SIMULATION IN CLINICAL PRACTICE: FIRST EXPERIENCE WITH SIM&SIZE BEFORE IMPLANTATION OF FLOWDIVERTER (PIPELINE) OR WEB-DEVICE FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS

Markus Holtmannspötter¹, Mario Martinez-Galdamez², Matti Isokangas⁴ Riccardo Ferrara³, Mathieu Sanchez³

¹ Rigshospitalet Copenhagen (Denmark)  
² Fundacion Jimenez Diaz Madrid (Spain)  
³ Sim&Cure (France)  
⁴ Oulu, Finland

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Disclosures

• Proctor and Consultant for Covidien/Medtronic

• Proctor and Consultant for MicroVention

• Consultant for Neuravi

• Proctor and Consultant for Sequent Medical

• Consultant for Stryker

• Consultant for Mentice
Proper sizing of devices to be implanted in intracranial aneurysms is mandatory

3D-angiography is accepted goldstandard to understand the anatomy and to perform reliable measurements

However measuring technique is usually restricted to several 2D-measurements on the 3D images, which are used to select the device

These measurements don’t account for complex 3D anatomy and the final behaviour of the device to be implanted – this is based mainly on the experience of the interventionalist

regarding prediction of foreshortening and proper wall apposition there are no tools in clinical use available
3D image Quality is the key

To achieve reliable precise measurements for 2D or 3D calculations you need:

• A well calibrated angiography machine
• The target region placed in the ISO Center
• And to make sure you have proper contrast filling of vessels and aneurysm without washout and possible contrast retention inside the aneurysm from previous runs using proper preparation of contrast bolus with enough x-ray delay
Aneurysm measurement
Result after WEB deployment SCA aneurysm
Supraopthalmic ICA aneurysm
3D and Measuring

– Vessel analysis tool and virtual stent
FRED deployed
243 patient-specific cases in the world
(91 retrospective cases + 152 prospective cases)
FD-SIZE
Flowdiverter

Aim in FD size is to select the best suitable FD (Pipeline) to assure:

• Good wall apposition and neck coverage

• Reduce the length to the shortest possible stent (with reason) to avoid torque (safety and ease of deployment) and to reduce the amount of possibly thrombogenic material inside the vessel

• To select the best fitting diameter which has effects on opening and on metal coverage
ID-Size
(intrasaccular device)

Aim ID-Size (WEB device):

• Proper selection of size
• Predict shape of device
• Predict the compression, "degree of activation" inside the aneurysm
• Predict Coverage of neck, bulging and covering of intraaneurysmal spaces /blebs/irregular shapes
Process of image handling and analysis: FD-Size

1 - Importing the DICOM files
2 - Select the region of interest (ROI)
3 - Threshold check
4 - Select the micro-catheter inlet
5 - Initialize the stent deployment
6 - Stent sizing
FD-SIZE Experience in Copenhagen

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<tr>
<th>Clinician:</th>
<th>Markus Holtmannspötter</th>
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<td>medtronic Sales representative:</td>
<td>Pertti Finnila</td>
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<td>Sim&amp;Cure adviser:</td>
<td>Riccardo Ferrara, Mathieu Sanchez</td>
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Color legend:
(vessel cut)
FD-Size Experience in Oulu Finland
FD Size experience in Madrid

Clinician: Medtronic Sales representative: Sim&Cure adviser:
Mario Galdamez
Felix Lasheras
Riccardo Ferrara and Mathieu Sanchez

1st choice - without Sim&Size
Looking at the Philips images of the old DICOM the proximal diameters measures 4.33. For this reason Mario would like to use a 4.25 pipeline.

2nd choice - with Sim&Size, with old DICOM
Using the software and the same DICOM, apparently, a 3.75 could be sufficient.

3rd choice – with Sim&Size, with new “fresh” 3D images
regarding the choice of the flow-diverter diameter we have the same results: a 3.75 could be good but we may take a 4 to be sure
Process of image handling and analysis: ID-Size

1. Import the DICOM files
2. Select the region of interest (ROI)
3. Threshold check
4. Click on the aneurysm dome
5. Place the neck center position
6. Choose and place your WEB device
WEB ID-SIZE used for WEB selection

In this case, the considerations were between 2 WEB sizes (7 SLS and 7X6 SL) even though the shape of the aneurysmal bag corresponded more to an SLS model.

In the end, the 7SLS presented a less dangerous bulging and a better apposition to the wall.

The control imaging shows a good correspondence with the simulation.
Difficult Sizing Case for WEB implantation
No access to ID-Size software from SIM & CURE that day
First and second attempt where device was too big:

WEB SL 11x5 and WEB SL 10x6
Unexpectedly the SLS 9 x 7,6 proved suitable
Retrospectively analysis of 3D data by SIM & Cure, blinded to the treatment decisions and WEB-Selection

- **10SLS**: clearly too large even before launching the computation
- **10X6SL**: Dangerous bulging = too big
- **10X5 SL**: I think this one could be an option because we over-estimate a little bit the bulging in the software.
- **9SLS**: I have a real hesitation on this size, it seems possible but risky because it covers a little bit the small branch out of the sac
- **8SLS**: the less risky choice but the wall apposition is not great but acceptable especially at the neck, but more recurrence risk as the device is less activated
Conclusions FD-Size:

Provided there is good quality of 3D-Angiography base data,

- **FD-size**, allows **precise preimplantation simulation** for available Pipeline sizes accounting especially for foreshortening or lengthening in tapered vessel course
  
- **Displaying degrees of circular wall apposition** of the FD device over the length of the device/vessel is helpful to choose more often shorter devices, than in manual measuring where I sometimes tend to add some more safety margins
  
- Allows to see **changes in apposition by manipulation of the device** by more or less compression during deployment, thus it’s possible to select the smallest fitting diameter, not to lose FD effect by unnecessary oversizing which would result in reduced metal coverage at the neck
Conclusions ID-Size:

• ID size allows like FD-size good prediction of aneurysm wall apposition of the device
• Prediction of the to be expected compression/activation of the WEB device, which is important to have a stable configuration of the WEB of time, to avoid recurrences
• Reliable prediction of the bulging into the parent vessel, thus avoiding dangerous oversizing

In summary, both software modules allow to test virtually several different devices before implantation and are very helpful to select the best size of the device and to anticipate the behaviour of the device in the given anatomy
All this in reasonable time of around 10 min
Thank you for your attention!