Battelle
The Business of Innovation

Landscape of MC Devices

Kampala, Uganda
March 13 – 14, 2008

R. Reade Harpham

Director of Design

Battelle

- **One of the largest *not-for profit* R&D companies in the world.**
  - Our Mission - *"To translate scientific discovery into innovative solutions for the benefit of our fellow citizens, and to be a benefactor for charitable activities especially - education."*
  - Began operations in 1929 and is a global science and technology company that helps clients develop and commercialize technology
  - Oversee ~ $3.8B in annual R&D and 19,000 staff at more than 100 WW locations

Program Objective

- The objective of this project is to assess the feasibility of, and develop new concepts for a low-cost, easy-to-train male circumcision device or method
  - Focus of work based on the forceps guided procedure and includes:
    - *Review of existing devices*
    - *Concept generation*
    - Concept refinement and evaluation

Existing Devices

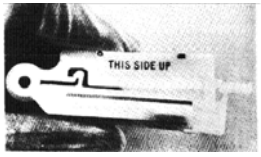


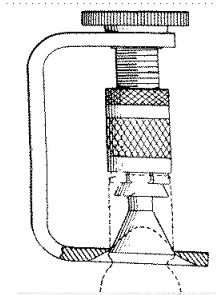


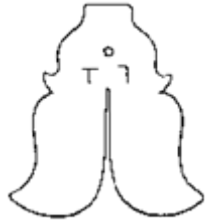


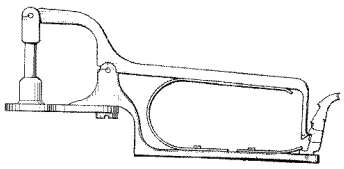
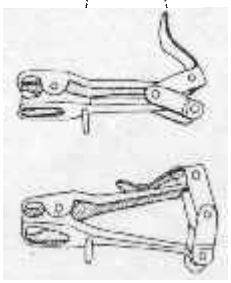
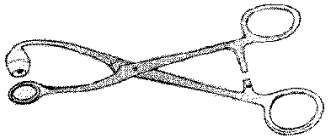
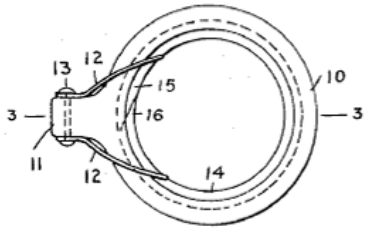








Existing Devices

- Over 20 Devices Identified
- Selected 10 representative devices based on functionality and potential availability for use
- 5 Countries of Origin
  - United States
  - Turkey
  - Netherlands
  - Malaysia
  - South Korea
- Categorized based on method of hemostasis
  - ***Crush***
  - ***Clamp***
  - ***Ligature***

Important Device Functions and Features

- Protect glans
- Position foreskin for tissue removal
- Provide a guide for tissue removal
- Control the amount of tissue removed
- Minimal blood loss (hemostasis)
- Easy to train and easy to use
- Low adverse event rate
- Acceptable cosmetic result
- Low cost
- Sterile

Hemostasis: Crush

Gomco Clamp

Mogen Clamp

Hemostasis: Crush

- Advantages
  - Does not need to stay on the patient
  - Works well with infants
  - Sutures are not typically required for infants
- Disadvantages
  - Only crushes the tissue, may not always prevent bleeding in adults
  - No information on adult use

Hemostasis: Clamp

Ali's Klamp

Ismail Clamp

TaraKLamp

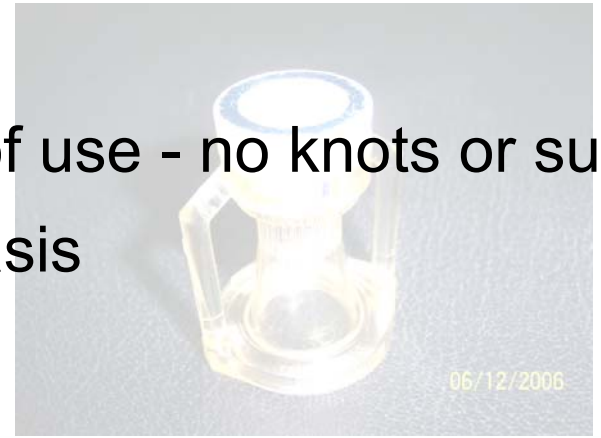
SmartKlamp

Kirve Klamp

Sunathrone

Hemostasis: Clamp

- Advantages
  - Perceived ease of use - no knots or sutures
  - Reliable hemostasis
- Disadvantages
  - Must be worn from 3 to 12 days, depending on device
  - Can be uncomfortable due to size
  - Patient may experience pain due to difficulty during removal
  - Potential for complications if swelling or erection occurs.



