**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

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

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

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

| **Table de fgroup par ACO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rate(Aneurysm complete occlusion rate at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 12 8.82 13.79 63.16 | 75 55.15 86.21 64.10 | 87 63.97 |
| **FRED X** | 7 5.15 14.29 36.84 | 42 30.88 85.71 35.90 | 49 36.03 |
| **Total** | 19 13.97 | 117 86.03 | 136 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0063 | 0.9366 |
| **Test du rapport de vraisemblance** | 1 | 0.0063 | 0.9367 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0063 | 0.9368 |
| **Coefficient Phi** |  | -0.0068 |  |
| **Coefficient de contingence** |  | 0.0068 |  |
| **V de Cramer** |  | -0.0068 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 12 |
| **Pr <= F unilatérale à gauche** | 0.5636 |
| **Pr >= F unilatérale à droite** | 0.6375 |
|  |  |
| **Probabilité de la table (P)** | 0.2011 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 136*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 12 (13.8%) | 7 (14.3%) | 19 (14.0%) |
|  | Yes | 75 (86.2%) | 42 (85.7%) | 117 (86.0%) |
|  | 95% CI | 79.0% - 93.5% | 75.9% - 95.5% | 80.2% - 91.9% |
|  | Between group test |  |  | 0.937 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

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

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

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

| **Table de fgroup par ACO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rateb(Aneurysm complete occlusion rate at 12 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 7 6.14 9.72 53.85 | 65 57.02 90.28 64.36 | 72 63.16 |
| **FRED X** | 6 5.26 14.29 46.15 | 36 31.58 85.71 35.64 | 42 36.84 |
| **Total** | 13 11.40 | 101 88.60 | 114 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.5468 | 0.4596 |
| **Test du rapport de vraisemblance** | 1 | 0.5336 | 0.4651 |
| **Khi-2 continuité ajustée** | 1 | 0.1884 | 0.6643 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.5420 | 0.4616 |
| **Coefficient Phi** |  | -0.0693 |  |
| **Coefficient de contingence** |  | 0.0691 |  |
| **V de Cramer** |  | -0.0693 |  |
| **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)** | 7 |
| **Pr <= F unilatérale à gauche** | 0.3266 |
| **Pr >= F unilatérale à droite** | 0.8517 |
|  |  |
| **Probabilité de la table (P)** | 0.1783 |
| **Pr <= P bilatéral** | 0.5452 |

|  |
| --- |
| ***Taille de l'échantillon = 114*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months(OKM score)** | N | 72 |  | 72 |
|  | Missing data | 15 | 7 | 22 |
|  | No | 7 (9.7%) | 6 (14.3%) | 13 (11.4%) |
|  | Yes | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |
|  | 95% CI | 83.4% - 97.1% | 75.1% - 96.3% | 82.8% - 94.4% |
|  | Between group test |  |  | 0.545 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

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

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

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

| **Table de fgroup par AAO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rate(Adequate occlusion rate at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 9 6.62 10.34 75.00 | 78 57.35 89.66 62.90 | 87 63.97 |
| **FRED X** | 3 2.21 6.12 25.00 | 46 33.82 93.88 37.10 | 49 36.03 |
| **Total** | 12 8.82 | 124 91.18 | 136 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.6946 | 0.4046 |
| **Test du rapport de vraisemblance** | 1 | 0.7314 | 0.3924 |
| **Khi-2 continuité ajustée** | 1 | 0.2689 | 0.6040 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.6895 | 0.4063 |
| **Coefficient Phi** |  | 0.0715 |  |
| **Coefficient de contingence** |  | 0.0713 |  |
| **V de Cramer** |  | 0.0715 |  |
| **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)** | 9 |
| **Pr <= F unilatérale à gauche** | 0.8767 |
| **Pr >= F unilatérale à droite** | 0.3096 |
|  |  |
| **Probabilité de la table (P)** | 0.1863 |
| **Pr <= P bilatéral** | 0.5362 |

|  |
| --- |
| ***Taille de l'échantillon = 136*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 9 (10.3%) | 3 (6.1%) | 12 (8.8%) |
|  | Yes | 78 (89.7%) | 46 (93.9%) | 124 (91.2%) |
|  | 95% CI | 83.3% - 96.1% | 87.2% - 100.0% | 86.4% - 95.9% |
|  | Between group test |  |  | 0.536 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

