**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of post-procedural complications)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 84 58.74 92.31 63.64 | 7 4.90 7.69 63.64 | 91 63.64 |
| **FRED X** | 48 33.57 92.31 36.36 | 4 2.80 7.69 36.36 | 52 36.36 |
| **Total** | 132 92.31 | 11 7.69 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0000 | 1.0000 |
| **Test du rapport de vraisemblance** | 1 | 0.0000 | 1.0000 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0000 | 1.0000 |
| **Coefficient Phi** |  | 0.0000 |  |
| **Coefficient de contingence** |  | 0.0000 |  |
| **V de Cramer** |  | 0.0000 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 84 |
| **Pr <= F unilatérale à gauche** | 0.6358 |
| **Pr >= F unilatérale à droite** | 0.6179 |
|  |  |
| **Probabilité de la table (P)** | 0.2538 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPOTH** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPOTH(Occurrence of Other complication)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 86 60.14 94.51 64.18 | 5 3.50 5.49 55.56 | 91 63.64 |
| **FRED X** | 48 33.57 92.31 35.82 | 4 2.80 7.69 44.44 | 52 36.36 |
| **Total** | 134 93.71 | 9 6.29 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPOTH*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.2710 | 0.6026 |
| **Test du rapport de vraisemblance** | 1 | 0.2644 | 0.6071 |
| **Khi-2 continuité ajustée** | 1 | 0.0265 | 0.8708 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.2691 | 0.6039 |
| **Coefficient Phi** |  | 0.0435 |  |
| **Coefficient de contingence** |  | 0.0435 |  |
| **V de Cramer** |  | 0.0435 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 86 |
| **Pr <= F unilatérale à gauche** | 0.8116 |
| **Pr >= F unilatérale à droite** | 0.4246 |
|  |  |
| **Probabilité de la table (P)** | 0.2362 |
| **Pr <= P bilatéral** | 0.7236 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPSER** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPSER(Occurrence of serious adverse events)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 88 61.54 96.70 63.31 | 3 2.10 3.30 75.00 | 91 63.64 |
| **FRED X** | 51 35.66 98.08 36.69 | 1 0.70 1.92 25.00 | 52 36.36 |
| **Total** | 139 97.20 | 4 2.80 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPSER*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.2296 | 0.6318 |
| **Test du rapport de vraisemblance** | 1 | 0.2428 | 0.6222 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.2280 | 0.6330 |
| **Coefficient Phi** |  | -0.0401 |  |
| **Coefficient de contingence** |  | 0.0400 |  |
| **V de Cramer** |  | -0.0401 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 88 |
| **Pr <= F unilatérale à gauche** | 0.5383 |
| **Pr >= F unilatérale à droite** | 0.8400 |
|  |  |
| **Probabilité de la table (P)** | 0.3782 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPDEV** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPDEV(Occurrence of device-related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 90 62.94 98.90 63.83 | 1 0.70 1.10 50.00 | 91 63.64 |
| **FRED X** | 51 35.66 98.08 36.17 | 1 0.70 1.92 50.00 | 52 36.36 |
| **Total** | 141 98.60 | 2 1.40 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPDEV*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1630 | 0.6864 |
| **Test du rapport de vraisemblance** | 1 | 0.1569 | 0.6921 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1619 | 0.6875 |
| **Coefficient Phi** |  | 0.0338 |  |
| **Coefficient de contingence** |  | 0.0337 |  |
| **V de Cramer** |  | 0.0338 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 90 |
| **Pr <= F unilatérale à gauche** | 0.8694 |
| **Pr >= F unilatérale à droite** | 0.5967 |
|  |  |
| **Probabilité de la table (P)** | 0.4661 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPPRO** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPPRO(Occurrence of procedure related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 91 63.64 100.00 64.08 | 0 0.00 0.00 0.00 | 91 63.64 |
| **FRED X** | 51 35.66 98.08 35.92 | 1 0.70 1.92 100.00 | 52 36.36 |
| **Total** | 142 99.30 | 1 0.70 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPPRO*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 1.7623 | 0.1843 |
| **Test du rapport de vraisemblance** | 1 | 2.0355 | 0.1537 |
| **Khi-2 continuité ajustée** | 1 | 0.0809 | 0.7761 |
| **Khi-2 de Mantel-Haenszel** | 1 | 1.7500 | 0.1859 |
| **Coefficient Phi** |  | 0.1110 |  |
| **Coefficient de contingence** |  | 0.1103 |  |
| **V de Cramer** |  | 0.1110 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 91 |
| **Pr <= F unilatérale à gauche** | 1.0000 |
| **Pr >= F unilatérale à droite** | 0.3636 |
|  |  |
| **Probabilité de la table (P)** | 0.3636 |
| **Pr <= P bilatéral** | 0.3636 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of post-procedural complications** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 84 (92.3%) | 48 (92.3%) | 132 (92.3%) |
|  | Yes | 7 (7.7%) | 4 (7.7%) | 11 (7.7%) |
|  | 95% CI | 2.2% - 13.2% | 0.4% - 14.9% | 3.3% - 12.1% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of Thromboembolic complication** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 89 (97.8%) | 52 (100.0%) | 141 (98.6%) |
|  | Yes | 2 (2.2%) |  | 2 (1.4%) |
|  |  |  |  |  |
| **Occurrence of Delayed intracranial hematoma** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 91 (100.0%) | 52 (100.0%) | 143 (100.0%) |
|  |  |  |  |  |
| **Occurrence of Other complication** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 86 (94.5%) | 48 (92.3%) | 134 (93.7%) |
|  | Yes | 5 (5.5%) | 4 (7.7%) | 9 (6.3%) |
|  | 95% CI | 0.8% - 10.2% | 0.4% - 14.9% | 2.3% - 10.3% |
|  | Between group test |  |  | 0.724 (Fisher) |
|  |  |  |  |  |
| **Occurrence of serious adverse events** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 88 (96.7%) | 51 (98.1%) | 139 (97.2%) |
|  | Yes | 3 (3.3%) | 1 (1.9%) | 4 (2.8%) |
|  | 95% CI | 0.0% - 7.0% | 0.0% - 5.7% | 0.1% - 5.5% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device-related AEs only** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 90 (98.9%) | 51 (98.1%) | 141 (98.6%) |
|  | Yes | 1 (1.1%) | 1 (1.9%) | 2 (1.4%) |
|  | 95% CI | 0.0% - 3.2% | 0.0% - 5.7% | 0% - 3.3% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of procedure related AEs only** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 91 (100.0%) | 51 (98.1%) | 142 (99.3%) |
|  | Yes | 0 | 1 (1.9%) | 1 (0.7%) |
|  | Between group test |  |  | 0.364 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device and procedure related AEs** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 89 (97.8%) | 52 (100.0%) | 141 (98.6%) |
|  | Yes | 2 (2.2%) |  | 2 (1.4%) |