Hemostasis: Ligature

Plastibell

Circ-Ring (self applied)

Hemostasis: Ligature

- Advantages
  - Small size when compared with clamps
  - Potentially less discomfort for patient
  - Reliable hemostasis
- Disadvantages
  - High potential for self-use error (Circ-Ring)
  - Can be difficult to hold in place while tying ligature
  - Must be worn from 3 to 7 days, depending on device
  - Little information regarding use on adults
  - Potential for complications if swelling or erection occurs
  - Requires proper technique to reduce complications
  - Clinic must stock multiple sizes

Initial Performance Criteria for Device Evaluation

- Hemostasis
- Glans Protection
- Prevention of Reuse
- Complexity of Device
- Complexity of Procedure
- Amount of Post Operative Care
- Cosmetic Acceptability of Results
- Cost of the Device Per Use
- Infection Control

Initial Observations

- Similar steps are required for all device procedures
  - Apply anesthesia
  - Check for adhesions
  - Mark line of circumcision
  - Manipulate and position foreskin
- Size and complexity of devices vary significantly
- Most devices address protection of the glans
- Some devices prevent bleeding, but must be worn by the patient for several days
- Potential for improvement to better address patient comfort and ease of device use
- *There is not a broad base of evidence regarding performance of devices – performance claims come from manufacturer*

Initial Conclusions

- No single device provides sufficient functionality to adequately address all initial performance criteria
- *Alternative methods to control and stop bleeding and to close wound should be investigated*
- *Additional input from practitioners is needed* relative to;
  - important functions and features
  - performance criteria
  - assessing and evaluating existing devices
  - alternative methods for wound closure

Contact Information

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Objectives for Breakout Session

- Discussion on Device Features and Functions
- Review Potential Issues with Wearable Devices
- Discussion of Alternative Wound Closure Methods

Support Information: Full Device Summary

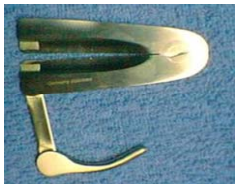
Full Device Summary

					
Product Name	ALi'SKLAMP	Gomco Clamp	Ismail Clamp	Mogen Clamp	PlastiBell
Company Name	ABA GROUP Ltd.	Allied Healthcare Products, Inc.	DRIMS TRADING SDN. BHD.	Mogen Instruments, Ltd.	Hollister
Website	http://www.alisklamp.com	www.alliedhpi.com	http://www.ismailclamp.com	None available	http://www.hollister.com
County of Origin	Turkey	USA	Malaysia	USA	USA
In Production	Yes	Yes	Yes	Yes	Yes
Widespread Usage	Unknown	Most widely used circumcision instrument worldwide	Unknown	Popular, especially with Jewish Mohels	The Plastibell is used in nearly 60% of all routine infant circumcisions in the US.
Size Range	Infant to Adult	Infant to Adult	Infant to Adult	Infant to Adult	Infant
Number of Sizes	5	9	4	2	6
Number of Parts	2	4	3	1	1
Sizing Complexity (# Sizes X # Parts)	10	36	12	2	6
Sizing Procedure	Included measurement guide	Clinician	Included measurement guide	None	Handle Shape Indicates Size
Cost Range	Unknown	$225 (Spectrum Surgical)	$11	$250 (Spectrum Surgical)	$0.35 (Medical College of Georgia)
Materials	Polycarbonate	Metal	Plastic	Metal	Clear Plastic
Pre-Sterilization	Ethylene Oxide	No	Ethylene Oxide	No	Unknown
Disposable	Yes	No	Yes	No	Yes
Circumcision Method	Scalpel	Scalpel	Scalpel	Scalpel	Ligature
Glans Protection	Yes	Yes	Yes	Yes, but can crush glans if not done properly	Plastic Bell covers the glans
Homeostasis	Clamp left on patient for several days	Clamp left in place for 5 minutes	Clamp left on patient for 5-10 days	Clamp left in place for 1-1.5 minutes. Bleeding is one of the most common complications	Ligature minimizes bleeding. Left in place for 1 week
Usage Procedure	alisklamp.mht	gomco.mht	http://www.ismailclamp.com/Index_files/clampingprocedurestep1.htm	mogen.mht	plastibell.mht
US Patent	None Found	3874389	None Found	2747576	None Found
Approval	CE	FDA	None Found	FDA	FDA