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

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

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

| **Table de fgroup par AAO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rateb(Adequate occlusion rate at 12 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 7 6.14 9.72 63.64 | 65 57.02 90.28 63.11 | 72 63.16 |
| **FRED X** | 4 3.51 9.52 36.36 | 38 33.33 90.48 36.89 | 42 36.84 |
| **Total** | 11 9.65 | 103 90.35 | 114 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0012 | 0.9724 |
| **Test du rapport de vraisemblance** | 1 | 0.0012 | 0.9724 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0012 | 0.9725 |
| **Coefficient Phi** |  | 0.0032 |  |
| **Coefficient de contingence** |  | 0.0032 |  |
| **V de Cramer** |  | 0.0032 |  |
| **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)** | 7 |
| **Pr <= F unilatérale à gauche** | 0.6329 |
| **Pr >= F unilatérale à droite** | 0.6234 |
|  |  |
| **Probabilité de la table (P)** | 0.2562 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 114*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months(OKM score)** | N | 72 |  | 72 |
|  | Missing data | 15 | 7 | 22 |
|  | No | 7 (9.7%) | 4 (9.5%) | 11 (9.6%) |
|  | Yes | 65 (90.3%) | 38 (90.5%) | 103 (90.4%) |
|  | 95% CI | 83.4% - 97.1% | 81.6% - 99.4% | 84.9% - 95.8% |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm occlusion degree** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Obliteration | 75 (86.2%) | 42 (85.7%) | 117 (86.0%) |
|  | Residual neck | 3 (3.4%) | 4 (8.2%) | 7 (5.1%) |
|  | Residual aneurysm | 9 (10.3%) | 3 (6.1%) | 12 (8.8%) |
|  | Between group test |  |  | 0.393 (Fisher) |
|  |  |  |  |  |
| **1Y : Aneurysm occlusion degree specification** | N | 3 |  | 3 |
|  | Missing data | 84 | 48 | 132 |
|  | Class IIIa | 0 | 1 (100.0%) | 1 (25.0%) |
|  | Class IIIb | 3 (100.0%) |  | 3 (75.0%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm filling** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | A: total filling (>95%) | 3 (3.4%) | 2 (4.1%) | 5 (3.7%) |
|  | B: subtotal filling (5-95%) | 5 (5.7%) | 2 (4.1%) | 7 (5.1%) |
|  | C: entry remnant (<5%) | 0 | 2 (4.1%) | 2 (1.5%) |
|  | D: no filling (0%) | 65 (74.7%) | 36 (73.5%) | 101 (74.3%) |
|  | Cannot be assessed from the imaging | 13 (14.9%) | 7 (14.3%) | 20 (14.7%) |
|  | Not applicable | 1 (1.1%) |  | 1 (0.7%) |
|  | Between group test |  |  | 0.600 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Aneurysm Occlusion stability at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm Occlusion stability** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Better | 41 (47.1%) | 19 (38.8%) | 60 (44.1%) |
|  | Same | 31 (35.6%) | 20 (40.8%) | 51 (37.5%) |
|  | Cannot be assessed from the imaging | 15 (17.2%) | 10 (20.4%) | 25 (18.4%) |
|  | Between group test |  |  | 0.640 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stasis phase at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stasis phase** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | 1: no stasis (arterial phase clearance, before capillary phase) | 1 (1.1%) | 1 (2.0%) | 2 (1.5%) |
|  | 2: moderate stasis (clearance before venous phase) | 2 (2.3%) | 2 (4.1%) | 4 (2.9%) |
|  | 3: significant stasis (persistent contrast at venous phase) | 4 (4.6%) | 3 (6.1%) | 7 (5.1%) |
|  | Cannot be assessed from the imaging | 12 (13.8%) | 8 (16.3%) | 20 (14.7%) |
|  | Not applicable | 68 (78.2%) | 35 (71.4%) | 103 (75.7%) |
|  | Between group test |  |  | 0.831 (Fisher) |

