FIGURE 1A

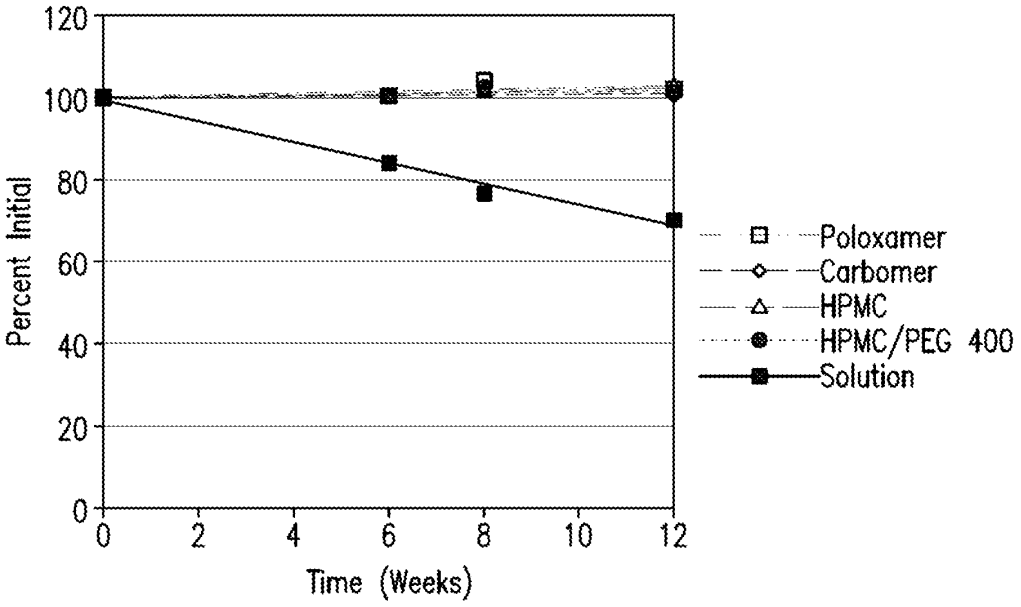
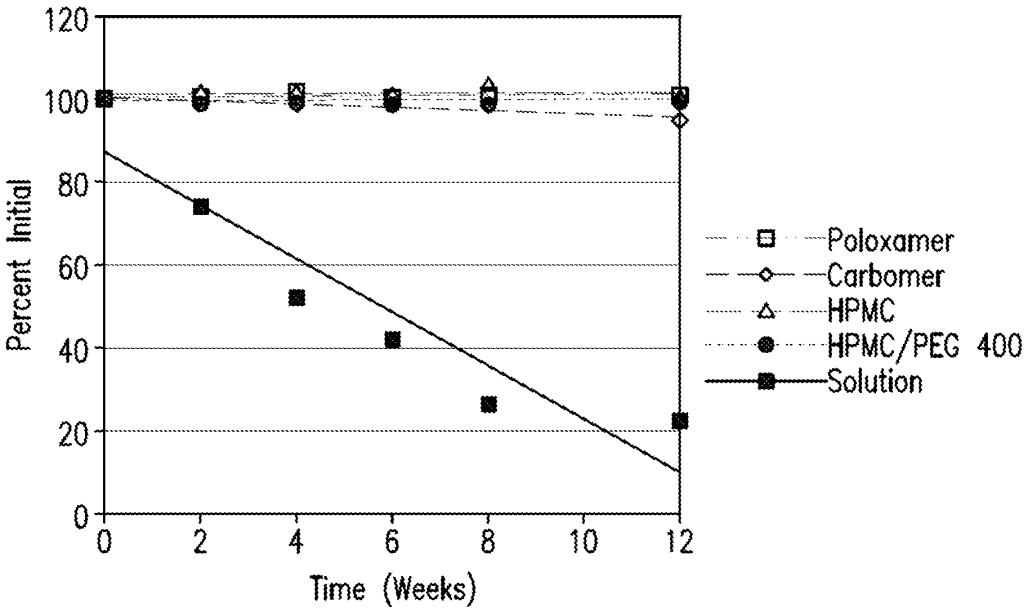