Full Device Summary

					
Product Name	SmartKlamp	Tara Klamp	Circ-Ring	Kirve Klamp	Sunathrone
Company Name	Circumvent BV	Carpe Diem Enterprises	Weihai Zhenxi Medical Equipment Corporation	BÜŞRA ÖZEL SAĞLIK HİZM. TİC. VE SAN.LTD ŞTİ	Sunathrone Bio-Medical
Website	http://www.smartklamp.com	http://www.taraklampsa.co.za	http://zhenxi-korea.com/	http://www.kirveklamp.com	http://www.sunathrone.com/
County of Origin	Netherlands	South Africa	Korean	Turkey	Malaysia
In Production	Yes	Yes	Yes	Yes	Yes
Widespread Usage	Unknown	Website lists clinics in South Africa that use the device	Unknown	Unknown	Unknown
Size Range	Infant to Adult	Infant to Adult	Adult	Infant to Young Adult	Infant to Adult
Number of Sizes	6	8	7	5	5
Number of Parts	2	1	1	3	2
Sizing Complexity (# Sizes X # Parts)	12	8	7	15	10
Sizing Procedure	Included measurement guide	Included measurement guide	Measure the perimeter of glans with a string	Included measurement guide	Included measurement guide
Cost Range	Unknown	$23-$36 (CIRCLIST)	Unknown	Unknown	Unknown
Materials	Polycarbonate and Nylon	Plastic	Plastic	Translucent Plastic	Clear Plastic
Sterilization	Ethylene Oxide	Unknown	Unknown	Unknown	Unknown
Disposable	Yes	Yes	Yes	Yes	Yes
Circumcision Method	Scalpel	Provided tissue cutter	Knife or scissors to cut off necrotic tissue	Scalpel	Scalpel
Glans Protection	Yes	Yes	Yes	Yes	Yes
Homeostasis	Clamp left on patient for 5 days	Clamp left on patient for 5 days	Ligature left on for 50 hours	Clamp left on patient for 3-5 days	Clamp left on patient for 8-12 days
Usage Procedure	smartklamp.mht	Tara KLamp Booklet.doc	circring.mht	kirveklamp.mht	sunathrone.jpg
US Patent	None Found	None Found	None Found	None Found	None Found
Approval	FDA, CE	None Found	None Found	None Found	None Found

Full Device Summary

				
ALİ'SKLAMP ABA GROUP Ltd.	Gomco Clamp Allied Healthcare Products, Inc.	Ismail Clamp DRIMS TRADING SDN. BHD.	Mogen Clamp Mogen Instruments, Ltd.	PlastiBell Hollister
1. Hygienic Circumcision: It is protected against any infection risks as there is no cut on the skin. 2. Aesthetic Circumcision: The length of the mucosa is the same in every part of the glans and its length can be adjusted as wished by the surgeon. 3. Secure Circumcision: The glans prevents the accidental cuts on the penis. 4. Easy Circumcision: Learning to use minimum training. There is no need to use assistant personnel. 5. Quick Circumcision: It is a quicker method than the others. As it provides a very short time it reduces circumcision stress on children. 6. Cosmetically Good Results 7. No Sutures 8. No Bleeding 9. No Gauze And Bandage 10. No Need To Use Antibiotic Cream After Circumcision 11. Comfort After Circumcision: Circumcised person can wear underwear and pants, walk, play and go on daily activities.	No manufacturer's claims found	1. Easy to use - 3 step circumcision procedure i. Inset inner tube ii. Insert clamp iii. Tighten with screw nut 2. Safe : Maintains glans penis in it's anatomical position. 3. Incidence and severity of complication is less. More clinical study by a third party would have to be done to substantiate this claim. 4. Features unique to Ismail Clamp i. Reversible clamping : Clamp can be removed just by turning screw nut anticlockwise a. Clamp can be removed at home by family members. If family member do not able to do it, clamp can be removed by attending doctor. b. In case of complication, easy to remove clamp and proceed conventional circumcision. c. Prepuce can be adjusted, prior to it's removal. ii. Easy, spontaneous and relatively painless removal. To achieve this, the only active intervention required is to unscrew and remove screwnut.	No manufacturer's claims found	1. 45+ years of successful clinical use have proven its safety and effectiveness. 2. PlastiBell Circumcision Device provides a clean of excision and helps to promote rapid healing. 3. Ligature minimizes bleeding and eliminates the need for post-operative dressings. Individually sterile package reduces risk of infection. 4. Proven design of Plastibell anchors ligature securely; protects glans and allows complete visual inspection.
	The use of Gomco® and gomco-type clamps that have been reassembled by users with parts from different manufacturers, or that have bent parts or mismatched components, has led to clamps breaking, slipping, falling off during use, tearing penile tissue or failing to make a tight seal. Please note that although Gomco® and gomco-type clamps may appear to have interchangeable parts, these parts may not always be safely interchanged because they may vary slightly in dimensions.		The use of Mogen® and mogen-type clamps that have jaw gap dimensions greater than those in the manufacturer's specifications, or use of clamps inappropriately sized for patients, has led to patient injuries. In such cases, the clamp may allow too much tissue to be drawn through the opening of the device, thus facilitating the removal of an excessive amount of foreskin and in some cases, a portion of the glans penis.	

