

Performance of Sino-implant (II) during routine service delivery in Kenya and Pakistan

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Sino-implant (II)

- 2-rod subdermal hormonal implant with levonorgestrel used for up to 4 years
- Cost approximately US \$8
- Made by Dahua in Shanghai, China
- In published studies, first-year pregnancy rates near zero
- Approved in over 20 countries, including Kenya (branded Zarin) and Pakistan (branded Femplant)
- Over nine million units distributed since 1996



Two Sino-implant (II) Studies under PROGRESS

- Clinical data on the product mainly limited to China
- Most research conducted during the 1990s
- Results mainly published in Chinese literature

Purpose → To collect key information on performance of Sino-implant (II) as used in routine service settings in Kenya and Pakistan

Study Sites

Kenya



- 3 clinics on periphery of Nairobi
- All affiliated with MOH
- N = 602 participants

Pakistan



- Study in collaboration with Marie Stopes Pakistan
- 19 clinics in Karachi, Rawalpindi, Hyderabad, other cities:
 - 13 MSI clinics
 - 6 MOH clinics
- N = 724 participants



Study Objectives

- Measure **contraceptive effectiveness** during first year of use
- Collect **safety information**: side effects and serious adverse events (SAEs)
- Collect information on **complications** during insertion and removal
- Assess **acceptability** of implant during first year of use and measure removal rates

Study Design

- Approximately 600 women in each country who decide to use Sino-implant (II) enrolled and randomly assigned to:
 - Active cohort, or
 - Passive cohort
- Active cohort scheduled for follow-up visits at 3 and 12 months after insertion
- Passive cohort asked to return in case of problems, suspected pregnancy, or desired removal
- Standardized questionnaires at each clinic visit

Eligibility Criteria

- Decided to receive Sino-implant (II) for contraceptive purposes, and met clinic criteria for use
- Age 18-44
- Willing to sign informed consent form
- Willing to give contact information
- Willing to return for follow-up visits



PRELIMINARY RESULTS

Sociodemographic Characteristics

Characteristic	Kenya (n=602) n (%)	Pakistan (n=724) n (%)
Age: Mean (median; range)	28 (27; 18-44)	28 (28; 18-41)
Marital status		
Married/living in couple	531 (88.4)	724 (100)
Single, widowed, divorced or separated	70 (11.7)	-
Education level		
None/non-formal/some primary	47 (7.8)	318 (43.9)
Completed primary	357 (59.3)	172 (23.8)
Completed secondary/vocational or technical training	166 (27.6)	136 (18.8)
Higher than secondary	32 (5.3)	98 (13.5)
Profession		
Unemployed/housewife	247 (41.0)	656 (90.6)
Other	355 (59.0)	68 (9.5)

Baseline Obstetric and Contraceptive History

Characteristic	Kenya (n=602) n (%)	Pakistan (n=724) n (%)
Parity: mean (median; range)	2.4 (2; 1 to 8)	3.7 (3; 0 to 20)
Living children: mean (median; range)	2.4 (2; 1 to 8)	3.4 (3; 0 to 12)
Most recent contraceptive method		
None	112 (18.6)	445 (61.5)
Oral	228 (37.9)	43 (5.9)
Injectable	151 (25.1)	79 (10.9)
Implant	20 (3.3)	nil
Condom	14 (2.3)	108 (14.9)
Other	77 (12.8)	49 (6.8)

Insertion Characteristics

Characteristic	Kenya (n=602) n (%)	Pakistan (n=724) n (%)
Duration in minutes: mean (median; range)	3.6 (3; 2 to 8)	8.5 (7; 2 to 20)
Complications during insertion		
No	601 (99.8)	717 (99.0)
Yes	1 (0.2)	7 (1.0)
Discomfort during insertion would prevent future insertion		
No	591 (98.2)	391 (54.0)
Yes	11 (1.8)	135 (18.6)
Don't know	-	198 (27.3)

