

Flex to Alpha: Is there a learning curve?

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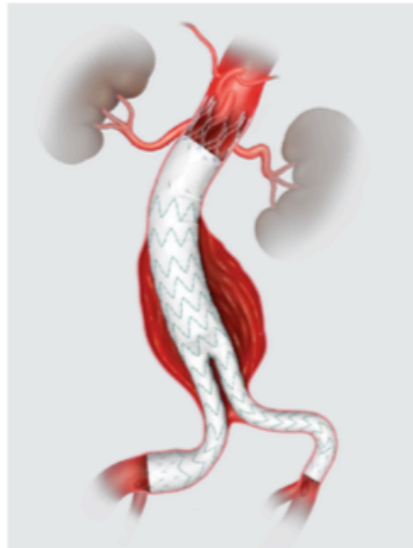
Background

- The Cook Zenith Alpha is the new Endovascular Platform for treating Infra-renal AAA replacing the Cook Zenith Flex.

ADVANTAGES:

- Simplified Deployment
- Lower Profile Device
- Nitinol Stents

- Typically learning curve seen with EVAR - requires 35 cases to reach stable high rate technical success¹



Depiction of the new Cook Zenith alpha in situ

Aims

- Assess if there a learning curve with fluoroscopic times and radiation exposure in the Cook Zenith Alpha
- Assess if there a significant difference in operative measures when changing from Cook Flex to Cook Alpha Endovascular platforms for infra-renal AAA repair

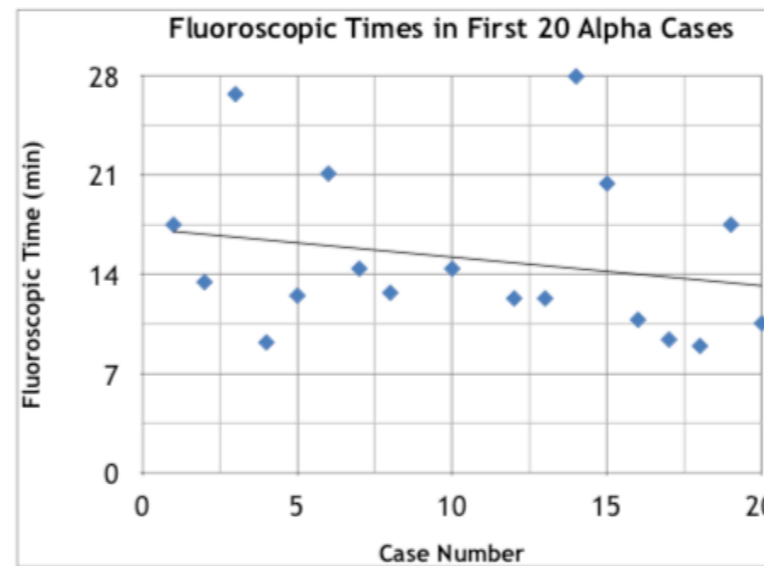
Methods

- Retrospective review of last 20 Cook Flex cases and first 20 Cook Alpha cases (operative time, radiation exposure, fluoroscopic time, 30-day mortality, adverse CT findings at 6-week surveillance). With this data, following outcomes defined:
 - 1) Compare fluoroscopic times for first 20 Alpha cases
 - 2) Compare radiation exposures for first 20 Alpha cases
 - 3) Compare operative measures for last 20 Flex cases and first 20 Alpha cases
 - 4) Comparison of post-operative measures for Flex vs Alpha = 30-day mortality, evidence of adverse findings on 6-week surveillance CT