**FRITS**

**EFFICACY**

**Table : OKM scale at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale at 12 months** | N | 72 |  | 72 |
|  | Missing data | 15 | 7 | 22 |
|  | A1 | 1 (1.4%) | 1 (2.4%) | 2 (1.8%) |
|  | A2 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | A3 | 1 (1.4%) |  | 1 (0.9%) |
|  | B2 | 2 (2.8%) |  | 2 (1.8%) |
|  | B3 | 3 (4.2%) | 2 (4.8%) | 5 (4.4%) |
|  | C2 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | C3 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | D1 | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |

**FRITS**

**EFFICACY**

**Table : OKM grade at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade at 12 months** | N | 72 |  | 72 |
|  | Missing data | 15 | 7 | 22 |
|  | OKM A | 2 (2.8%) | 2 (4.8%) | 4 (3.5%) |
|  | OKM B | 5 (6.9%) | 2 (4.8%) | 7 (6.1%) |
|  | OKM C | 0 | 2 (4.8%) | 2 (1.8%) |
|  | OKM D | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm sac size change at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm sac size change** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Increased sac size | 1 (1.1%) |  | 1 (0.7%) |
|  | Stable | 26 (29.9%) | 18 (36.7%) | 44 (32.4%) |
|  | Decreased sac size | 17 (19.5%) | 7 (14.3%) | 24 (17.6%) |
|  | Cannot be assessed from the imaging | 43 (49.4%) | 24 (49.0%) | 67 (49.3%) |
|  | Between group test |  |  | 0.758 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Stent Stability at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stent Stability** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 1 (1.1%) | 3 (6.1%) | 4 (2.9%) |
|  | Yes | 79 (90.8%) | 46 (93.9%) | 125 (91.9%) |
|  | Cannot be assessed from the imaging | 7 (8.0%) |  | 7 (5.1%) |
|  | Between group test |  |  | 0.035 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Stent covering the neck at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stent covering the neck** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 4 (4.6%) | 1 (2.0%) | 5 (3.7%) |
|  | Yes | 77 (88.5%) | 48 (98.0%) | 125 (91.9%) |
|  | Cannot be assessed from the imaging | 6 (6.9%) |  | 6 (4.4%) |
|  | Between group test |  |  | 0.145 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Parent artery permeability at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Parent Artery permeability** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No stenosis | 56 (64.4%) | 29 (59.2%) | 85 (62.5%) |
|  | Stenosis < 50% | 13 (14.9%) | 7 (14.3%) | 20 (14.7%) |
|  | On MRA or CTA images, no stenosis or Stenosis < 50% | 13 (14.9%) | 11 (22.4%) | 24 (17.6%) |
|  | Stenosis >= 50 % | 2 (2.3%) | 2 (4.1%) | 4 (2.9%) |
|  | Complete occlusion | 1 (1.1%) |  | 1 (0.7%) |
|  | On MRA or CTA images, Stenosis >= 50 % or complete occlusion | 1 (1.1%) |  | 1 (0.7%) |
|  | Cannot be assessed from the imaging | 1 (1.1%) |  | 1 (0.7%) |
|  | Between group test |  |  | 0.895 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Retreatment** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 87 (100.0%) | 49 (100.0%) | 136 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 12 months (INVESTIGATORS) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y: Retreatment** | 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%) |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Listing of patient with missing data for Retreatment at 12 months (INVESTIGATORS) [ITT - N=136 patients]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-021 | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| 05-004 | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| 07-002 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 07-036 | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| N = 4 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Iteration Number** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | Yes | 59 | Female | FRED / FRED Jr | FRED | 19/05/2020 | 1 | 1 |
| Yes | Yes | Yes | 65 | Female | FRED X | FRED X | 30/04/2021 | 1 | 1 |
| No | No | No | 86 | Female | FRED / FRED Jr | FRED | 21/11/2019 | 1 | 1 |
| Yes | Yes | Yes | 48 | Female | FRED / FRED Jr | FRED | 21/10/2021 | 1 | 1 |
| N = 4 | | | | | | | | | |