Post-insertion Pregnancies

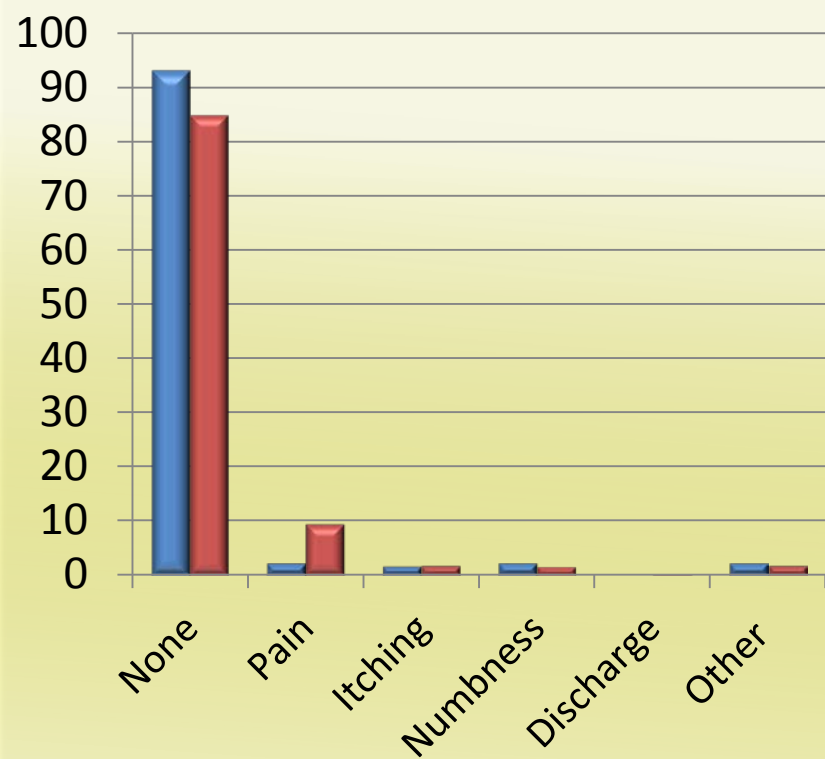
- 1 post-insertion pregnancy reported in Kenya
 - ruptured ectopic at 14 months post-insertion
- 4 post-insertion pregnancies in Pakistan
 - 2 followed post-abortion care
 - 2 women did not use barrier method post-insertion
- Pregnancy rate (Pearl) at 12 months
 - Kenya: 0.2 per 100 woman-years (0.0, 1.1)
 - Pakistan: 0.6 per 100 woman-years (0.2, 1.6)

Serious Adverse Events (SAEs)

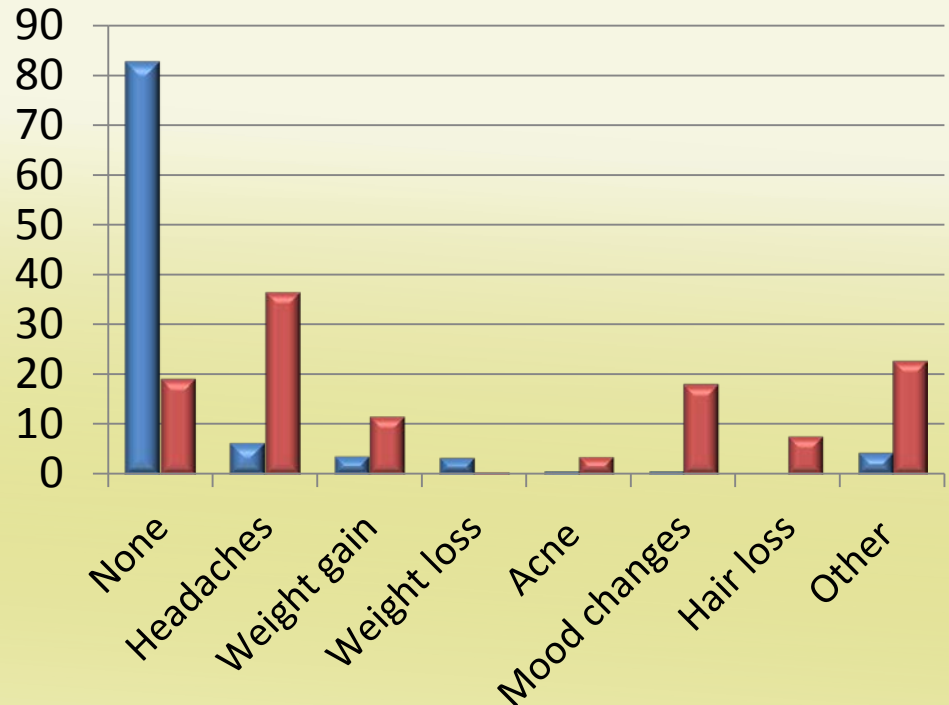
- 4 reported SAEs during the studies
 - All in Kenya study
 - 3 of the SAEs were unrelated to study product or procedures
 - 1 SAE was possibly related to Sino-implant
 - ruptured ectopic pregnancy in Kenya which resulted in laparotomy and hospitalization