**FRITS**

**Complications**

**Table : Summary of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=11 complications]**

|  | | **FRED / FRED Jr N=7** | **FRED X N=4** | **Total N=11** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Thromboembolic complications | 2 (28.6%) | 0 | 2 (18.2%) |
|  | Other complications | 5 (71.4%) | 4 (100.0%) | 9 (81.8%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 2 (28.6%) | 1 (25.0%) | 3 (27.3%) |
|  | Patient symptomatic | 5 (71.4%) | 3 (75.0%) | 8 (72.7%) |
|  |  |  |  |  |
| **AE severity** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 4 (57.1%) | 2 (50.0%) | 6 (54.5%) |
|  | Moderate | 2 (28.6%) | 1 (25.0%) | 3 (27.3%) |
|  | Severe | 1 (14.3%) | 1 (25.0%) | 2 (18.2%) |
|  |  |  |  |  |
| **Causal relationship** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 1 (14.3%) | 1 (25.0%) | 2 (18.2%) |
|  | Procedure related AE | 0 | 1 (25.0%) | 1 (9.1%) |
|  | Device and procedure related AE | 2 (28.6%) | 0 | 2 (18.2%) |
|  | Oher | 4 (57.1%) | 2 (50.0%) | 6 (54.5%) |
|  |  |  |  |  |
| **Other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 3 | 4 | 7 |
|  | checked | 4 (100.0%) | 0 | 4 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Concurrent condition | 1 (25.0%) |  | 1 (25.0%) |
|  | Other | 3 (75.0%) |  | 3 (75.0%) |
|  |  |  |  |  |
| **Serious AE** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 4 (57.1%) | 3 (75.0%) | 7 (63.6%) |
|  | Yes | 3 (42.9%) | 1 (25.0%) | 4 (36.4%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 3 | 1 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 3 (100.0%) | 0 | 3 (75.0%) |
|  | Permanent damage / Disability | 0 | 1 (100.0%) | 1 (25.0%) |
|  |  |  |  |  |
| **Event outcome** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 4 (57.1%) | 2 (50.0%) | 6 (54.5%) |
|  | Not resolved / ongoing | 3 (42.9%) | 2 (50.0%) | 5 (45.5%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 227.14 (109.99) | 283.75 (138.26) | 247.73 (117.51) |
|  | Median | 193.00 | 308.50 | 250.00 |
|  | Q1 - Q3 | 121.00 - 309.00 | 177.00 - 390.50 | 121.00 - 367.00 |
|  | Min - Max | 105.00 - 408.00 | 104.00 - 414.00 | 104.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 7.46 (3.61) | 9.33 (4.54) | 8.14 (3.86) |
|  | Median | 6.34 | 10.14 | 8.22 |
|  | Q1 - Q3 | 3.98 - 10.14 | 5.82 - 12.83 | 3.98 - 12.06 |
|  | Min - Max | 3.44 - 13.40 | 3.42 - 13.60 | 3.42 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N= complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 9 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 9 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 13.40 |
| 8.22 |
| 13.60 |
| 3.44 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 9 |

**FRITS**

**Complications**

**Table : Listing of all post-procedural complications between 6-month and 12-month (CEC) [ITT - N=11 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 11 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 11 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 10.14 |
| 13.40 |
| 3.98 |
| 8.22 |
| 13.60 |
| 3.44 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 11 |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) [ITT - N=11 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| N = 2 | | | | | | | |