| **1Y: visit performed** | **1Y: reason for not performed** | **1Y Date** | **1Y Date - Partial date** | **1Y: mRS** | **1Y: Antiplatelet changes** | **1Y: AE** | **1Y: Imaging done** | **1Y Imaging: Date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes |  | 02/02/2021 | 02/02/2021 | 0 - No symptoms at all | No | No | Yes | 02/02/2021 |
| Yes |  | 07/06/2022 | 07/06/2022 | 0 - No symptoms at all | Yes | No | Yes | 07/06/2022 |
| Yes |  | 10/11/2020 | 10/11/2020 | 1 - No significant disability despite symptoms; able to carry out all usual duties and activities | Yes | No | Yes | 10/11/2020 |
| Yes |  | 09/05/2023 | 09/05/2023 | 0 - No symptoms at all | No | Yes | Yes | 09/05/2023 |
| N = 4 | | | | | | | | |

| **1Y Imaging: Date - Partial date** | **1Y: Imaging type** | **1Y: Stent placement** | **1Y: Aneurysm occlusion degree** | **1Y: Aneurysm occlusion degree OKM scale** | **Y1\_StasisPhase\_OKM\_LD** | **1Y: Aneurysm occlusion change** | **1Y: Aneurysm sac size change** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 02/02/2021 | Angiography (DSA) | Correct | Class I: Obliteration | Grade C: Entry remnant | 1 | Same | Stable |
| 07/06/2022 | Angiography (DSA) | Correct | Class I: Obliteration | Grade B: Subtotal filling | Non applicable | Same | Stable |
| 10/11/2020 | Magnetic resonance angiography (MRA) | Cannot be assessed from the imaging | Class II: Residual neck | Not applicable | Non applicable | Worse | Stable |
| 09/05/2023 | Angiography (DSA) | Correct | Class I: Obliteration | Grade D: No filling | Non applicable | Same | Stable |
| N = 4 | | | | | | | |

| **1Y: Parent artery permeability** | **1Y: Retreatment** | **1Y Retreatment: Date** | **1Y Retreatment: Date - Partial date** | **1Y: Coils implanted** | **1Y: Number of coils** | **1Y: Other intrasaccular device** | **1Y: Specify other intrasaccular device** | **1Y: Standard stent** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Stenosis < 50 % | Yes | 02/02/2021 | 02/02/2021 | . | . | . |  | . |
| No stenosis | Yes | 02/09/2021 | 02/09/2021 | . | . | . |  | . |
| No stenosis | Yes | 16/03/2021 | 16/03/2021 | checked | 1 | . |  | checked |
| No stenosis | Yes | 13/05/2022 | 13/05/2022 | checked | D | checked | ONYX EMBOLISATION | . |
| N = 4 | | | | | | | | |

| **1Y: Specify standard stent** | **1Y: Flow diverter** | **1Y: Specify flow diverter** | **1Y: retreatment specify other FD** | **1Y: retreatment FRED reference** | **1Y: retreatment FRED batch number** | **1Y : Permeability of the parent artery at the end of the 1Yedure** |
| --- | --- | --- | --- | --- | --- | --- |
|  | checked | FRED |  | FRED3507 | 20040251Y | Stenosis < 50 % |
|  | checked | Other | SURPASS EVOLVE |  |  | No stenosis |
| SILK STENT | . | . |  |  |  | No stenosis |
|  | . | . |  |  |  | No stenosis |
| N = 4 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

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

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

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

| **Table de fgroup par ACO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rate(Aneurysm complete occlusion rate at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 12 9.68 15.19 63.16 | 67 54.03 84.81 63.81 | 79 63.71 |
| **FRED X** | 7 5.65 15.56 36.84 | 38 30.65 84.44 36.19 | 45 36.29 |
| **Total** | 19 15.32 | 105 84.68 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0030 | 0.9566 |
| **Test du rapport de vraisemblance** | 1 | 0.0029 | 0.9567 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0029 | 0.9568 |
| **Coefficient Phi** |  | -0.0049 |  |
| **Coefficient de contingence** |  | 0.0049 |  |
| **V de Cramer** |  | -0.0049 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 12 |
| **Pr <= F unilatérale à gauche** | 0.5745 |
| **Pr >= F unilatérale à droite** | 0.6285 |
|  |  |
| **Probabilité de la table (P)** | 0.2030 |
| **Pr <= P bilatéral** | 1.0000 |

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

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 12 (15.2%) | 7 (15.6%) | 19 (15.3%) |
|  | Yes | 67 (84.8%) | 38 (84.4%) | 105 (84.7%) |
|  | 95% CI | 76.9% - 92.7% | 73.9% - 95.0% | 78.3% - 91% |
|  | Between group test |  |  | 0.957 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

