

**WS™**

## **FAR-INFRARED THERAPY UNIT**

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WS FAR-IR Medical Technology

## **About WS™ Far-infrared Therapy Unit**

- Quality Management System Certification:
  - ISO 13485:2003**
  - GMP (Taiwan)**
- Product Certification:
  - CE 0120 (Class IIa device)**
  - Korean FDA Approval**
  - Thailand FDA Approval**
  - Taiwan Dept. of Health Approval**
  - US FDA 510(k)**

## Product Certification

- **Medical Device Classification**
  - Europe : Class IIa
  - US : Class II
- **Indication for Use :**
  - The WS Far Infrared Therapy Unit may be used for temporary relief of muscle and joint pain, stiffness, and spasm by temporary increase in local blood circulation and muscle relaxation at location where the treatment is applied.
- **Electromagnetic Compatibility Testing :**
  - **IEC 60601-1-2:2001, IEC 60601-1-1:2000**
- Patented in Taiwan, US, mainland China; patents pending in the US

## Hemodialysis in Taiwan

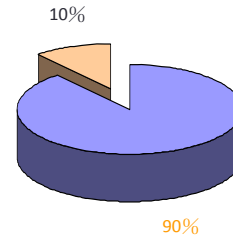
### In Taiwan...

- Population: 23million
- Dialysis population : around 60,000 with 55,000 on HD
- HD center : about 550



## Current FIR Application

- HD center equipped with FIR : about 500
- # FIR purchased by HD center : about 1500
- Patients that purchased FIR : about 2,000
- HD center equipped with FIR : **90%**



6

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## Current FIR Application

- **Out of the 55,000 HD patients in Taiwan...**
  - At least 26,000 have used WS Far Infrared Therapy Unit during HD
  - More than 2,500 use WS Far Infrared Therapy Unit for home care



## Penetration Point

- After Vascular Access Surgery
  - Home use for daily care during maturation
  - 3 time/week treatment in HD clinics
- Routine Care of VA in HD clinics
  - 3 time/week treatment in HD clinics during Dialysis
  - Special treatment before dialysis for difficulty-puncture VA