Side Effects Reported at Follow-up

Percent of women who ever experienced problem at insertion site



Percent of women who ever reported other physical or emotional problems



■ Kenya (n=298)

■ Pakistan (n=443)

Implant Removals

- **Cumulative probability of removal at 12 months**
 - Kenya: 3.5 per 100 women (95% CI 1.9, 5.0)
 - Pakistan: 10.8 per 100 women (95% CI 8.5, 13.2)
- **Removal complications**
 - Kenya: nil
 - Pakistan: 2 (pain)

Implant Removal Reasons

Kenya – Removal reasons (n=13)



- Improper insertion (2)
- Discomfort/pain (4)
- Medical problem (4)
- Non-medical problem (2)
- Not her decision, opposition (1)

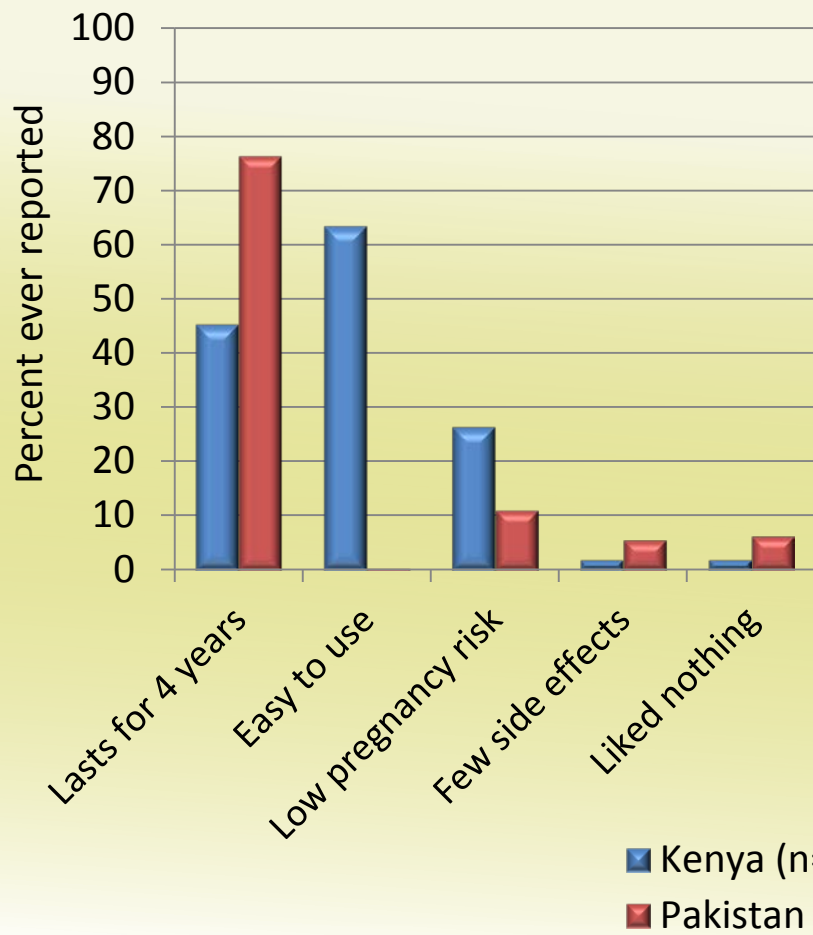
Pakistan – Removal reasons (n=77)



