# BIOFILM PREVENTION BY SURFACE ACOUSTIC NANOWAVES: A NEW APPROACH TO URINARY TRACT INFECTIONS?

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## INTRODUCTION AND OBJECTIVE

Catheter associated urinary tract infection (CAUTI) is a major cause of morbidity and mortality in hospitalized patients. The longer the catheter remains in place, the greater the tendency of certain organisms to develop biofilms, resulting in CAUTI's and antibiotic resistance. (Fig 1) We used a new device that is clipped onto the urinary catheter and that is designed to prevent biofilm by creating low-energy acoustic nanowaves on the inner and outer surfaces of the indwelling urinary catheter (UroShield™, NanoVibronix Inc., Cedarhurst, N.Y.) (Figs 2 & 3). After performing in-vitro and animal studies, we undertook the first clinical study of UroShield.

## MATERIAL AND METHODS

Between October 2005 and January 2006 we performed a double blind sham controlled randomized study which included 22 patients with various urologic cancers (prostate: n=16, kidney: n=4, other: n=2). (See Table 1). Average catheterization was necessary for 9+/-2 days (range: 5-13 days). At termination of the study, the urinary catheters were fixed in formaldehyde and examined by scanning electron microscopy (SEM) analysis.

## RESULTS

SEM analysis of the catheters revealed that there was no biofilm formation in the group of patients, which were treated with UroShield, compared to the sham-group in which 7 catheters had biofilm (See Table 2). No statistical significance was found with respect to bacteriuria. The UroShield proved to be safe and well tolerated with no difference in reported adverse events between the 2 groups.

## CONCLUSIONS

After performing successful animal studies, the first clinical study showed that biofilm formation can be prevented or delayed by applying low energy nanowaves along the surfaces of an indwelling catheter. This approach opens new options for prevention and/or non-antibiotic treatment of urinary tract infections. In addition, UroShield is being studied in the area of enhanced in-vitro penetration of antibiotics into the biofilm structure. There is also ongoing research on the ability of UroShield to reduce pain and discomfort associated with indwelling urinary catheters.

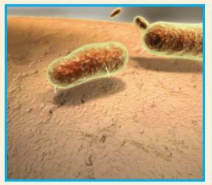


**Figure 1:** Illustration of bacterial attachment to catheter surface

**Figure 2:** UroShield from NanoVibronix

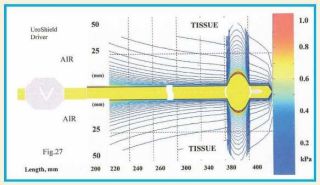


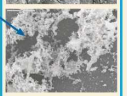

**Figure 3:** Acoustic pressure distribution on urinary catheter surfaces when Uroshield is applied

**Table 1:** Primary Reason for Hospitalization

| Reason | Control Group (N=11) | | Active Group (N+11) | |
|---|---|---|---|---|
| | N | % | N | % |
| Prostate Cancer | 9 | 81% | 7 | 64% |
| Kidney Cancer | 1 | 9% | 3 | 27% |
| Kidney Cyst | 0 | 1% | 1 | 9% |
| Tumor of Penis | 1 | 9% | 0 | 0% |
| **TOTAL** | **11** | **100** | **11** | **100%** |

**Table 2:** SEM analysis of the catheters revealed that no biofilm formed on catheters which were treated with UroShield, compared to the control group in which 7 catheters had biofilm

| Treated group | Pt# | Presence of biofilm | SEM examples (mag x 3500) |
|---|---|---|---|
| N = 11 | 3 | - |  |
| | 4 | - | |
| | 5 | - | |
| | 6 | - | |
| | 10 | - |  |
| | 12 | - | |
| | 13 | - | |
| | 15 | - | |
| | 17 | - | |
| | 20 | - | |
| | 22 | - | |
| Total biofilm presence | | N=0 | |

| Control group | Pt# | Presence of biofilm | SEM examples (mag x 3500) |
|---|---|---|---|
| N = 11 | 1 | X |  |
| | 2 | X | |
| | 7 | - | |
| | 8 | - | |
| | 9 | X |  |
| | 11 | - | |
| | 14 | - | |
| | 16 | X | |
| | 18 | X | |
| | 19 | X | |
| | 21 | X | |
| Total biofilm presence | | N=7 | |