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

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

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

| **Table de fgroup par ACO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rateb(Aneurysm complete occlusion rate at 12 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 7 6.80 10.77 53.85 | 58 56.31 89.23 64.44 | 65 63.11 |
| **FRED X** | 6 5.83 15.79 46.15 | 32 31.07 84.21 35.56 | 38 36.89 |
| **Total** | 13 12.62 | 90 87.38 | 103 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.5480 | 0.4591 |
| **Test du rapport de vraisemblance** | 1 | 0.5352 | 0.4644 |
| **Khi-2 continuité ajustée** | 1 | 0.1873 | 0.6651 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.5427 | 0.4613 |
| **Coefficient Phi** |  | -0.0729 |  |
| **Coefficient de contingence** |  | 0.0727 |  |
| **V de Cramer** |  | -0.0729 |  |
| **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)** | 7 |
| **Pr <= F unilatérale à gauche** | 0.3272 |
| **Pr >= F unilatérale à droite** | 0.8524 |
|  |  |
| **Probabilité de la table (P)** | 0.1796 |
| **Pr <= P bilatéral** | 0.5429 |

|  |
| --- |
| ***Taille de l'échantillon = 103*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months(OKM score)** | N | 65 |  | 65 |
|  | Missing data | 14 | 7 | 21 |
|  | No | 7 (10.8%) | 6 (15.8%) | 13 (12.6%) |
|  | Yes | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |
|  | 95% CI | 81.7% - 96.8% | 72.6% - 95.8% | 81% - 93.8% |
|  | Between group test |  |  | 0.543 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

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

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

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

| **Table de fgroup par AAO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rate(Adequate occlusion rate at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 9 7.26 11.39 75.00 | 70 56.45 88.61 62.50 | 79 63.71 |
| **FRED X** | 3 2.42 6.67 25.00 | 42 33.87 93.33 37.50 | 45 36.29 |
| **Total** | 12 9.68 | 112 90.32 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.7325 | 0.3921 |
| **Test du rapport de vraisemblance** | 1 | 0.7712 | 0.3798 |
| **Khi-2 continuité ajustée** | 1 | 0.2916 | 0.5892 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.7266 | 0.3940 |
| **Coefficient Phi** |  | 0.0769 |  |
| **Coefficient de contingence** |  | 0.0766 |  |
| **V de Cramer** |  | 0.0769 |  |
| **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)** | 9 |
| **Pr <= F unilatérale à gauche** | 0.8817 |
| **Pr >= F unilatérale à droite** | 0.3017 |
|  |  |
| **Probabilité de la table (P)** | 0.1834 |
| **Pr <= P bilatéral** | 0.5335 |

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

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 9 (11.4%) | 3 (6.7%) | 12 (9.7%) |
|  | Yes | 70 (88.6%) | 42 (93.3%) | 112 (90.3%) |
|  | 95% CI | 81.6% - 95.6% | 86.0% - 100.0% | 85.1% - 95.5% |
|  | Between group test |  |  | 0.534 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