FIGURE 1B



5

FIGURE 2

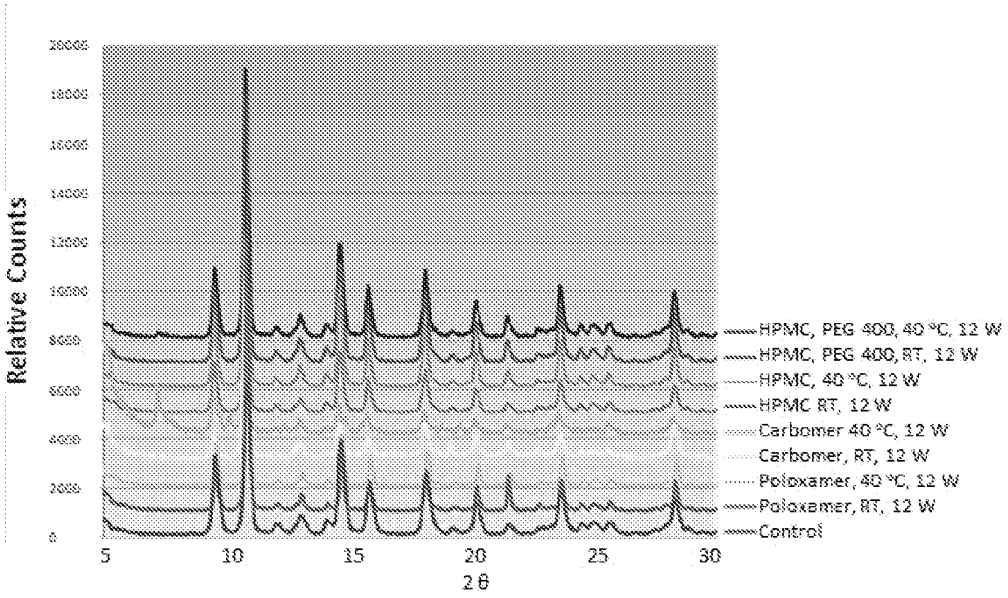

Relative Counts
5
10
15
20
25
30
2θ
HPMC, PEG 400, 40 °C, 12 W
HPMC, PEG 400, RT, 12 W
HPMC, 40 °C, 12 W
HPMC RT, 12 W
Carbomer 40 °C, 12 W
Carbomer, RT, 12 W
Poloxamer, 40 °C, 12 W
Poloxamer, RT, 12 W
Control

