

Iontophoresis Patch Comparison: Short and Long Treatment Duration 80 mAmp*min Devices

Michael Johnson M.D.

Self-contained iontophoresis patches deliver a calibrated charge over a predetermined treatment period. The dosage of drug ions driven into the skin is directly proportional to the charge delivered. The charge dosage is calculated as mAmp*min. Four brands of iontophoresis patches were compared in terms of the delivered electrical dosage.

- ActivaTek *IontoGo 4.0* is a wearable patch designed to output an average 80 mAmp*min dosage over a 4-hour treatment period. This patch has a starting voltage of 6 Volts.
- ActivaTek *IontoGo 12.0* is a wearable patch designed to output an average 80 mAmp*min dosage for a 12-hour treatment period. The patch has a starting voltage of 3.0 Volts.
- Travanti *IontoPatch 80* is a wearable patch designed to output an average 80 mAmp*min nominal dosage over a 14-hour treatment period. The patch has starting voltage of 1.0 Volt.
- Travanti *IontoPatch STAT* is a wearable patch designed to output an average 80 mAmp*min nominal dosage over a treatment period of 4 hours. The patch has a starting voltage of 4.0 Volts.

Each of these iontophoresis patches are labeled to deliver an average 80 mAmp*min dosage over a treatment period detailed in the instructions for use. The iontophoresis patches can be classified as short treatment duration and long treatment duration devices. The *IontoGo 4.0* and *IontoPatch STAT* are examples of short 4 hour treatment time devices. The *IontoPatch 80* and *IontoGo 12.0* are examples of long 12 to 14 hour treatment time devices.

The accuracy and repeatability of dose delivery is compared for short and long treatment time iontophoresis patches. The actual dose delivered was measured and compared for these four brand of iontophoresis patches. These iontophoresis patches were evaluated using an industry standard testing protocol¹. A sample of 38 patches were tested for each type of device. All patches were sampled from at least two lots. Average skin resistance was approximated as 10 kOhm.

Results

The time course of accumulated electrical dosage (mAmp*min) was measured for each of the iontophoresis patches in Figure 1. Each of the 38 traces represents one tested sample.

The dosage time course for the ActivaTek *IontoGo 4.0* is shown in the upper right graph. This patch was designed to deliver an average 80 mAmp*min in 4 hours. All patches approached the specified 80 mAmp*min dosage in 4 hours. The mean dosage at 4 hours was 63 mAmp*min (see Table 1).

The ActivaTek *IontoGo12.0* is showing the upper left. This patch approached the specified 80 mAmp*min dosage in 12 hours. The mean dosage was 64.7 mAmp*min.

The *IontoPatch 80* is graphed in the lower left. The *IontoPatch* is specified to deliver 80 mAmp*min in 14 hours. In this accumulated electrical dosage plot, the average total dosage delivered was 42.5 mAmp*min, far less than the advertised average 80 mAmp*min.

The *IontoPatch STAT* is the lower right graph. This is a 4 hour, 80 mAmp*min patch. The average total dosage delivered was 57.8 mAmp*min.

