authors are employees of Coloplast A/S
CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the Sefton Local Research Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.