FIGURE 3

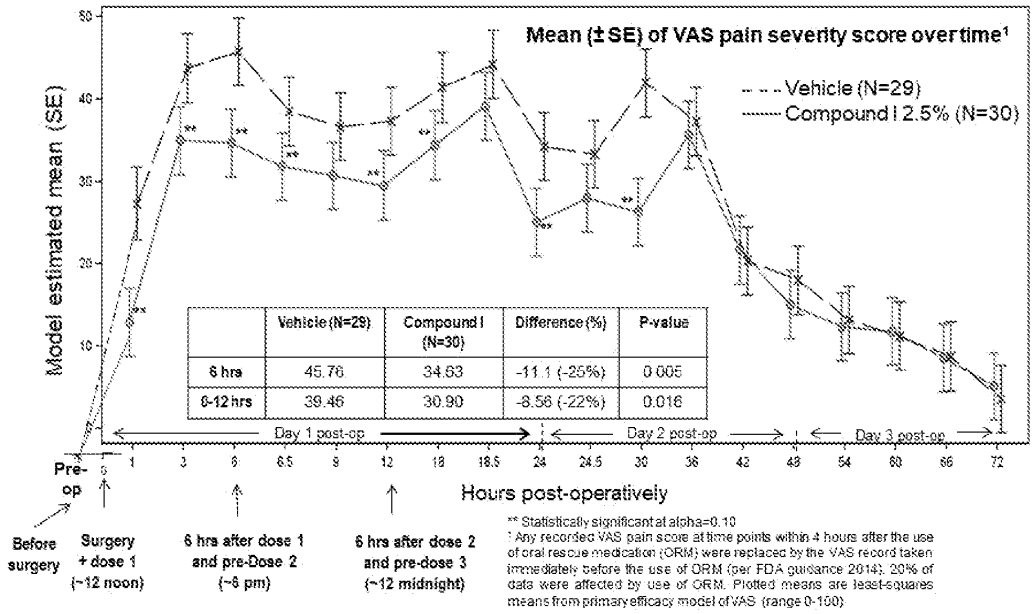

Mean (±SE) of VAS pain severity score over time¹
Vehicle (N=29)
Compound I 2.5% (N=30)
Model estimated mean (SE)
Vehicle (N=29)
Compound I (N=30)
Difference (%)
P-value
6 hrs
45.76
34.83
-11.1 (-25%)
0.005
6-12 hrs
39.46
30.90
-8.56 (-22%)
0.016
Day 1 post-op
Day 2 post-op
Day 3 post-op
Pre-op
Hours post-operatively
Before surgery
Surgery + dose 1 (~12 noon)
6 hrs after dose 1 and pre-Dose 2 (~6 pm)
6 hrs after dose 2 and pre-dose 3 (~12 midnight)
** Statistically significant at alpha=0.10
¹ Any recorded VAS pain score at time points within 4 hours after the use of oral rescue medication (ORM) were replaced by the VAS record taken immediately before the use of ORM (per FDA guidance 2014). 20% of data were affected by use of ORM. Plotted means are least-squares means from primary efficacy model of VAS (range 0-100)

FIGURE 4

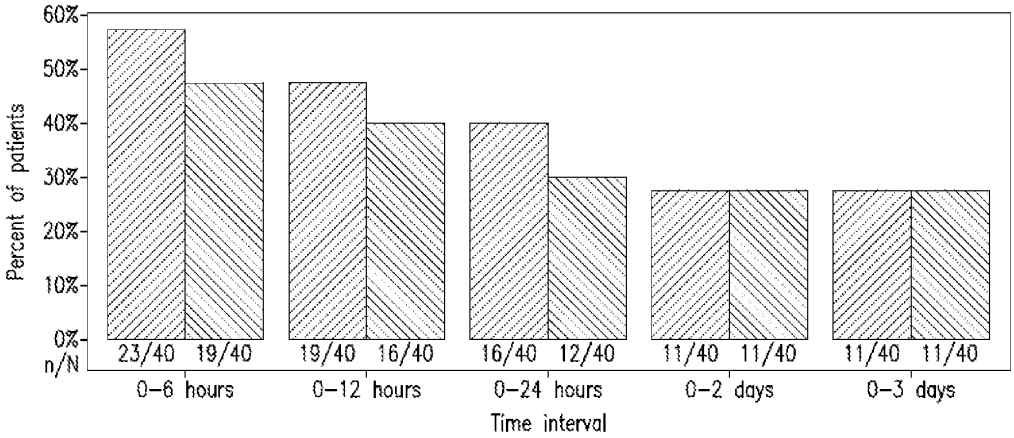

60%
50%
40%
30%
20%
10%
0%
Percent of patients
n/N
23/40 19/40
19/40 16/40
16/40 12/40
11/40 11/40
11/40 11/40
0–6 hours
0–12 hours
0–24 hours
0–2 days
0–3 days
Time interval