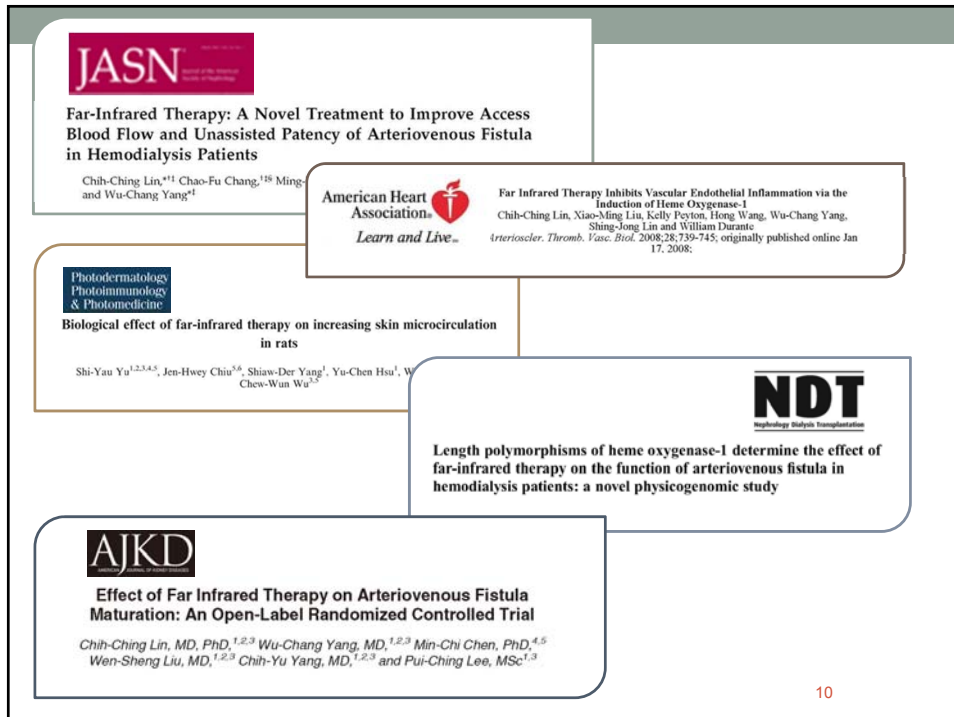


## User Comment

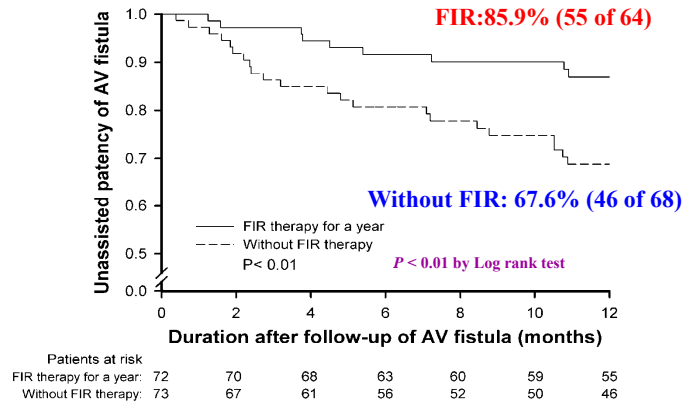
- Blood Flow
- Puncture
- Pain
- Hematoma
- Steal Syndrome
- Vein Pressure
- Hypertension during HD

## Research Outcome

- Vascular Access
  - Improving blood flow
  - Improving AVF maturation
  - Prolong patent period of vascular Access
  - Decrease restenosis rate of Graft
- Ischemia
  - promote Angiogenesis
  - Improving Ischemia/reperfusion injury
  - Improving chronic wound healing

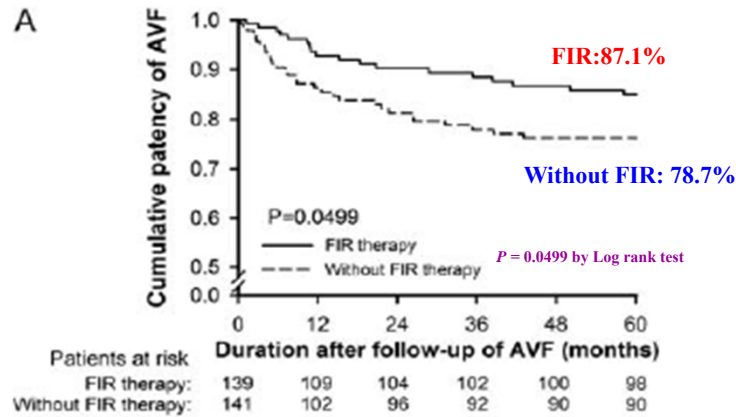


## 1 -year Survival Curves for Unassisted Patency of AVF between the two HD Groups



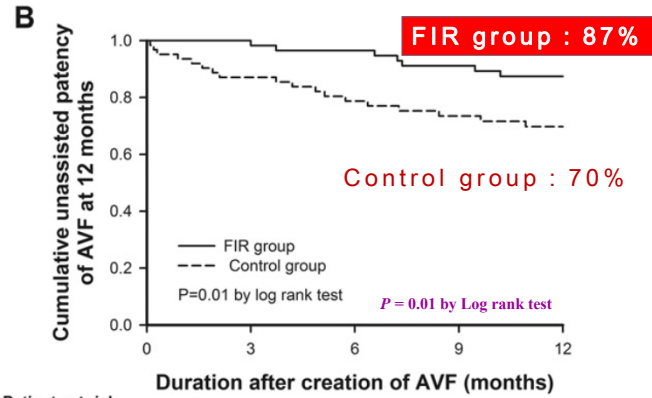
CC Lin et al. *J Am Soc Nephrol.* 2007; 18:985-992