| **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| N = 2 | | | | | | | |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of post-procedural complications)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 76 58.46 92.68 63.33 | 6 4.62 7.32 60.00 | 82 63.08 |
| **FRED X** | 44 33.85 91.67 36.67 | 4 3.08 8.33 40.00 | 48 36.92 |
| **Total** | 120 92.31 | 10 7.69 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0440 | 0.8338 |
| **Test du rapport de vraisemblance** | 1 | 0.0436 | 0.8346 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0437 | 0.8344 |
| **Coefficient Phi** |  | 0.0184 |  |
| **Coefficient de contingence** |  | 0.0184 |  |
| **V de Cramer** |  | 0.0184 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 76 |
| **Pr <= F unilatérale à gauche** | 0.7143 |
| **Pr >= F unilatérale à droite** | 0.5414 |
|  |  |
| **Probabilité de la table (P)** | 0.2558 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPOTH** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPOTH(Occurrence of Other complication)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 78 60.00 95.12 63.93 | 4 3.08 4.88 50.00 | 82 63.08 |
| **FRED X** | 44 33.85 91.67 36.07 | 4 3.08 8.33 50.00 | 48 36.92 |
| **Total** | 122 93.85 | 8 6.15 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPOTH*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.6259 | 0.4289 |
| **Test du rapport de vraisemblance** | 1 | 0.6055 | 0.4365 |
| **Khi-2 continuité ajustée** | 1 | 0.1706 | 0.6796 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.6211 | 0.4306 |
| **Coefficient Phi** |  | 0.0694 |  |
| **Coefficient de contingence** |  | 0.0692 |  |
| **V de Cramer** |  | 0.0694 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 78 |
| **Pr <= F unilatérale à gauche** | 0.8776 |
| **Pr >= F unilatérale à droite** | 0.3319 |
|  |  |
| **Probabilité de la table (P)** | 0.2095 |
| **Pr <= P bilatéral** | 0.4662 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPSER** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPSER(Occurrence of serious adverse events)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 79 60.77 96.34 62.70 | 3 2.31 3.66 75.00 | 82 63.08 |
| **FRED X** | 47 36.15 97.92 37.30 | 1 0.77 2.08 25.00 | 48 36.92 |
| **Total** | 126 96.92 | 4 3.08 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPSER*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.2519 | 0.6157 |
| **Test du rapport de vraisemblance** | 1 | 0.2666 | 0.6056 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.2500 | 0.6171 |
| **Coefficient Phi** |  | -0.0440 |  |
| **Coefficient de contingence** |  | 0.0440 |  |
| **V de Cramer** |  | -0.0440 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 79 |
| **Pr <= F unilatérale à gauche** | 0.5282 |
| **Pr >= F unilatérale à droite** | 0.8460 |
|  |  |
| **Probabilité de la table (P)** | 0.3742 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPDEV** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPDEV(Occurrence of device-related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 81 62.31 98.78 63.28 | 1 0.77 1.22 50.00 | 82 63.08 |
| **FRED X** | 47 36.15 97.92 36.72 | 1 0.77 2.08 50.00 | 48 36.92 |
| **Total** | 128 98.46 | 2 1.54 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPDEV*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1491 | 0.6994 |