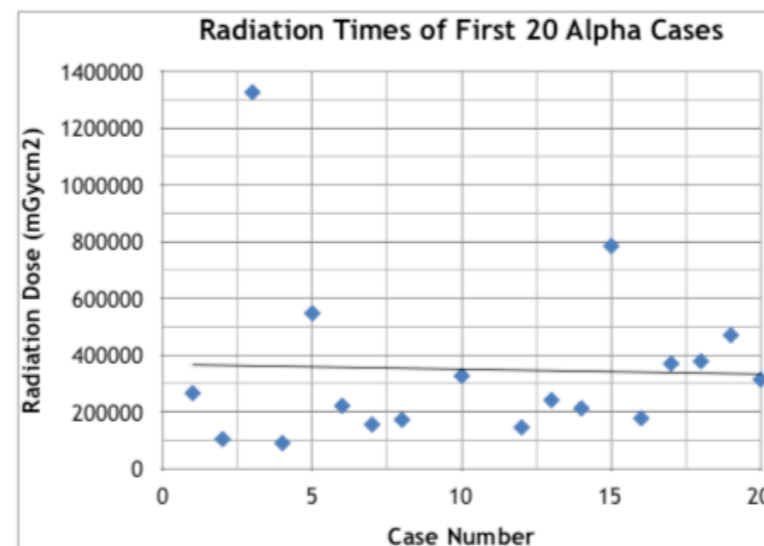
Results

- All data available in 37/40 patients

1) Slight trend towards decreasing fluoroscopic times across first 20 Alpha cases.



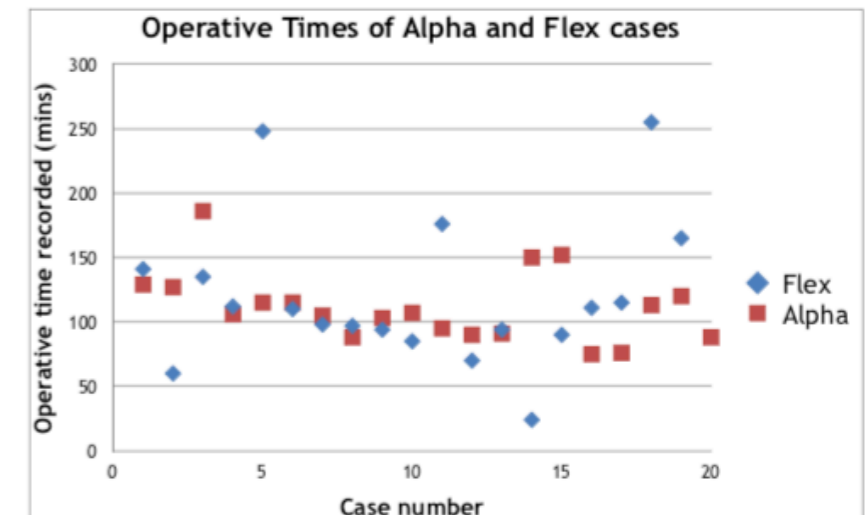
2) Minimal difference for radiation doses across first 20 Alpha cases.



Results

3) No significant difference between operative times for Alpha vs Flex (20 minutes vs 112 minutes, p=0.28)

- No significant difference for fluoroscopic times between Alpha and Flex (350289 mGycm² vs 323962 mGycm² p=0.37)
- No significant difference for radiation exposure between Alpha and Flex (15m 08s vs 16m 26s, p=0.34)



4) Comparison of post-operative measures:

30-day Mortality = 0% in both groups

Endoleaks - 1 x type 1 in each group at 6 week surveillance

Conclusions

- Early cases with Alpha stent had slightly higher fluoroscopic times and radiation exposures as expected.
- In this small series, overall there was no significant difference in operative measures (fluoroscopic times, radiation exposure and operative times) when changing Endovascular Platforms for Infra-renal AAA repair
- With appropriate industry support, a smooth transition can be achieved with equivalent outcomes for the Cook Alpha Platform for treating Infra-renal AAA repair

References

- 1) Kalteis M, Benedikt P, Huber F, Haller F, Kastner M, Lugmayr H. Looking for a learning curve in EVAR based on the Zenith Stent Graft. *Int J Angio*, 2012;21:223-228