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MCC News

An e-newsletter about male circumcision for HIV prevention in Kenya

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Dr. Quentin Awori, one of the investigators conducting the Shang Ring study, uses a model to show a potential client how the device works.

Photo by Dan Ouma/EngenderHealth

Innovative device could transform delivery of male circumcision

Men began enrolling in a study at Homa Bay District Hospital this month to help assess a medical device that could revolutionise how male circumcision services are offered in areas hardest hit by the HIV epidemic.

The device, known as the Shang Ring, could help Kenya and other countries in sub-Saharan Africa meet the rising demand for voluntary medical male circumcision (VMMC) services and prevent the spread of HIV.

Thousands of men in the communities most affected by HIV have been seeking VMMC services since three randomised controlled trials found that male circumcision reduces a man's chances of contracting HIV through vaginal

intercourse by as much as 60 percent. In Kenya, more than 230,000 men and boys have become circumcised in the past two-and-half years.

Meeting this growing demand for male circumcision could have a dramatic impact on the HIV/AIDS epidemic. An estimated 4 million HIV infections could be prevented over 20 years if 28 million men in 14 countries in sub-Saharan Africa became circumcised in the next five years. In Nyanza Province alone, circumcising 640,584 men (80 percent of the uncircumcised men) by 2013 could avert about 900,000 HIV infections in men, women, and children over 20 years.

Results from previous studies—including two conducted at Homa Bay District Hospital—suggest that the Shang Ring could help bring these ambitious goals within reach.

“The Shang Ring reduces the time needed to perform male circumcision surgery from 20 or 30 minutes to about five minutes or less, greatly increasing the potential number of men who can be circumcised during the same time period,” said David Sokal of FHI, who is one of the principal investigators on the Shang Ring studies. He added that administering anaesthesia adds about five minutes to the time needed for both types of procedures.

“Using this device, rather than standard surgical procedures, could enable areas that have been devastated by the HIV epidemic to dramatically expand access to safe, high-quality male circumcision services,” Dr. Sokal said.

Assessments of the Shang Ring in Africa began with a pilot study conducted at Homa Bay District Hospital by EngenderHealth in collaboration with Dr. Marc Goldstein and Dr. Philip Li, urologists at the Weill Cornell Medical College. The results were promising, said Dr. Mark Barone, senior clinical advisor at EngenderHealth. “As a sutureless procedure with little or no bleeding, it is faster to perform, less invasive, and—based on preliminary data—highly acceptable to men,” he said.

In the pilot **study**, published in the 21 February online issue of the *Journal of Acquired Immune Deficiency Syndromes* by EngenderHealth, Weill Cornell Medical College, and the Kenyan Ministry of Health, all 40 participants said that they were satisfied with their circumcisions and would recommend the procedure to others. Eighty percent of the men in this pilot study reported that they were back to work two days after the surgery.

Building on the promising results of the first study, FHI, EngenderHealth, and Weill Cornell Medical College are conducting three additional studies, supported by a grant to FHI from the Bill & Melinda Gates Foundation, to understand how

the Shang Ring might transform the provision of male circumcision services.

The first study by the FHI-led group was completed in February. It was designed to address concerns about what might happen if a man circumcised with the Shang Ring did not return for his follow-up visit after seven days, which is recommended for all male circumcision clients in Kenya.

Like the Plastibell device that is widely used in the United States for infant male circumcision, the Shang Ring remains on the penis after the procedure. The Plastibell device falls off after several days. But the Shang Ring stays on longer, because adults heal more slowly than infants. Therefore, the Shang Ring label recommends removal on the seventh day after surgery.

The 50 men participating in the study were assigned to have the Shang Ring removed at seven, 14, or 21 days. The device detached spontaneously before 21 days in most men, and often before 14 days, with no significant adverse effects.

These results are reassuring, because they show that the Shang Ring can be used safely in settings where long distances from health facilities and other constraints can make it difficult for clients to return on time for medical follow-up.

Investigators at Homa Bay District Hospital report that men are eager to participate in the second study, which began this month. “The results from the previous Shang Ring studies generated significant local interest in and acceptance of the Shang Ring.” said Dr. Quentin Awori of EngenderHealth. “We know that demand is high for male circumcision using the Shang Ring, and we are more committed than ever to ensure that it can be provided safely.”