| **Test du rapport de vraisemblance** | 1 | 0.1440 | 0.7043 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1480 | 0.7005 |
| **Coefficient Phi** |  | 0.0339 |  |
| **Coefficient de contingence** |  | 0.0339 |  |
| **V de Cramer** |  | 0.0339 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 81 |
| **Pr <= F unilatérale à gauche** | 0.8655 |
| **Pr >= F unilatérale à droite** | 0.6039 |
|  |  |
| **Probabilité de la table (P)** | 0.4694 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPPRO** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPPRO(Occurrence of procedure related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 82 63.08 100.00 63.57 | 0 0.00 0.00 0.00 | 82 63.08 |
| **FRED X** | 47 36.15 97.92 36.43 | 1 0.77 2.08 100.00 | 48 36.92 |
| **Total** | 129 99.23 | 1 0.77 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPPRO*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 1.7216 | 0.1895 |
| **Test du rapport de vraisemblance** | 1 | 2.0059 | 0.1567 |
| **Khi-2 continuité ajustée** | 1 | 0.0740 | 0.7856 |
| **Khi-2 de Mantel-Haenszel** | 1 | 1.7083 | 0.1912 |
| **Coefficient Phi** |  | 0.1151 |  |
| **Coefficient de contingence** |  | 0.1143 |  |
| **V de Cramer** |  | 0.1151 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 82 |
| **Pr <= F unilatérale à gauche** | 1.0000 |
| **Pr >= F unilatérale à droite** | 0.3692 |
|  |  |
| **Probabilité de la table (P)** | 0.3692 |
| **Pr <= P bilatéral** | 0.3692 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of post-procedural complications** | N | 82 | 48 | 130 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 76 (92.7%) | 44 (91.7%) | 120 (92.3%) |
|  | Yes | 6 (7.3%) | 4 (8.3%) | 10 (7.7%) |
|  | 95% CI | 1.7% - 13.0% | 0.5% - 16.2% | 3.1% - 12.3% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of Thromboembolic complication** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 80 (97.6%) | 48 (100.0%) | 128 (98.5%) |
|  | Yes | 2 (2.4%) |  | 2 (1.5%) |
|  |  |  |  |  |
| **Occurrence of Delayed intracranial hematoma** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 82 (100.0%) | 48 (100.0%) | 130 (100.0%) |
|  |  |  |  |  |
| **Occurrence of Other complication** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (95.1%) | 44 (91.7%) | 122 (93.8%) |
|  | Yes | 4 (4.9%) | 4 (8.3%) | 8 (6.2%) |
|  | 95% CI | 0.2% - 9.5% | 0.5% - 16.2% | 2% - 10.3% |
|  | Between group test |  |  | 0.466 (Fisher) |
|  |  |  |  |  |
| **Occurrence of serious adverse events** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 79 (96.3%) | 47 (97.9%) | 126 (96.9%) |
|  | Yes | 3 (3.7%) | 1 (2.1%) | 4 (3.1%) |
|  | 95% CI | 0.0% - 7.7% | 0.0% - 6.1% | 0.1% - 6% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device-related AEs only** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 81 (98.8%) | 47 (97.9%) | 128 (98.5%) |
|  | Yes | 1 (1.2%) | 1 (2.1%) | 2 (1.5%) |
|  | 95% CI | 0.0% - 3.6% | 0.0% - 6.1% | 0% - 3.7% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of procedure related AEs only** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 82 (100.0%) | 47 (97.9%) | 129 (99.2%) |
|  | Yes | 0 | 1 (2.1%) | 1 (0.8%) |
|  | Between group test |  |  | 0.369 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device and procedure related AEs** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 81 (98.8%) | 48 (100.0%) | 129 (99.2%) |
|  | Yes | 1 (1.2%) |  | 1 (0.8%) |