## 5-year Survival Curves for Unassisted Patency of AVF between the two HD Groups



CC Lin et al. *Nephrol Dial Transplant* 2013 May; 28(5): 1284-93

## 1-year Survival Curves for Unassisted Patency of newly created AVF between the two HD Groups

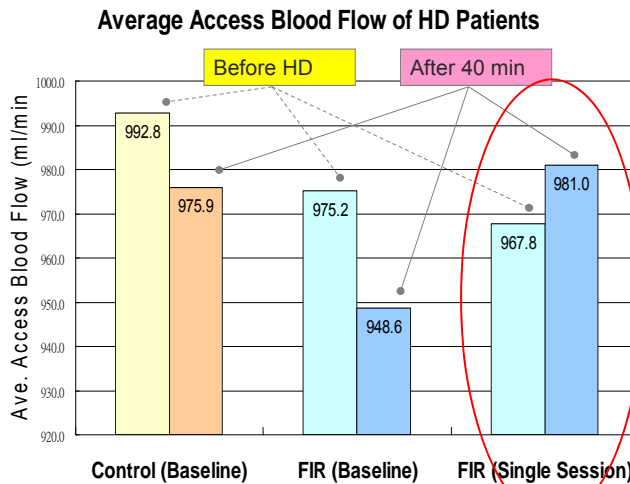


**Patients at risk**

|                |    |    |    |    |    |
|----------------|----|----|----|----|----|
| FIR group:     | 60 | 56 | 54 | 49 | 46 |
| Control group: | 62 | 53 | 46 | 41 | 37 |

CC Lin et al. *Am J Kidney Dis.* 2013; 62(2):304-311

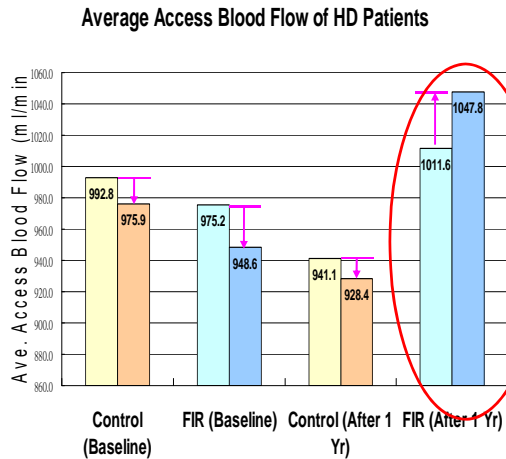
## Blood flow slightly increase by single treatment of Far-infrared Therapy



- Both control and FIR group experience a decrease of access blood flow after 40 minutes for baseline measurement
- After one session of 40 minutes of FIR, the test group experienced an increase of access blood flow

CC Lin et al. *J Am Soc Nephrol.* 2007; 18:985-992

## Blood flow increase after 1 year treatment of Far-infrared Therapy

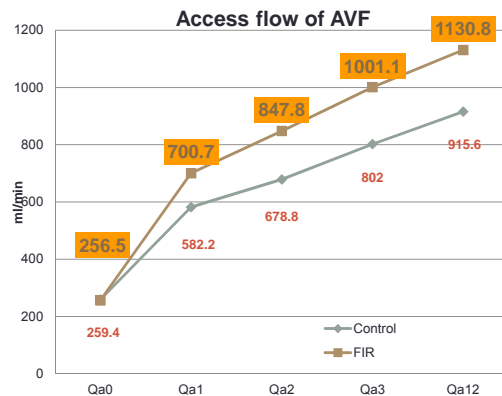


- After 1 year, the ave. access blood flow of the control group before HD shows a decrease. Whereas that of the FIR group shows an increase.

- At one year, after 40 minutes of FIR, the test group experience a bigger increase of access blood flow

CC Lin et al. *J Am Soc Nephrol.* 2007; 18:985-992

## FIR Progressively increase of access blood flow of newly created AVF from the 1<sup>st</sup> to 12<sup>th</sup> month



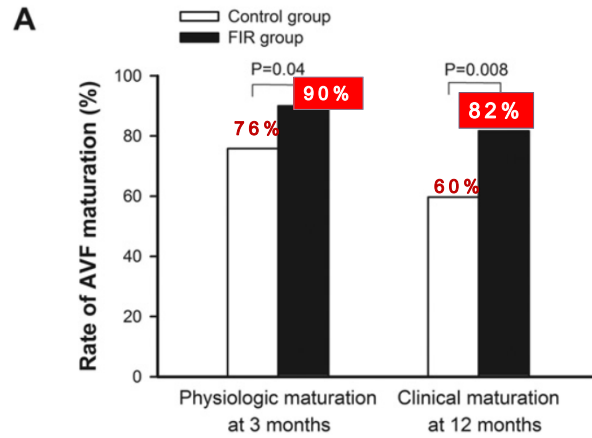
- For new AVF, using FIR within one year,

- Increase 450ml/min of blood flow within one month
- The change of blood flow is 37% higher than control group.