The current study, which will enroll 400 men who wish to be circumcised in Kenya and Zambia, is a randomised controlled trial comparing the use of the Shang Ring with the standard male circumcision procedure. “If this trial proves that the Shang Ring procedure is a safer, more efficient alternative to conventional male circumcision surgery, then it could pave the way for the third study, a larger demonstration project involving 1,000 men,” explained Dr. Goldstein of Weill Cornell Medical Center.

This phased approach to studying the Shang Ring follows the recommendations of the World Health Organization (WHO), which has called for introductory research to establish the safety, effectiveness, and acceptability of various male circumcision devices in different settings before proceeding with more widespread implementation in sub-Saharan Africa.

The Shang Ring was approved for marketing in China in 2005, where about

40,000 of the devices have been sold in the past few years. In October 2008, it received the European Union's CE mark, certifying that it meets EU safety standards and is approved for marketing in Europe.



How the Shang Ring Works: After the administration of local anaesthesia, the inner ring of the Shang Ring is fitted at the base of the glans of the penis. The foreskin is everted (turned inside out) over the inner ring, and then the outer ring is secured over the inner ring. This forms a tight seal around the foreskin, which minimises the risk of infection. Next, the foreskin is removed with sterile scissors. Bleeding is minimal, and no stitches are required.

Photos by Quentin Awori/EngenderHealth

Male circumcision offers lasting protection

Male circumcision continues to provide significant protection from HIV infection years after the procedure, said scientists reporting on a study from Rakai, Uganda, at the 18th Conference on Retroviruses and Opportunistic Infections in Boston, Massachusetts, USA, on 28 February.

The study followed 1,700 of the almost 5,000 Ugandan men who had participated in a randomised controlled trial—one of three trials that confirmed male circumcision's protective effect against HIV infection. Four out of five participants in the Uganda trial who had not been circumcised during the trial opted to get circumcised at its conclusion in December 2006.

The follow-up study found that after more than two years, the risk of HIV infection was reduced by 68 percent among the men circumcised after the trial compared to those who had declined male circumcision at the end of the trial.

This protective effect was sustained among men who had been circumcised during the trial more than four years ago. Overall, from the beginning of the trial, the men who became circumcised—during or after trial—had a 73 percent reduced risk of HIV infection compared to the uncircumcised men.

The study found no evidence that men were engaging in riskier behaviour after becoming circumcised. Although consistent condom use declined by about 4

percent after the trial, when the men were no longer receiving intensive counselling on risk reduction, changes in condom use did not differ significantly between circumcised and uncircumcised men.

These preliminary results from Uganda mirror those of an ongoing study in Kisumu among almost 1,500 men who participated in another randomised controlled trial of male circumcision for HIV prevention. At the XVIIIth International AIDS Conference in July 2010, researchers from the Universities of Nairobi, Illinois, and Manitoba (UNIM) Project reported a 66 percent reduced risk of HIV infection among circumcised men compared to uncircumcised men after four-and-a-half years of follow-up.

Both studies found that uncircumcised men had more than double the risk of becoming infected with HIV, and they suggest that the protective effect of male circumcision may be strengthened over time.

Male circumcision in the news

Male circumcision outreach spurs treatment demand in Kenya

Science Speaks: HIV and TB News, 7 March

Moonlight circumcision offers new hope in battle against HIV-Aids

Nairobi Star, 21 March

Resources

The Clearinghouse on Male Circumcision for HIV Prevention

Developed by the World Health Organization, AVAC, and FHI, this Web site is a comprehensive source of information and resources about male circumcision for HIV prevention.

The Male Circumcision Consortium (MCC) works with the Government of Kenya and other partners—including the US President's Emergency Plan for AIDS Relief (PEPFAR), which supports service delivery—to prevent HIV and save lives by expanding access to safe and voluntary male circumcision services. FHI, EngenderHealth, and the University of Illinois at Chicago, working with the Nyanza Reproductive Health Society, are partners in the Consortium, which is funded by a grant to FHI from the Bill & Melinda Gates Foundation.

Please send questions or comments to Silas Achar at: mccinfo@fhi.org; also, please indicate whether you want to continue receiving this e-newsletter regularly.