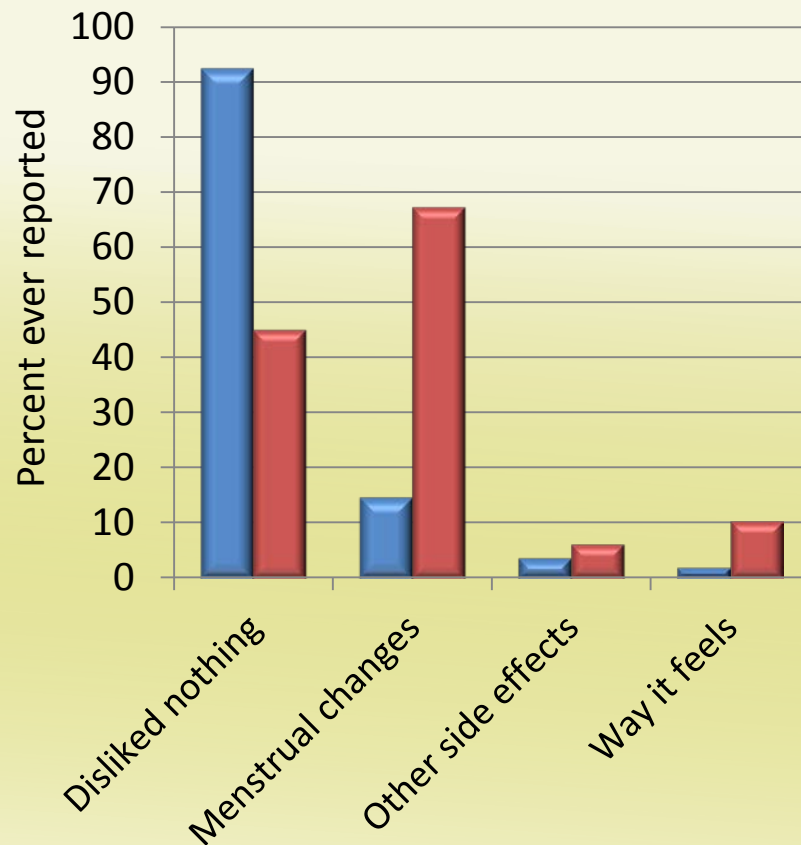
- Improper insertion (3%)
- Discomfort/pain (9%)
- Medical problem (61%)
- Non-medical problem (13%)
- Wanted to get pregnant (14%)

Acceptability - 1

What women liked about the implant



What women disliked about the implant



Acceptability - 2

- **Overall experience with implant (ever reported)**
 - ***Very favorable***: Kenya 96%; Pakistan 31%
 - ***Somewhat favorable***: Kenya 9%; Pakistan 75%
 - ***Indifferent***: Kenya: <1%; Pakistan 21%
 - ***Somewhat unfavorable***: Kenya 4%; Pakistan 5%
 - ***Very unfavorable***: Kenya 1%; Pakistan 2%
- **Acceptability of bleeding pattern (ever reported)**
 - Kenya: 94% acceptable; 19% unacceptable
 - Pakistan: 73% acceptable; 26% unacceptable

Conclusions

- The implant was safe and effective in these studies during the first year of use
- Few insertion and removal complications were reported
- Acceptability rates were high, though higher in Kenya than Pakistan
- Bleeding patterns were generally acceptable, though more so in Kenya than Pakistan
- Removals were more common in Pakistan than Kenya