CC Lin et al. *Am J Kidney Dis.* 2013; 62(2):304-311

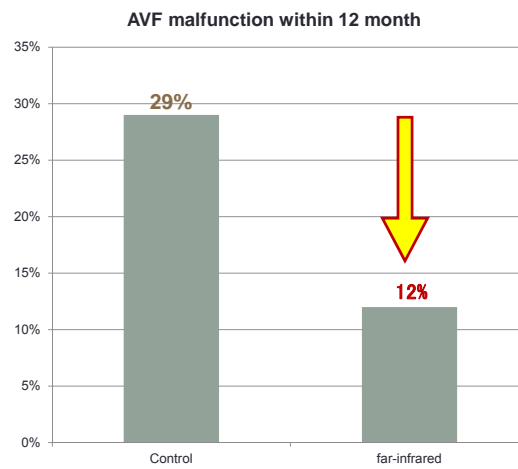


Increase 14% AVF physiologic maturation rate (3 month) and 22% AVF clinical maturation rate (12 month)

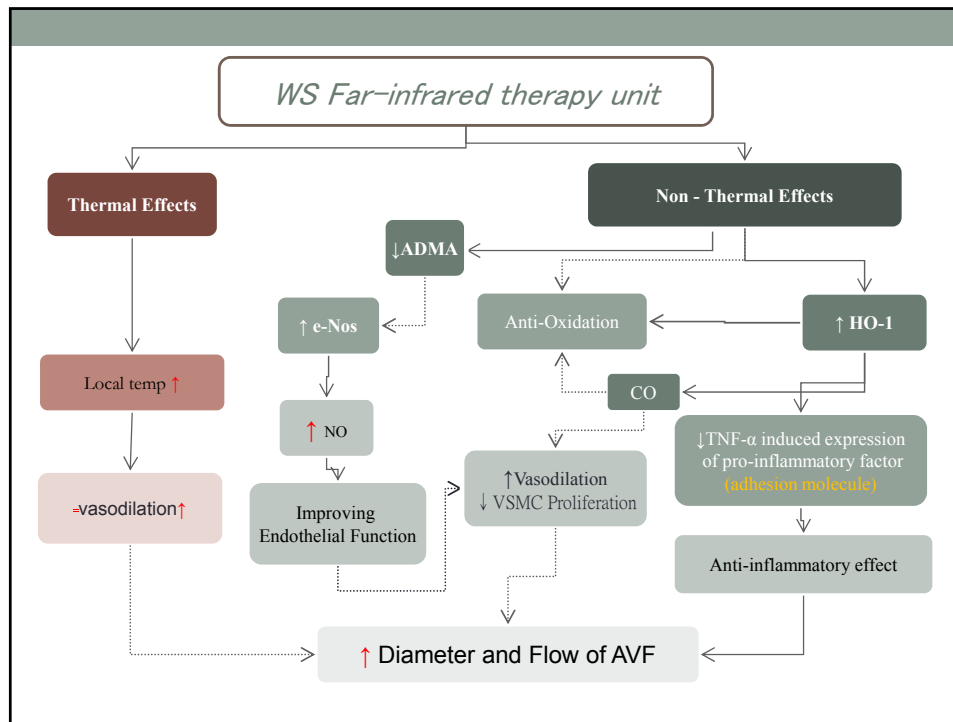


CC Lin et al. *Am J Kidney Dis.* 2013; 62(2):304-311

Dramatically reduction of malfunction of newly created AVF at 12 month (ARR:17%, RRR:59%)



CC Lin et al. *Am J Kidney Dis.* 2013; 62(2):304-311



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