A076

Evaluation of the Effectiveness of Peripheral artery Self-expanding Sirolimus Drug-Eluting Stent using miniature pigs

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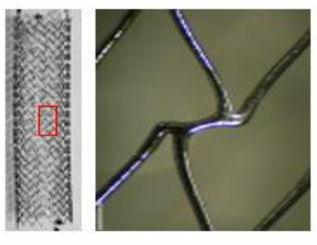
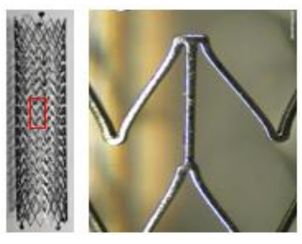
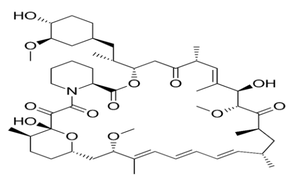
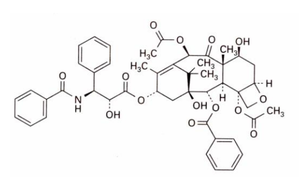
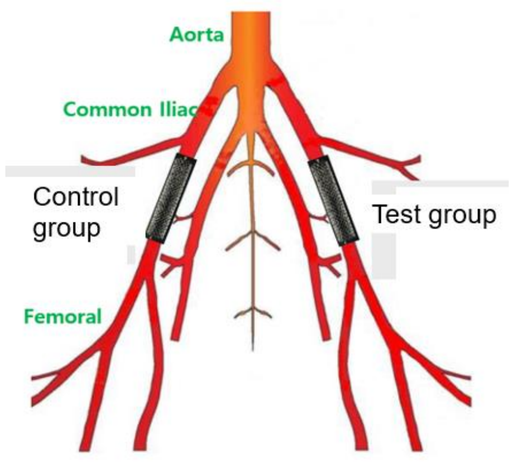
Abstract

Among drug-eluting stents used in vascular intervention, the drug Paclitaxel has been widely used in peripheral blood vessels. However, the drug Paclitaxel is very toxic and many side effects have been reported, therefore many doctors are reluctant to use it. Accordingly, an alternative drug called Sirolimus has been studied, and a lot of data and products are available in the cardiovascular field. Consequently, the development of products using Sirolimus as drug-eluting stents for peripheral blood vessels is being actively conducted. The safety and effectiveness of Sirolimus drug were evaluated through large animal testing of the Sirolimus drug-eluting stent for peripheral blood vessels being developed by Genoss.

Experiment

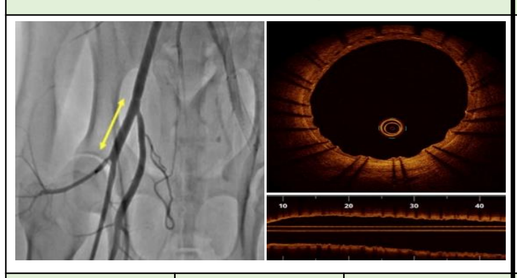
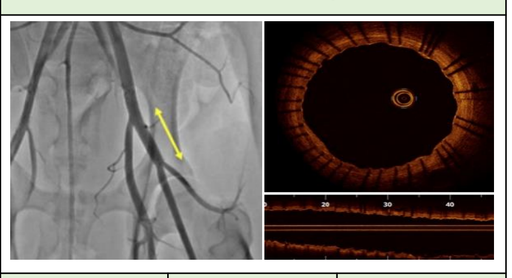
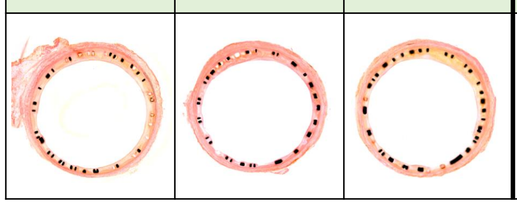
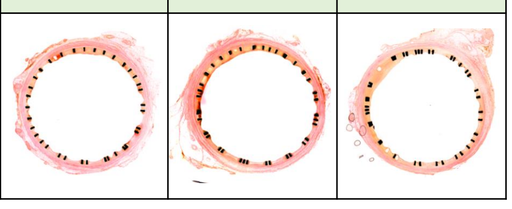
	Test group	Control group
Stent		
Drug	Sirolimus 	Paclitaxel 