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

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

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

| **Table de fgroup par AAO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rateb(Adequate occlusion rate at 12 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 7 6.80 10.77 63.64 | 58 56.31 89.23 63.04 | 65 63.11 |
| **FRED X** | 4 3.88 10.53 36.36 | 34 33.01 89.47 36.96 | 38 36.89 |
| **Total** | 11 10.68 | 92 89.32 | 103 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0015 | 0.9693 |
| **Test du rapport de vraisemblance** | 1 | 0.0015 | 0.9692 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0015 | 0.9694 |
| **Coefficient Phi** |  | 0.0038 |  |
| **Coefficient de contingence** |  | 0.0038 |  |
| **V de Cramer** |  | 0.0038 |  |
| **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)** | 7 |
| **Pr <= F unilatérale à gauche** | 0.6353 |
| **Pr >= F unilatérale à droite** | 0.6224 |
|  |  |
| **Probabilité de la table (P)** | 0.2577 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 103*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months(OKM score)** | N | 65 |  | 65 |
|  | Missing data | 14 | 7 | 21 |
|  | No | 7 (10.8%) | 4 (10.5%) | 11 (10.7%) |
|  | Yes | 58 (89.2%) | 34 (89.5%) | 92 (89.3%) |
|  | 95% CI | 81.7% - 96.8% | 79.7% - 99.2% | 83.4% - 95.3% |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm occlusion degree** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | Obliteration | 67 (84.8%) | 38 (84.4%) | 105 (84.7%) |
|  | Residual neck | 3 (3.8%) | 4 (8.9%) | 7 (5.6%) |
|  | Residual aneurysm | 9 (11.4%) | 3 (6.7%) | 12 (9.7%) |
|  | Between group test |  |  | 0.390 (Fisher) |
|  |  |  |  |  |
| **1Y : Aneurysm occlusion degree specification** | N | 3 |  | 3 |
|  | Missing data | 76 | 44 | 120 |
|  | Class IIIa | 0 | 1 (100.0%) | 1 (25.0%) |
|  | Class IIIb | 3 (100.0%) |  | 3 (75.0%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm filling** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | A: total filling (>95%) | 3 (3.8%) | 2 (4.4%) | 5 (4.0%) |
|  | B: subtotal filling (5-95%) | 5 (6.3%) | 2 (4.4%) | 7 (5.6%) |
|  | C: entry remnant (<5%) | 0 | 2 (4.4%) | 2 (1.6%) |
|  | D: no filling (0%) | 58 (73.4%) | 32 (71.1%) | 90 (72.6%) |
|  | Cannot be assessed from the imaging | 12 (15.2%) | 7 (15.6%) | 19 (15.3%) |
|  | Not applicable | 1 (1.3%) |  | 1 (0.8%) |
|  | Between group test |  |  | 0.609 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Aneurysm Occlusion stability at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm Occlusion stability** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | Better | 37 (46.8%) | 15 (33.3%) | 52 (41.9%) |
|  | Same | 27 (34.2%) | 20 (44.4%) | 47 (37.9%) |
|  | Cannot be assessed from the imaging | 15 (19.0%) | 10 (22.2%) | 25 (20.2%) |
|  | Between group test |  |  | 0.334 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stasis phase at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stasis phase** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | 1: no stasis (arterial phase clearance, before capillary phase) | 1 (1.3%) | 1 (2.2%) | 2 (1.6%) |
|  | 2: moderate stasis (clearance before venous phase) | 2 (2.5%) | 2 (4.4%) | 4 (3.2%) |
|  | 3: significant stasis (persistent contrast at venous phase) | 4 (5.1%) | 3 (6.7%) | 7 (5.6%) |
|  | Cannot be assessed from the imaging | 11 (13.9%) | 8 (17.8%) | 19 (15.3%) |
|  | Not applicable | 61 (77.2%) | 31 (68.9%) | 92 (74.2%) |
|  | Between group test |  |  | 0.806 (Fisher) |

**FRITS**

**EFFICACY**

**Table : OKM scale at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale at 12 months** | N | 65 |  | 65 |
|  | Missing data | 14 | 7 | 21 |
|  | A1 | 1 (1.5%) | 1 (2.6%) | 2 (1.9%) |
|  | A2 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | A3 | 1 (1.5%) |  | 1 (1.0%) |
|  | B2 | 2 (3.1%) |  | 2 (1.9%) |
|  | B3 | 3 (4.6%) | 2 (5.3%) | 5 (4.9%) |
|  | C2 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | C3 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | D1 | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |

