

SUMMARY OF HISTOFREEZER® CLINICAL TRIAL RESULTS ACTINIC KERATOSES AND LENTIGO

OBJECTIVE:

This study was convened to determine the clinical efficacy of the Histofreezer® treatment of Actinic Keratoses and Lentigo.

SUBJECTS:

For each of the 2 indications, a panel of at least 25 healthy adults over 50 years of age were enrolled into the testing program. Participating panelists had to exhibit at least one discernible external Actinic Keratoses and/or Lentigo.

STUDY DESIGN:

The panelists were treated with the Histofreezer® as per the package inserts instructions. Panelists were instructed to return to the office every other week or at the point of complete healing of the treated area, which ever came first, for a maximum of 4 treatments (8 weeks).

Type of Wart	Recommended Freezing Time
Actinic Keratoses	Facial 15 second treatment Non-Facial 40 second treatment
Lentigo	Facial 15 second treatment Non-Facial 40 second treatment

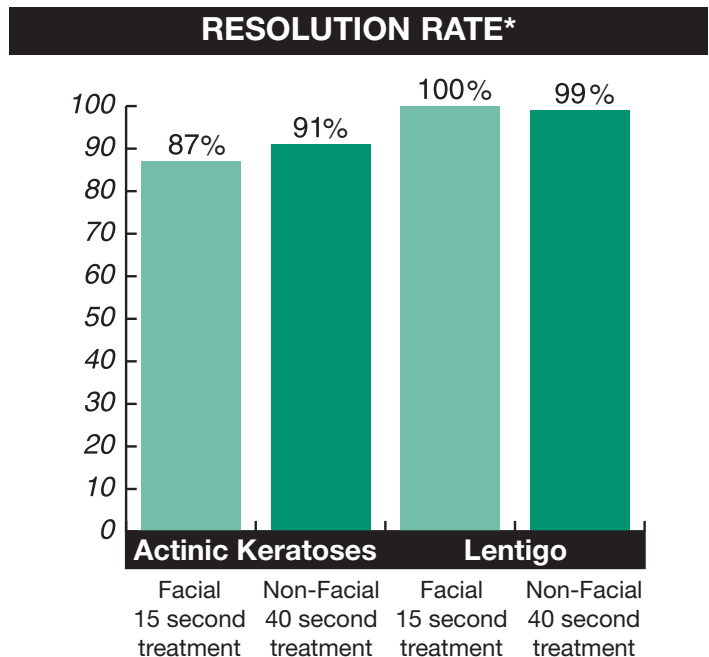
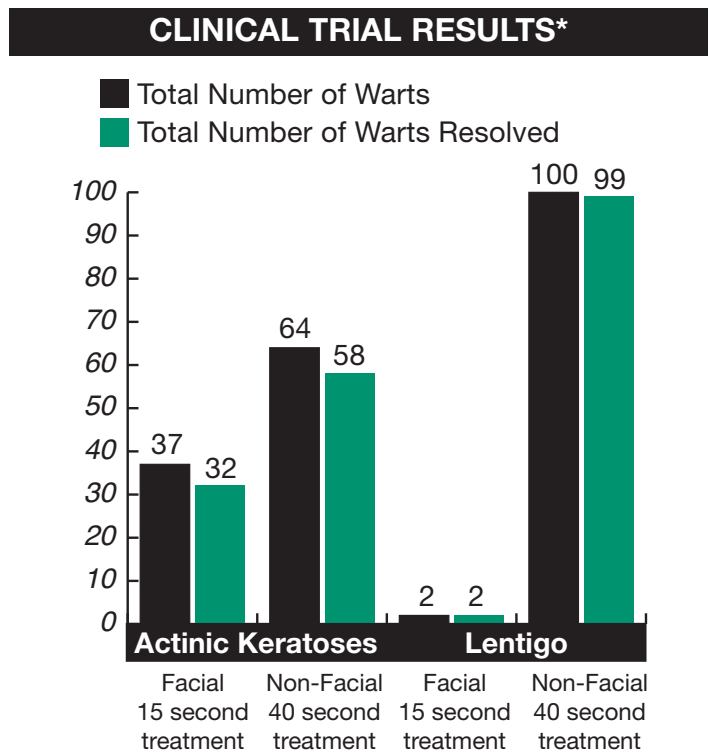
Prior to each treatment, the sites will be examined by the principal investigator to determine whether the Actinic Keratoses or Lentigo lesions had been removed. At the end of the 4 treatments, a pass/fail system of grading was employed.

A passing score was constituted as those Actinic Keratoses or Lentigo lesions that were successfully removed by the cryogenic surgical procedure within the allotted time period. A fail score was assigned to those sites still intact at the conclusion of the study. In the event of Actinic Keratoses or Lentigo being cleared from the site prior to completing 4 treatments, the subject was released from the study with no further treatment.

OBSERVATIONS:

No adverse reactions were observed.

RESULTS:



CONCLUSION:

As shown above, the Histofreezer was effective in the treatment of both Actinic Keratoses and Lentigo. The Resolution rates of 87, 91, 100 and 99% resolving the lesions.

* Study on AK & Lentigo, Claire Mills, R.N., Sonora Women's Clinic, 1999