**FRITS**

**Complications**

**Table : Summary of post-procedural complications between 6-month and 12-month (CEC) [FAS - N=10 complications]**

|  | | **FRED / FRED Jr N=6** | **FRED X N=4** | **Total N=10** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Thromboembolic complications | 2 (33.3%) | 0 | 2 (20.0%) |
|  | Other complications | 4 (66.7%) | 4 (100.0%) | 8 (80.0%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 2 (33.3%) | 1 (25.0%) | 3 (30.0%) |
|  | Patient symptomatic | 4 (66.7%) | 3 (75.0%) | 7 (70.0%) |
|  |  |  |  |  |
| **AE severity** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  | Moderate | 2 (33.3%) | 1 (25.0%) | 3 (30.0%) |
|  | Severe | 1 (16.7%) | 1 (25.0%) | 2 (20.0%) |
|  |  |  |  |  |
| **Causal relationship** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 1 (16.7%) | 1 (25.0%) | 2 (20.0%) |
|  | Procedure related AE | 0 | 1 (25.0%) | 1 (10.0%) |
|  | Device and procedure related AE | 1 (16.7%) | 0 | 1 (10.0%) |
|  | Oher | 4 (66.7%) | 2 (50.0%) | 6 (60.0%) |
|  |  |  |  |  |
| **Other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 2 | 4 | 6 |
|  | checked | 4 (100.0%) | 0 | 4 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Concurrent condition | 1 (25.0%) |  | 1 (25.0%) |
|  | Other | 3 (75.0%) |  | 3 (75.0%) |
|  |  |  |  |  |
| **Serious** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 3 (50.0%) | 3 (75.0%) | 6 (60.0%) |
|  | Yes | 3 (50.0%) | 1 (25.0%) | 4 (40.0%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 3 | 1 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 3 (100.0%) | 0 | 3 (75.0%) |
|  | Permanent damage / Disability | 0 | 1 (100.0%) | 1 (25.0%) |
|  |  |  |  |  |
| **Event outcome** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  | Not resolved / ongoing | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 247.50 (105.06) | 283.75 (138.26) | 262.00 (113.38) |
|  | Median | 237.00 | 308.50 | 265.50 |
|  | Q1 - Q3 | 173.00 - 309.00 | 177.00 - 390.50 | 173.00 - 367.00 |
|  | Min - Max | 121.00 - 408.00 | 104.00 - 414.00 | 104.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 8.13 (3.45) | 9.33 (4.54) | 8.61 (3.72) |
|  | Median | 7.78 | 10.14 | 8.72 |
|  | Q1 - Q3 | 5.68 - 10.14 | 5.82 - 12.83 | 5.68 - 12.06 |
|  | Min - Max | 3.98 - 13.40 | 3.42 - 13.60 | 3.42 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other post-procedural complications between 6-month and 12-month (CEC) [FAS - N= complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 8 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 8 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 13.40 |
| 8.22 |
| 13.60 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 8 |