FIGURE 5A

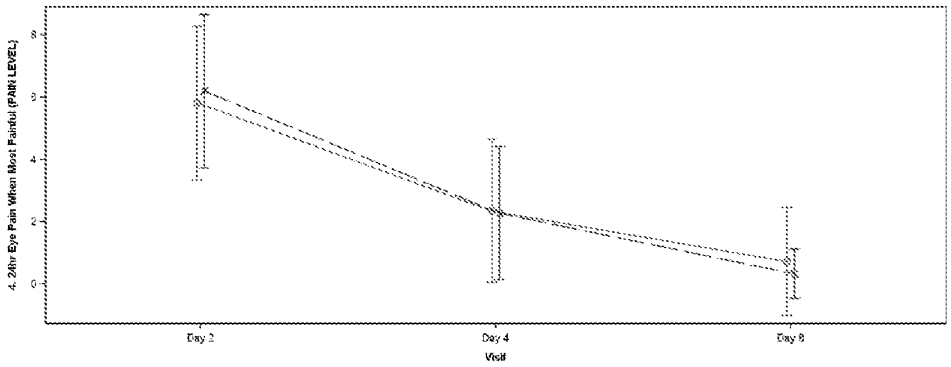


FIGURE 5B

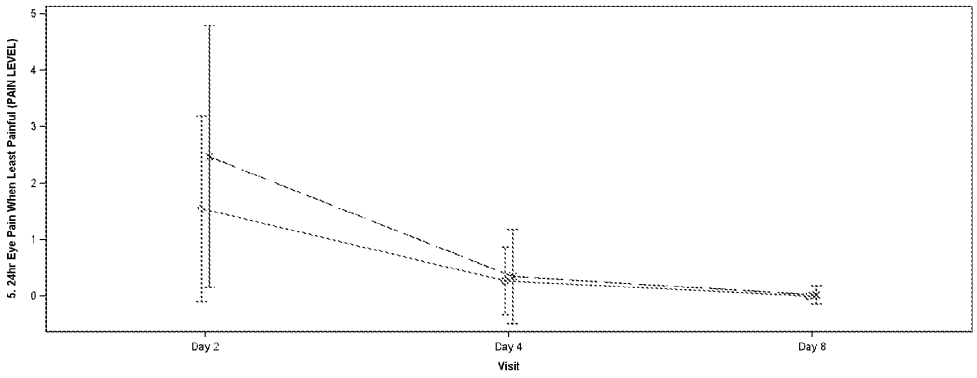


FIGURE 5C

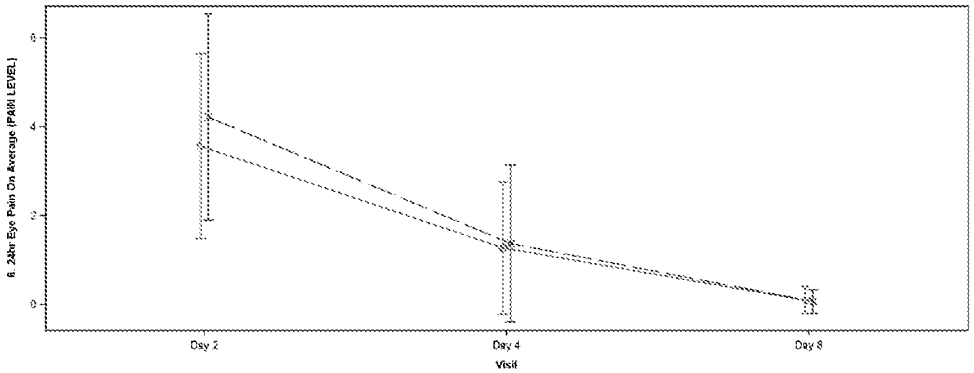


FIGURE 6A

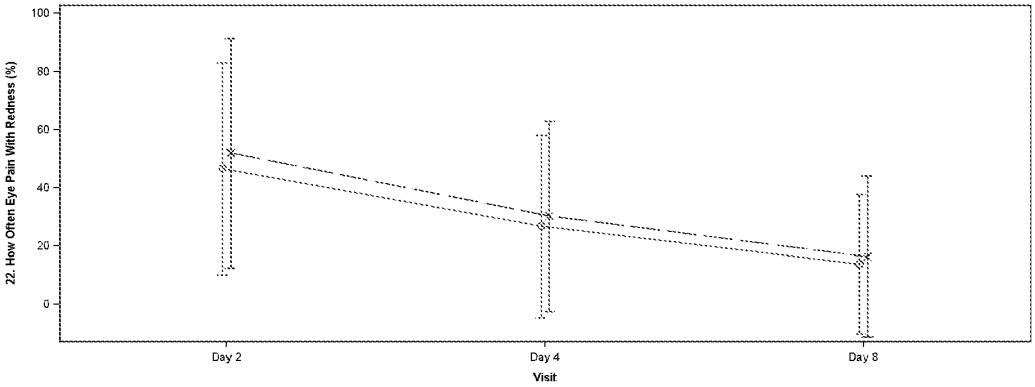