**FRITS**

**EFFICACY**

**Table : OKM grade at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade at 12 months** | N | 65 |  | 65 |
|  | Missing data | 14 | 7 | 21 |
|  | OKM A | 2 (3.1%) | 2 (5.3%) | 4 (3.9%) |
|  | OKM B | 5 (7.7%) | 2 (5.3%) | 7 (6.8%) |
|  | OKM C | 0 | 2 (5.3%) | 2 (1.9%) |
|  | OKM D | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm sac size change at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm sac size change** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | Increased sac size | 1 (1.3%) |  | 1 (0.8%) |
|  | Stable | 23 (29.1%) | 18 (40.0%) | 41 (33.1%) |
|  | Decreased sac size | 16 (20.3%) | 5 (11.1%) | 21 (16.9%) |
|  | Cannot be assessed from the imaging | 39 (49.4%) | 22 (48.9%) | 61 (49.2%) |
|  | Between group test |  |  | 0.408 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Stent Stability at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stent Stability** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 1 (1.3%) | 1 (2.2%) | 2 (1.6%) |
|  | Yes | 73 (92.4%) | 44 (97.8%) | 117 (94.4%) |
|  | Cannot be assessed from the imaging | 5 (6.3%) |  | 5 (4.0%) |
|  | Between group test |  |  | 0.267 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Stent covering the neck at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stent covering the neck** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 4 (5.1%) | 1 (2.2%) | 5 (4.0%) |
|  | Yes | 70 (88.6%) | 44 (97.8%) | 114 (91.9%) |
|  | Cannot be assessed from the imaging | 5 (6.3%) |  | 5 (4.0%) |
|  | Between group test |  |  | 0.220 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Parent artery permeability at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Parent Artery permeability** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No stenosis | 52 (65.8%) | 27 (60.0%) | 79 (63.7%) |
|  | Stenosis < 50% | 13 (16.5%) | 5 (11.1%) | 18 (14.5%) |
|  | On MRA or CTA images, no stenosis or Stenosis < 50% | 10 (12.7%) | 11 (24.4%) | 21 (16.9%) |
|  | Stenosis >= 50 % | 1 (1.3%) | 2 (4.4%) | 3 (2.4%) |
|  | Complete occlusion | 1 (1.3%) |  | 1 (0.8%) |
|  | On MRA or CTA images, Stenosis >= 50 % or complete occlusion | 1 (1.3%) |  | 1 (0.8%) |
|  | Cannot be assessed from the imaging | 1 (1.3%) |  | 1 (0.8%) |
|  | Between group test |  |  | 0.405 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Retreatment** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 79 (100.0%) | 45 (100.0%) | 124 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 12 months (INVESTIGATORS) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y: Retreatment** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (98.7%) | 45 (100.0%) | 123 (99.2%) |
|  | Yes | 1 (1.3%) |  | 1 (0.8%) |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Listing of patient with missing data for Retreatment at 12 months (INVESTIGATORS) [PP - N=124 patients]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-002 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| N = 1 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Iteration Number** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| No | No | No | 86 | Female | FRED / FRED Jr | FRED | 21/11/2019 | 1 | 1 |
| N = 1 | | | | | | | | | |

| **1Y: visit performed** | **1Y: reason for not performed** | **1Y Date** | **1Y Date - Partial date** | **1Y: mRS** | **1Y: Antiplatelet changes** | **1Y: AE** | **1Y: Imaging done** | **1Y Imaging: Date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes |  | 10/11/2020 | 10/11/2020 | 1 - No significant disability despite symptoms; able to carry out all usual duties and activities | Yes | No | Yes | 10/11/2020 |
| N = 1 | | | | | | | | |

| **1Y Imaging: Date - Partial date** | **1Y: Imaging type** | **1Y: Stent placement** | **1Y: Aneurysm occlusion degree** | **1Y: Aneurysm occlusion degree OKM scale** | **Y1\_StasisPhase\_OKM\_LD** | **1Y: Aneurysm occlusion change** | **1Y: Aneurysm sac size change** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 10/11/2020 | Magnetic resonance angiography (MRA) | Cannot be assessed from the imaging | Class II: Residual neck | Not applicable | Non applicable | Worse | Stable |
| N = 1 | | | | | | | |

| **1Y: Parent artery permeability** | **1Y: Retreatment** | **1Y Retreatment: Date** | **1Y Retreatment: Date - Partial date** | **1Y: Coils implanted** | **1Y: Number of coils** | **1Y: Other intrasaccular device** | **1Y: Specify other intrasaccular device** | **1Y: Standard stent** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| No stenosis | Yes | 16/03/2021 | 16/03/2021 | checked | 1 | . |  | checked |
| N = 1 | | | | | | | | |

| **1Y: Specify standard stent** | **1Y: Flow diverter** | **1Y: Specify flow diverter** | **1Y: retreatment specify other FD** | **1Y: retreatment FRED reference** | **1Y: retreatment FRED batch number** | **1Y : Permeability of the parent artery at the end of the 1Yedure** |
| --- | --- | --- | --- | --- | --- | --- |
| SILK STENT | . | . |  |  |  | No stenosis |
| N = 1 | | | | | | |