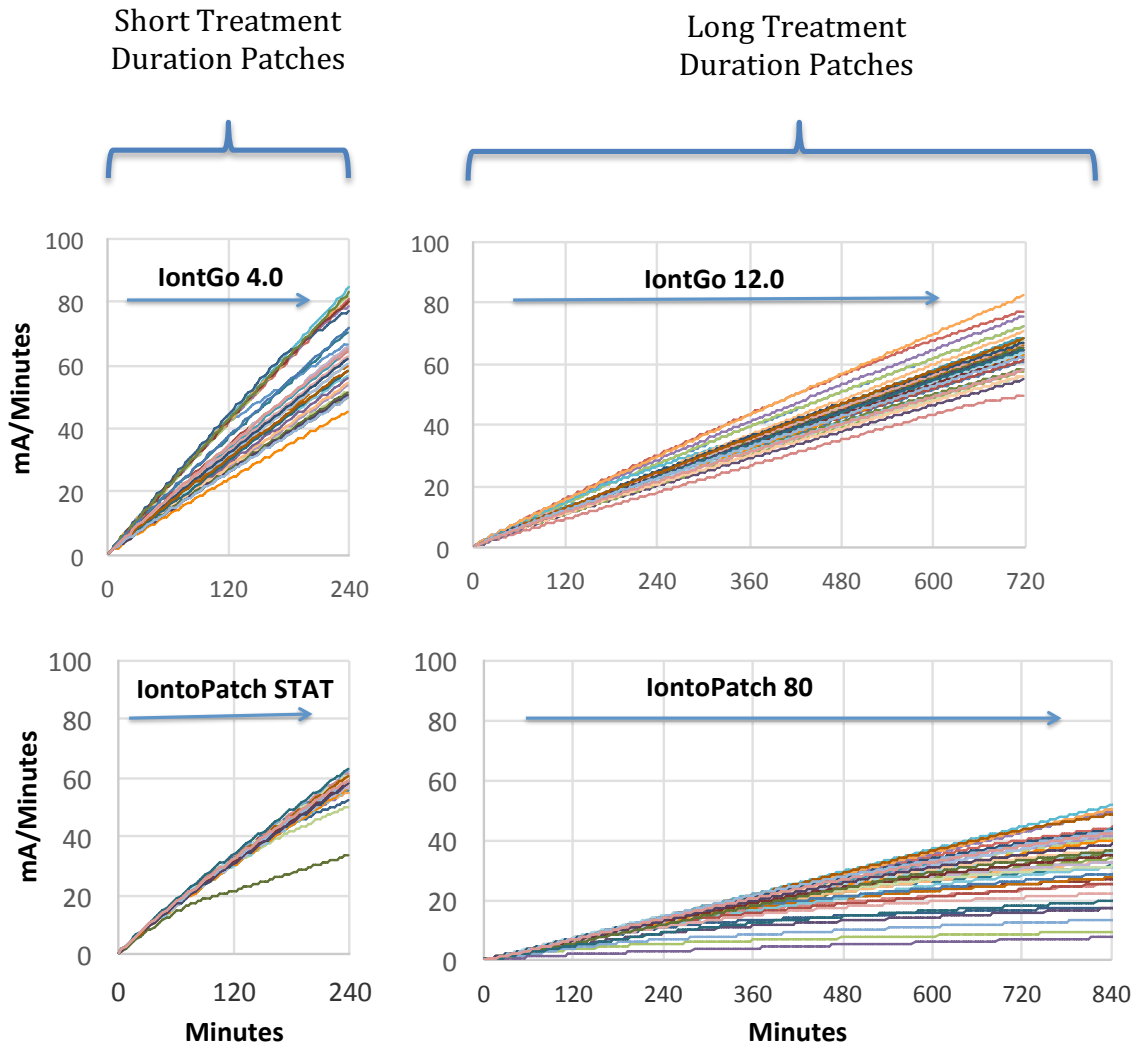


Figure 1: Long and Short Treatment Duration Average 80 mAmp*min iontophoresis patches compared. The dosage time course for the IontoGo 4.0, IontoGo 12.0, IontoPatch STAT and IontoPatch 80 are shown. Each of the 38 traces for each type of patch are shown. Horizontal axis is time in minutes. Vertical axis is dosage in mAmp*min. Arrow represents specified dosage.

Patch	Treatment Duration	Dosage Specification	Mean Dosage	Range Dosage
IontoGo 4.0	4 hours	80 mAmp*min	63.4	45.7-84.7
IontoGo 12.0	12 hours	80 mAmp*min	64.7	49.8-82.5
IontoPatch80	14 hours	80 mAmp*min	33.7	7.4-51.5
IontoPatch STAT	4 hours	80 mAmp*min	57.8	33.6-63.4

Table 1: Specified and measured dosage for four iontophoresis patches.

Conclusions

Differences in average dosage were observed across the four tested iontophoresis patches. Both short and long treatment duration patches could deliver the specified average 80 mAmp*min dosage. However, average dosage differences were most marked as a function of manufacturer.

- The *IontoGo 4.0* iontophoresis patch was specified to be worn for 4 hours and deliver an average dose of 80 mAmp*min. The sample of devices reached **79%** of the specified dosage in 4 hours.
- The *IontoGo 12.0* patch was specified for a 12-hour treatment period and an average charge delivery dose of 80 mAmp*min. The sampled devices delivered **81%** of the specified dosage in 12 hours.
- The *IontoPatch 80* was specified for a 14-hour treatment time and a delivered dose of 80 mAmp*min. It demonstrated increased variability with the outlier underperformance appearing to be due to battery failures. The average dose delivered was **42%** of the specified average 80 mAmp*min.
- The *IontoPatch STAT* was specified for a 4-hour treatment time and a delivered dose of 80 mAmp*min. At the end of the 4-hour treatment period, the dosage delivered was **72%** of specification.

Iontophoresis patches are used on human skin which is known to have a highly variable impedance, both between subjects and over time. Subjects with very low skin impedance will receive a higher dose. The ActivaTek *IontoGo* (4.0 and 12.0) electrodes present a balanced approach to the variability of skin impedance. Both *IontoGo* electrodes undershoot the nominal dosage by approximately 20%. This provides a safety factor for patients with low skin impedance. Conversely, the Travanti *IontoPatch* (80 and STAT) electrodes are heavily biased to under-deliver the dosage. They under-deliver by 30 to 60%.

Practitioners of iontophoresis therapy should keep in mind that the dosage of drug they think they are delivering may be under-delivered by some types of iontophoresis patches. Some brands of patches deliver less than half of the specified dosage.

1. Methods: The test system has been used for FDA dosage validation and is the basis for 510k performance testing for the last two decades. Two silver plates (2" x 2", 99.9% pure) were connected by a 10 kOhm resistor. Iontophoresis patches were placed so that positive and negative electrodes were separated on hydrated Delstar hydropolymer, adherent to each of the silver plates. The iontophoresis patches were hydrated with a 0.9% saline solution according to supplied instructions. The delivery electrode was filled with the prescribed amount of Dexamethasone Sodium Phosphate (4mg/ml). A digital data logger (Agilent 34970A) was used to measure voltage and current every minute.

2. Footnotes:

ActivaPatch® is a registered trademark of ActivaTek Inc.

IontoGo™ is a trademark of ActivaTek Inc.

IontoPatch® is a registered trademark of Travanti Pharma Inc.