FIGURE 6B

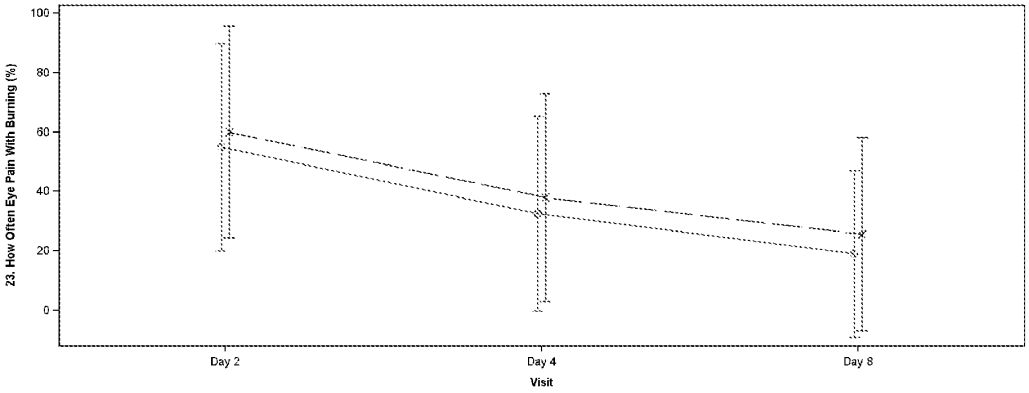


FIGURE 6C

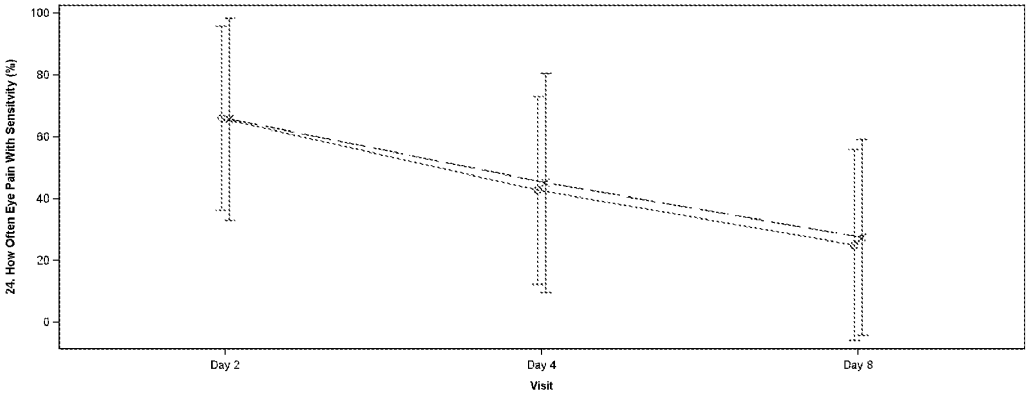


FIGURE 6D

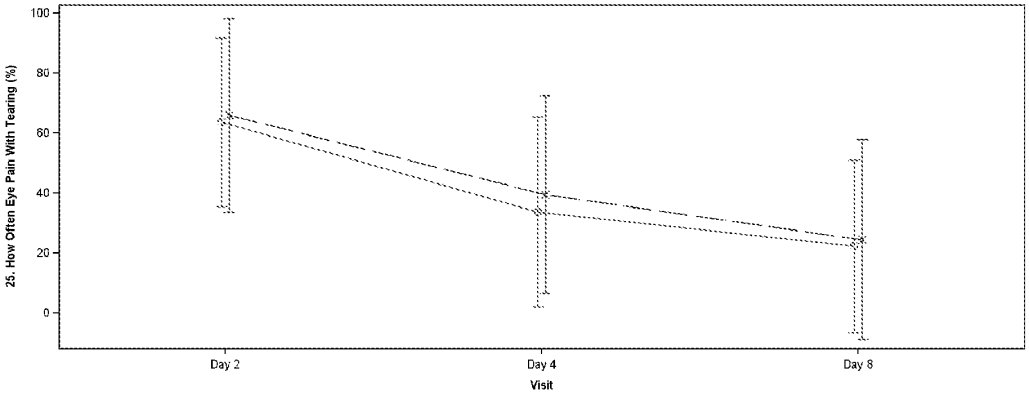


FIGURE 7A

