

Example of calculations of outcome continuous variables in a patient

| Locations | Preoperative visit (V0) | | | | 12 month follow-up (V5) | | | | Difference V5 - V0 | |
|---|-------------------------|--------|------|------|-------------------------|--------|-------|--------|-----------------------|---------|
| | A0 | U0 | D0 | R0 | A5 | U5 | D5 | R5 | D5-D0 | R5-R0 |
| 20 cm | | | | | | | | | | |
| 15 cm | 35 | 34.8 | 0.2 | 101% | 39 | 39 | 0.0 | 100% | -0.2 | -0.6% |
| 10 cm | 33 | 33 | 0.0 | 100% | 38 | 36 | 2.0 | 106% | 2.0 | 5.6% |
| 5 cm | 31 | 30 | 1.0 | 103% | 35 | 33.5 | 1.5 | 104% | 0.5 | 1.1% |
| Elbow fold | 26.2 | 26.5 | -0.3 | 99% | 29 | 28 | 1.0 | 104% | 1.3 | 4.7% |
| 5 cm | 27 | 27 | 0.0 | 100% | 29.5 | 28.5 | 1.0 | 104% | 1.0 | 3.5% |
| 10 cm | 24 | 24 | 0.0 | 100% | 26 | 26 | 0.0 | 100% | 0.0 | 0.0% |
| 15 cm | 19.5 | 20.2 | -0.7 | 97% | 22 | 21 | 1.0 | 105% | 1.7 | 8.2% |
| 20 cm | 16.5 | 17.5 | -1.0 | 94% | 19 | 17.5 | 1.5 | 109% | 2.5 | 14.3% |
| 25 cm | | | | | | | | | | |
| Hand | 18.5 | 18.2 | 0.3 | 102% | 19.5 | 19.5 | 0.0 | 100% | -0.3 | -1.6% |
| Maximum difference at 2 adjacent points | | | 0.0 | | | | 1.5 | | 1.7(a) | |
| Volumes | 2052.6 | 2050.6 | 2.0 | 100% | 2573.3 | 2399.4 | 173.9 | 107.2% | 171.9 | 7.2%(b) |

Measurements in each arm: **Locations:** Circumferences of the arm are taken at these locations from the elbow; **AX.** = Measurements on affected arm in visit “X”; **UX.** = Measurements on unaffected arm in visit “X”; **DX.** = Difference AX – UX; **RX** = Ratio AX / UX; **Volumes:** Hands are excluded from the computation of volumes.

Main outcome is based in these variables: **(a) M2CD5** = Maximum difference at two adjacent points in the inter-limb circumferential difference **(b) CVR** = Change (difference) in Volume Ratio.