**FRITS**

**Complications**

**Table : Listing of all post-procedural complications between 6-month and 12-month (CEC) [FAS - N=10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 10 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 10 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 10.14 |
| 13.40 |
| 3.98 |
| 8.22 |
| 13.60 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 10 |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) [FAS - N=10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| N = 2 | | | | | | | |

| **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| N = 2 | | | | | | | |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of post-procedural complications)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 73 58.87 92.41 64.04 | 6 4.84 7.59 60.00 | 79 63.71 |
| **FRED X** | 41 33.06 91.11 35.96 | 4 3.23 8.89 40.00 | 45 36.29 |
| **Total** | 114 91.94 | 10 8.06 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0647 | 0.7992 |
| **Test du rapport de vraisemblance** | 1 | 0.0640 | 0.8004 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0642 | 0.7999 |
| **Coefficient Phi** |  | 0.0228 |  |
| **Coefficient de contingence** |  | 0.0228 |  |
| **V de Cramer** |  | 0.0228 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 73 |
| **Pr <= F unilatérale à gauche** | 0.7297 |
| **Pr >= F unilatérale à droite** | 0.5241 |
|  |  |
| **Probabilité de la table (P)** | 0.2538 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPOTH** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPOTH(Occurrence of Other complication)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 75 60.48 94.94 64.66 | 4 3.23 5.06 50.00 | 79 63.71 |
| **FRED X** | 41 33.06 91.11 35.34 | 4 3.23 8.89 50.00 | 45 36.29 |
| **Total** | 116 93.55 | 8 6.45 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPOTH*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.6952 | 0.4044 |
| **Test du rapport de vraisemblance** | 1 | 0.6703 | 0.4130 |
| **Khi-2 continuité ajustée** | 1 | 0.2058 | 0.6501 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.6896 | 0.4063 |
| **Coefficient Phi** |  | 0.0749 |  |
| **Coefficient de contingence** |  | 0.0747 |  |
| **V de Cramer** |  | 0.0749 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 75 |
| **Pr <= F unilatérale à gauche** | 0.8860 |
| **Pr >= F unilatérale à droite** | 0.3174 |
|  |  |
| **Probabilité de la table (P)** | 0.2033 |
| **Pr <= P bilatéral** | 0.4595 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPSER** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPSER(Occurrence of serious adverse events)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 76 61.29 96.20 63.33 | 3 2.42 3.80 75.00 | 79 63.71 |
| **FRED X** | 44 35.48 97.78 36.67 | 1 0.81 2.22 25.00 | 45 36.29 |
| **Total** | 120 96.77 | 4 3.23 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPSER*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.2279 | 0.6331 |
| **Test du rapport de vraisemblance** | 1 | 0.2409 | 0.6236 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.2260 | 0.6345 |
| **Coefficient Phi** |  | -0.0429 |  |
| **Coefficient de contingence** |  | 0.0428 |  |
| **V de Cramer** |  | -0.0429 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 76 |
| **Pr <= F unilatérale à gauche** | 0.5395 |
| **Pr >= F unilatérale à droite** | 0.8398 |
|  |  |
| **Probabilité de la table (P)** | 0.3793 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPDEV** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPDEV(Occurrence of device-related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 78 62.90 98.73 63.93 | 1 0.81 1.27 50.00 | 79 63.71 |
