Table 1

Sociodemographic Variables

Table 2 Number and percentage of subjects with failure for each device

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Failure – usage phase** | | | | | |
| **ProVate (N=58)** | | **Control (N=58)** | | **95% Confidence Interval** | **P-value** |
|  | Subjects | % | Subjects | % |
| **Failure** | 9 | 15.5 | 9 | 15.5 | -13% : 13% | >0.999 |

Table 3 – Results of reported microflora growth endpoints

|  |  |  |
| --- | --- | --- |
| **Failure criteria** | **Usage Period** | |
| **ProVate (n,% )** | **Control (n,% )** |
| Patients with a >1 unit scale change (increase or decrease) from baseline to end of usage phase in any studied microorganism | 26 (44.8%) | 21 (36.2%) |
| Patients with Nugent score ≥ 7 following device usage | 4 (6.9%) | 2 (3.4%) |
| Patients with a >1 scale unit increase following device usage in *Staphylococcus aureus* | 2 (3.4%) | 3 (5.2%) |
| Patients with a >1 scale unit increase following device usage in *Candida* morphotype | 3 (5.2%) | 2 (3.4%) |
| Patients with vaginal symptoms that are bothersome | 0 (0.0%) | 2 (3.4%) |
| Patients with vaginal symptoms related to vaginal infection that require treatment | 0 (0.0%) | 1 (1.7%) |
| **Patients with a conclusion of vaginal infection (i.e. physician reported an overall conclusion of vaginal infection)** | 0 (0.0%) | 2 (3.4%) |