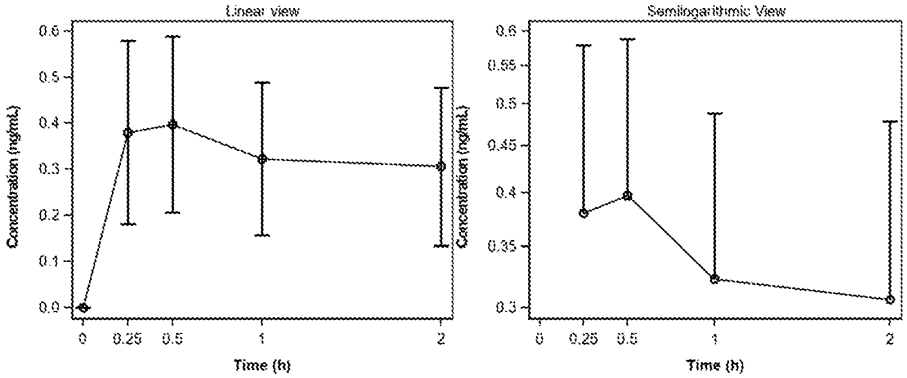
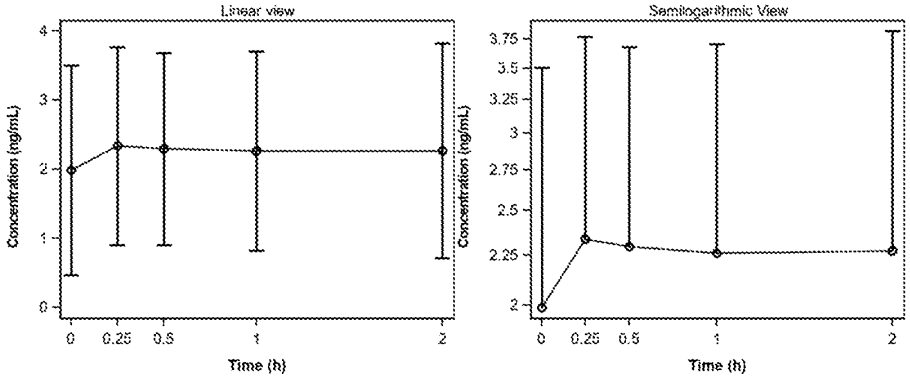
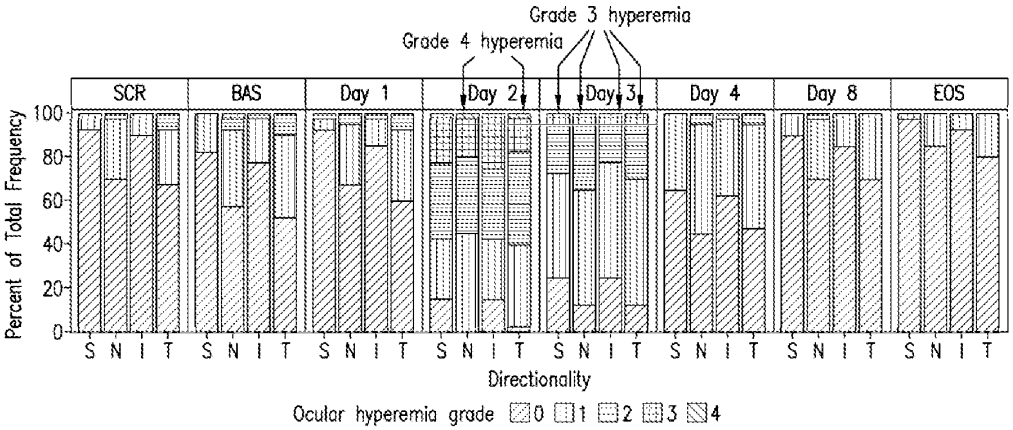


FIGURE 7B



5

FIGURE 8A



5

FIGURE 8B

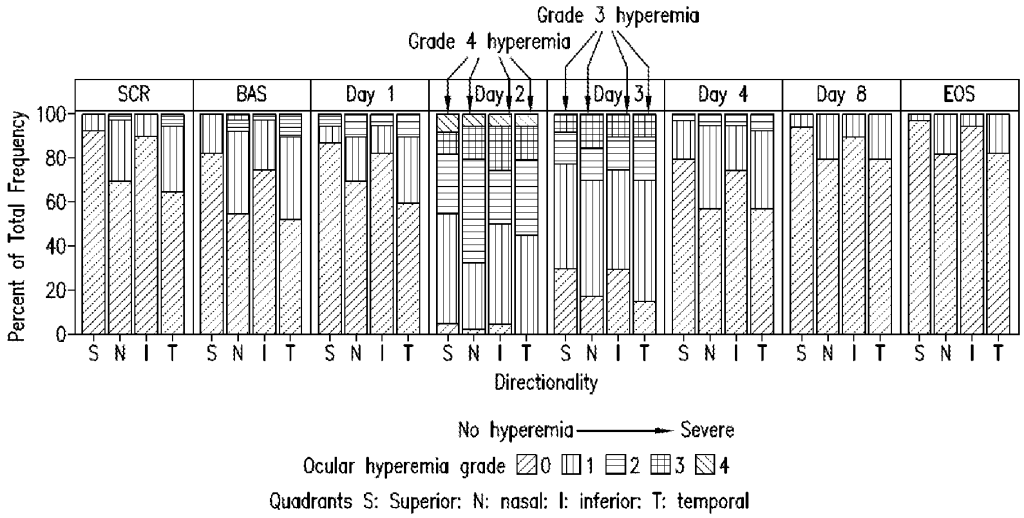


FIGURE 9