| **FRED X** | 44 35.48 97.78 36.07 | 1 0.81 2.22 50.00 | 45 36.29 |
| **Total** | 122 98.39 | 2 1.61 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPDEV*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1653 | 0.6844 |
| **Test du rapport de vraisemblance** | 1 | 0.1590 | 0.6901 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1639 | 0.6856 |
| **Coefficient Phi** |  | 0.0365 |  |
| **Coefficient de contingence** |  | 0.0365 |  |
| **V de Cramer** |  | 0.0365 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 78 |
| **Pr <= F unilatérale à gauche** | 0.8702 |
| **Pr >= F unilatérale à droite** | 0.5960 |
|  |  |
| **Probabilité de la table (P)** | 0.4662 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPPRO** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPPRO(Occurrence of procedure related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 79 63.71 100.00 64.23 | 0 0.00 0.00 0.00 | 79 63.71 |
| **FRED X** | 44 35.48 97.78 35.77 | 1 0.81 2.22 100.00 | 45 36.29 |
| **Total** | 123 99.19 | 1 0.81 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPPRO*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 1.7698 | 0.1834 |
| **Test du rapport de vraisemblance** | 1 | 2.0415 | 0.1531 |
| **Khi-2 continuité ajustée** | 1 | 0.0820 | 0.7747 |
| **Khi-2 de Mantel-Haenszel** | 1 | 1.7556 | 0.1852 |
| **Coefficient Phi** |  | 0.1195 |  |
| **Coefficient de contingence** |  | 0.1186 |  |
| **V de Cramer** |  | 0.1195 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 79 |
| **Pr <= F unilatérale à gauche** | 1.0000 |
| **Pr >= F unilatérale à droite** | 0.3629 |
|  |  |
| **Probabilité de la table (P)** | 0.3629 |
| **Pr <= P bilatéral** | 0.3629 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of post-procedural complications** | N | 79 | 45 | 124 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 73 (92.4%) | 41 (91.1%) | 114 (91.9%) |
|  | Yes | 6 (7.6%) | 4 (8.9%) | 10 (8.1%) |
|  | 95% CI | 1.8% - 13.4% | 0.6% - 17.2% | 3.3% - 12.9% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of Thromboembolic complication** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 77 (97.5%) | 45 (100.0%) | 122 (98.4%) |
|  | Yes | 2 (2.5%) |  | 2 (1.6%) |
|  |  |  |  |  |
| **Occurrence of Delayed intracranial hematoma** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 79 (100.0%) | 45 (100.0%) | 124 (100.0%) |
|  |  |  |  |  |
| **Occurrence of Other complication** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 75 (94.9%) | 41 (91.1%) | 116 (93.5%) |
|  | Yes | 4 (5.1%) | 4 (8.9%) | 8 (6.5%) |
|  | 95% CI | 0.2% - 9.9% | 0.6% - 17.2% | 2.1% - 10.8% |
|  | Between group test |  |  | 0.460 (Fisher) |
|  |  |  |  |  |
| **Occurrence of serious adverse events** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 76 (96.2%) | 44 (97.8%) | 120 (96.8%) |
|  | Yes | 3 (3.8%) | 1 (2.2%) | 4 (3.2%) |
|  | 95% CI | 0.0% - 8.0% | 0.0% - 6.5% | 0.1% - 6.3% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device-related AEs only** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (98.7%) | 44 (97.8%) | 122 (98.4%) |
|  | Yes | 1 (1.3%) | 1 (2.2%) | 2 (1.6%) |
|  | 95% CI | 0.0% - 3.7% | 0.0% - 6.5% | 0% - 3.8% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of procedure related AEs only** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 79 (100.0%) | 44 (97.8%) | 123 (99.2%) |
|  | Yes | 0 | 1 (2.2%) | 1 (0.8%) |
|  | Between group test |  |  | 0.363 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device and procedure related AEs** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (98.7%) | 45 (100.0%) | 123 (99.2%) |
|  | Yes | 1 (1.3%) |  | 1 (0.8%) |