Full Device Summary

					
Product Name Company Name	SmartKlamp Circumvent BV	Tara Klamp Carpe Diem Enterprises	Circ-Ring Weihai Zhenxi Medical Equipment Corporation	Kirve Klamp BÜŞRA ÖZEL SAĞLIK HİZM. TİC. VE SAN.LTD ŞTİ	Sunathrone Sunathrone Bio-Medical
Claimed Advantages	1. Safer: Protection of the glans penis during circumcision No bleeding, so no cross infections or transmission Hepatitis or HIV Easy to perform the operation 2. Faster: Free and easy access to the prepuce One click closing mechanism, no stitching required No need for operating theatre, thus shorter preparation and aftercare 3. Smarter: Superior cosmetic result Cost effective Improved convenience Reduced traumatic experience	1. Quicker operation time 2. Not requiring sterile operating conditions 3. "Bloodless" 4. Relatively painless 5. Requires no stitches or dressing; the wearer can even go swimming! 6. Quicker healing time 7. Aesthetically more pleasing due to the "moulded" cut	1. No need for scalpel or suture in the operation. 2. No bleeding in the operation. 3. Hardly any pain during the operation and taking free activities immediately after the operation. 4. Available in any seasons. 5. Healing up in 10~13days after the operation 6. Disposable and sterilized products and preventive against any infection 7. Salable. Taking the operation for oneself at home for any male over 18	1. The circumcision is completed in just a short time such as 2.5-5 minutes. Thus, the stress of the child for a long operation is eliminated. 2. Hygienic and sterile. Prevents all infections that may occur in mass operations due to the unsterilized surgical tools. 3. Prevents all kinds of post-circumcision infection thanks to the antimicrobial materials in its formation. 4. Disposable. Prevents the contagion of chronic viral infections. 5. Prevents post-circumcision bleeding thanks to its special design. The percentage for the post-circumcision bleeding is less than 1%. 6. Sutureless and bloodless. 7. Safe. Prevents miscircumcision. 8. No post-circumcision deformation thanks to the cutting guide. 9. The child can easily wear his trousers and even have a bath right after the operation.	1. Convenience • a breakable / separable tube guide and protect of the glans penis during circumcision • no fuss, considered bloodless, prevent any possible infections or transmission of bacteria, Hepatitis or HIV • very easy procedure to perform 2. User Friendly • surgeon has free access for the application of the cuff locking mechanism as the clamping system • cuffing direct locking mechanism, no stitching required • breakable tube leaving small remnant ring and cuff locking which does not require second visit for unnecessary usual painful removal as being observed with most disposable circumcision devices used. 3. No Clumsy Procedure • ultimate excellent design satisfy the surgeon and patient • eliminate traumatic experience with no unnecessary second visit for painful device removal • cuff locking clamp does not block scalpel / scissor for proper circumference free cut
Potential Complications					

