**Objective**

SynAgile has developed the DopaFuse Delivery System to noninvasively and continuously administer oral levodopa and carbidopa (LD/CD) into the mouths of patients with Parkinson’s Disease (PD). The system is intended to reduce fluctuation in plasma levodopa levels and the associated motor symptoms. The objective of this study is to evaluate the laboratory performance of the DopaFuse Delivery System.

**Background**

DopaFuse is the first of a new class of drug delivery devices that reside in the mouth and that non-invasively deliver drugs at a constant rate for four hours. The first timepoint is slightly lower due to the time it takes to prime the delivery tube. The average flow rate was 65 mg/LD/hr for 4 hours. Currently, the only FDA-approved method for continuous levodopa delivery is a levodopa-carbidopa intestinal (LD/CD) capsule (Sinemet® 25/100®). This study shows that the DopaFuse Delivery System should be able to provide non-invasive, continuous levodopa without the need for surgical implantation of a pump. DopaFuse products with multiple flow rates are under development to meet the needs of patients who require different dose rates. A Phase 2 pharmacokinetic study of the DopaFuse Delivery System is expected to begin in 2020.

**How it Works**

The DopaFuse® Delivery System is an ordinary retainer. Retainers are custom made for each patient using standard, commercially-available, thermofom retainer materials and molding processes used in dentistry.

The DopaFuse® Delivery System’s proprietary drug container, shown in Figures 1-3.

**Methods**

A study of 21 containers was conducted to assess flow rate variability. To test the flow, the delivery tube plug is removed and the paste begins to flow. The weight of the delivered paste is measured hourly. It takes a few minutes for the tube to fill with paste before the paste exits the delivery tube.

**Results**

The results show that after an initial ramp up period, the DopaFuse Paste is delivered at a constant rate over four hours. The first timepoint is slightly lower due to the time it takes to prime the delivery tube. The average flow rate was 64.7 mg/LD/hr for 4 hours.

**Discussion**

The study demonstrates that the DopaFuse container is able to deliver drug at a consistent flow rate for four hours. The average flow rate was 65 mg/LD/hr for 4 hours.

Currently, the only FDA-approved method for continuous levodopa delivery is a levodopa-carbidopa intestinal (LD/CD) capsule (Sinemet® 25/100®). This study shows that the DopaFuse Delivery System should be able to provide non-invasive, continuous levodopa without the need for surgical implantation of a pump. DopaFuse products with multiple flow rates are under development to meet the needs of patients who require different dose rates. A Phase 2 pharmacokinetic study of the DopaFuse Delivery System is expected to begin in 2020.

**FAQs**

Do you taste the drug?

Levodopa and carbidopa have no taste. Most other drugs would be infused so slowly that the user would not be able to perceive any taste.

How long can one drug container last?

It depends on the daily drug dose. For high dose drugs such as levodopa, the drug container should be changed 2-3 times per day. For low dose drugs, one drug container could last up to several weeks.

Can patients sleep with DopaFuse?

DopaFuse is designed to be safe for both daytime and nighttime use.

Is the DopaFuse system comfortable?

The DopaFuse system is similar to an ordinary retainer. Retainers are custom made for each patient. Patients will go through a fitting and adjustment with their dentist to ensure comfort.

Can patients eat or drink with DopaFuse?

DopaFuse should be removed for eating. Patients may drink liquids and swallow pills while wearing DopaFuse. Sugary drinks should be avoided while wearing the System.

How do you maintain the System?

The retainer should be cleaned daily with a toothbrush and toothpaste. The case should be cleaned daily with water and a soft cloth.

Is the System visible to others?

The system is designed to be invisible to others.

**References**