**FRITS**

**Complications**

**Table : Summary of post-procedural complications between 6-month and 12-month (CEC) [PP - N=10 complications]**

|  | | **FRED / FRED Jr N=6** | **FRED X N=4** | **Total N=10** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Thromboembolic complications | 2 (33.3%) | 0 | 2 (20.0%) |
|  | Other complications | 4 (66.7%) | 4 (100.0%) | 8 (80.0%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 2 (33.3%) | 1 (25.0%) | 3 (30.0%) |
|  | Patient symptomatic | 4 (66.7%) | 3 (75.0%) | 7 (70.0%) |
|  |  |  |  |  |
| **AE severity** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  | Moderate | 2 (33.3%) | 1 (25.0%) | 3 (30.0%) |
|  | Severe | 1 (16.7%) | 1 (25.0%) | 2 (20.0%) |
|  |  |  |  |  |
| **Causal relationship** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 1 (16.7%) | 1 (25.0%) | 2 (20.0%) |
|  | Procedure related AE | 0 | 1 (25.0%) | 1 (10.0%) |
|  | Device and procedure related AE | 1 (16.7%) | 0 | 1 (10.0%) |
|  | Oher | 4 (66.7%) | 2 (50.0%) | 6 (60.0%) |
|  |  |  |  |  |
| **Other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 2 | 4 | 6 |
|  | checked | 4 (100.0%) | 0 | 4 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Concurrent condition | 1 (25.0%) |  | 1 (25.0%) |
|  | Other | 3 (75.0%) |  | 3 (75.0%) |
|  |  |  |  |  |
| **Serious** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 3 (50.0%) | 3 (75.0%) | 6 (60.0%) |
|  | Yes | 3 (50.0%) | 1 (25.0%) | 4 (40.0%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 3 | 1 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 3 (100.0%) | 0 | 3 (75.0%) |
|  | Permanent damage / Disability | 0 | 1 (100.0%) | 1 (25.0%) |
|  |  |  |  |  |
| **Event outcome** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  | Not resolved / ongoing | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 247.50 (105.06) | 283.75 (138.26) | 262.00 (113.38) |
|  | Median | 237.00 | 308.50 | 265.50 |
|  | Q1 - Q3 | 173.00 - 309.00 | 177.00 - 390.50 | 173.00 - 367.00 |
|  | Min - Max | 121.00 - 408.00 | 104.00 - 414.00 | 104.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 8.13 (3.45) | 9.33 (4.54) | 8.61 (3.72) |
|  | Median | 7.78 | 10.14 | 8.72 |
|  | Q1 - Q3 | 5.68 - 10.14 | 5.82 - 12.83 | 5.68 - 12.06 |
|  | Min - Max | 3.98 - 13.40 | 3.42 - 13.60 | 3.42 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other post-procedural complications between 6-month and 12-month (CEC) [PP - N= complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 8 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 8 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 13.40 |
| 8.22 |
| 13.60 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 8 |

**FRITS**

**Complications**

**Table : Listing of all post-procedural complications between 6-month and 12-month (CEC) [PP - N=10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 10 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 10 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 10.14 |
| 13.40 |
| 3.98 |
| 8.22 |
| 13.60 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 10 |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) [PP - N=10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| N = 2 | | | | | | | |

| **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| N = 2 | | | | | | | |