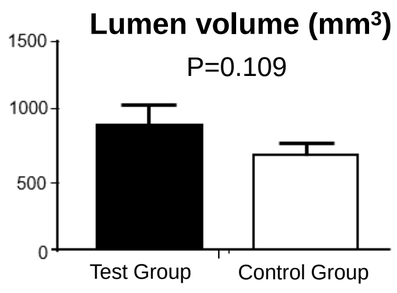
Purpose	Verification of safety and effectiveness
Animal	Miniature pig
Position	Iliofemoral arteries
Volume	twelve
Term	30 / 180 days
Methods	- Carotid puncture approach - Using the Ø6x40mm stent - Angiographic and OCT - Histopathlogy analysis

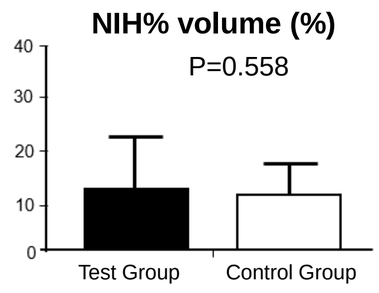


Results 1 (Short-term 30 days)

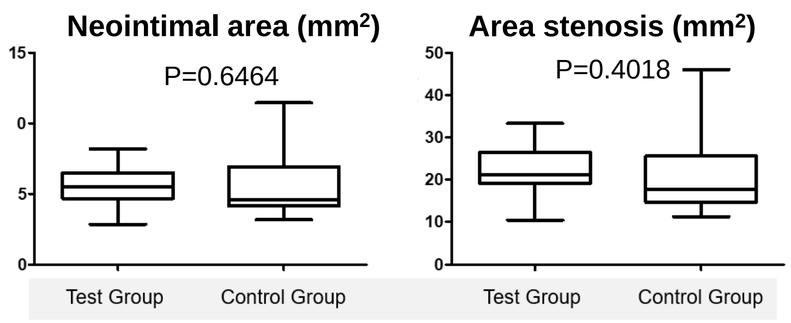
- **Angiographic & OCT & Histopathology analysis**

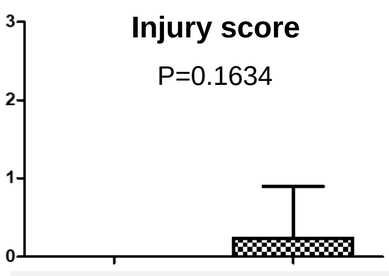
Test Group			Control Group		
					
Proximal	Middle	Distal	Proximal	Middle	Distal
					

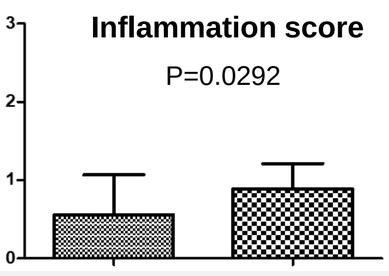




- Neither the test group nor the control group effectively inhibited NIH, showing stenosis of more than 50%.
- The test group sirolimus stent was good in late loss (mm), but there was no significant difference.



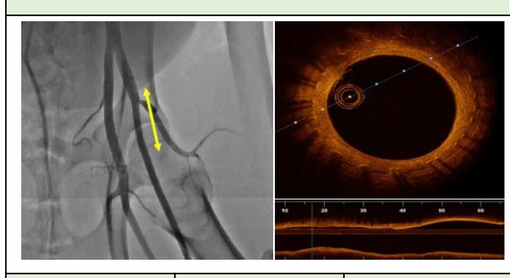
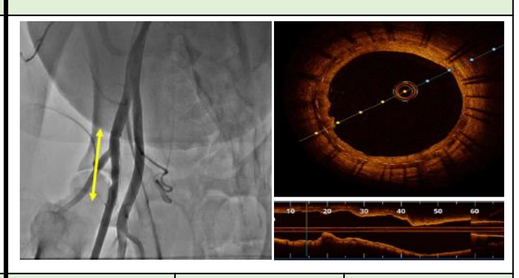
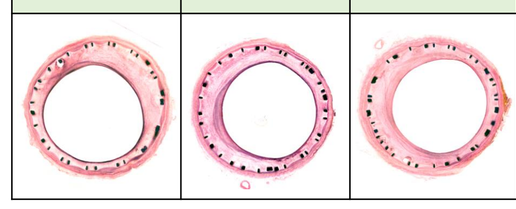
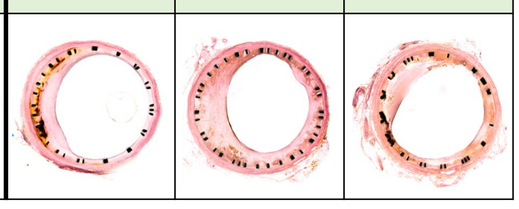


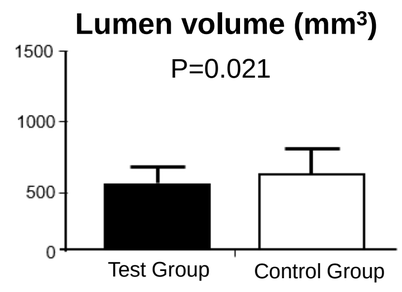


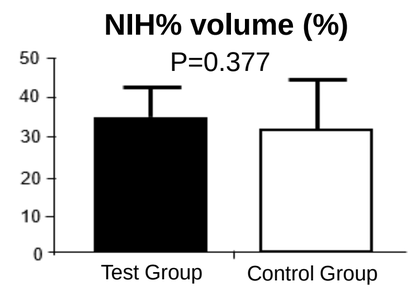
- There was no significant difference in the degree of vascular stenosis between the test group and the control group.
- In terms of the degree of vascular wall inflammatory cell infiltration, the control group was higher than the test group.

Results 2 (Long-term 180 days)

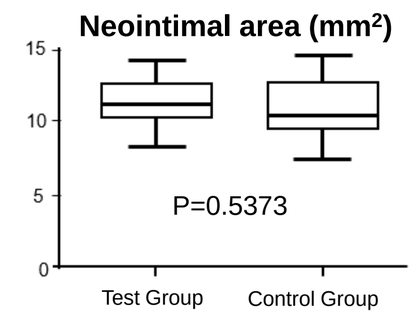
- **Angiographic & OCT & Histopathology analysis**

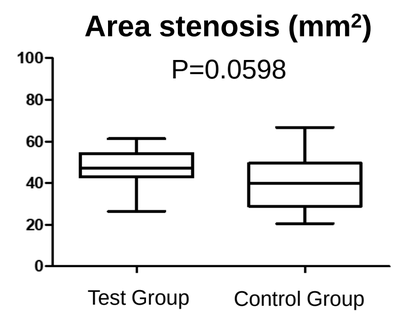
Test Group			Control Group		
					
Proximal	Middle	Distal	Proximal	Middle	Distal
					

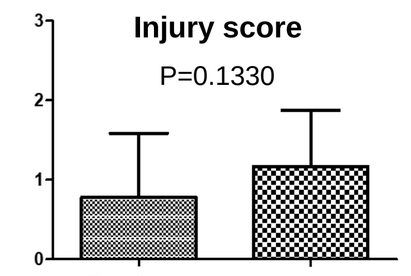


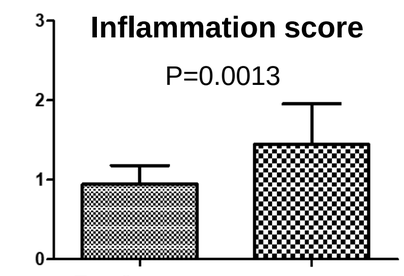


- Both the test group and control group confirmed the effect of effectively inhibiting NIH (neointimal in hyperplasia)
- NIH volume or NIH percent volume(%) dose not show a statistically significant difference between the two stent group.









- The ratio of vascular stenosis was slightly higher in the group, but there was no statistically significant difference.
- The degree of vascular wall inflammatory cell infiltration was high in the control group, and many above severe.

Summary

- As a result of comparing and evaluationg the long-term safety of 12 pigs, a total of 24 products, both the test and control groups confirmed the same effectiveness in inhibiting NIH (neointimal in hyperplasia)
- In terms of the safety of the two drugs, the Sirolimus drug (test group) showed statistically significant results compared to the paclitaxel drug (control group). (Inflammation, blood vessel damage, etc.)
- As a result of evaluation the long-term performance through animal experiments, it is judged that the Sirolimus drug has an equivalent effect compared to paclitaxel drug.

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