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Sources	*Alisklamp* . [Online]. Available: http://www.alisklamp.com/. [Accessed: Feb. 11 2008].	Baumgarten, Carl B., "Circumcision Clamp", US Patent 3874389. Apr. 1, 1975. Peleg D, Steiner A. "The Gomco circumcision: common problems and solutions." *Am Fam Physician* . vol. 58(4), pp. 891-8, Sep 15 1998 "Gomco Clamp," *CIRCLIST Homepage* . [Online]. Available: http://www.circlist.com/instrstechs/gomco.html. [Accessed: Feb. 11 2008]. "Device Listing Database Search," *Food and Drug Administration* . [Online]. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm?&ID=40907. [Accessed: Feb. 11 2008]. "Authentic Gomco® and Mogen Circumcision Clamps," *Spectrum Surgical Instruments Corp* . [Online]. Available: http://www.spectrumsurgical.com/catalog/instrument/circumcision.htm. [Accessed: Feb. 13 2008]. "Potential for Injury from Circumcision Clamps." *Food and Drug Administration,* Aug. 29, 2000. [Online]. Available: http://www.fda.gov/cdrh/safety/circumcision.html. [Accessed: Feb. 13 2008].	*Ismail Clamp* . [Online]. Available: http://www.ismailclamp.com/. [Accessed: Feb. 11 2008].	Bronstein, Harry., "Circumcision Clamp", US Patent 2747576. May 29, 1956. "Mogen Clamp," *CIRCLIST Homepage* . [Online]. Available: http://www.circlist.com/instrstechs/mogen.html. [Accessed: Feb. 11 2008]. "Device Listing Database Search," *Food and Drug Administration* . [Online]. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm?&ID=20838. [Accessed: Feb. 11 2008]. "Authentic Gomco® and Mogen Circumcision Clamps," *Spectrum Surgical Instruments Corp* . [Online]. Available: http://www.spectrumsurgical.com/catalog/instrument/circumcision.htm. [Accessed: Feb. 13 2008]. "Potential for Injury from Circumcision Clamps." *Food and Drug Administration,* Aug. 29, 2000. [Online]. Available: http://www.fda.gov/cdrh/safety/circumcision.html. [Accessed: Feb. 13 2008].	*Hollister Incorporated* . [Online]. Available: http://www.hollister.com/. [Accessed: Feb. 12 2008]. "Plastibell Circumcision." *Medical College of Georgia* . [Online]. Available: http://www.mcg.edu/pediatrics/CCNotebook/chapter2/circumsion.htm. [Accessed: Feb. 12 2008]. "Device Listing Database Search," *Food and Drug Administration* . [Online]. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=17425. [Accessed: Feb. 12 2008]. "Hollister Plastibell." *CIRCLIST Home Page* . [Online]. Available: http://www.circlist.com/instrstechs/plastibell.html. [Accessed: Feb. 13 2008].

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Sources	*SmartKlamp* . [Online]. Available: http://www.smartklamp.com/. [Accessed: Feb. 12 2008].	*Tara KLamp SA* . [Online]. Available: http://www.taraklampsa.co.za/. [Accessed: Feb. 12 2008]. "Tara Klamp," *CIRCLIST Homepage* . [Online]. Available: http://www.circlist.com/instrstechs/taraklamp.html. [Accessed: Feb. 11 2008].	*Weihai Zhenxi Medical Equipment Corporation* , [Online]. Available: http://zhenxi-korea.com/. [Accessed: Feb. 12 2008]. *Circ-Ring international* , [Online]. Available: http://www.zhenxi-europe.com/. [Accessed: Feb. 12 2008].	*Kirve Klamp* . [Online]. Available: http://www.kirveklamp.com/. [Accessed: Feb. 13 2008].	*Sunathrone* . [Online]. Available: http://www.sunathrone.com/Product.php. [Accessed: Feb. 13 2008].

Criteria Dictionary

Hemostasis

- Hemostasis
  - Measurement: Ability of the device to prevent lose of blood
  - Satisfaction:
    - High: Sutures, Ligature, Clamping
    - Mid: Crushing of blood vessels
    - Low: None

Glans Protection

- Glans Protection
  - Measurement: Ability of the device to protect the glans
  - Satisfaction:
    - High: Glans is fully protected from any cutting
    - Mid: Glans is protected, but can be damage if device is not used properly
    - Low: Glans are not protected

Prevention of Reuse

- Prevention of Reuse
  - Measurement: Ability to minimize cross-infection by preventing the reuse of unsterile material
  - Satisfaction:
    - High: Device is disposable and is destroyed at the end of the procedure
    - Mid: Device is non-disposable but is expected to be sterilized prior to use
    - Low: Device is disposable but is not destroyed at the end of the procedure

Complexity of Device

- Reduction in number of parts
  - Measurement: Number of parts handled by clinician
  - Satisfaction: Lower is better
- Number of size variations required for adult males
  - Measurement: Number size options required to cover variations in adult population
  - Satisfaction: Lower is better

Complexity of Procedure

- Safety of the procedure
  - Measurement: Opportunities to make a mistake in the procedure and injure the patient or the clinician/practitioner
  - Satisfaction:
    - High: Few or no opportunities to injure the patient
    - Mid: Several opportunities to injure the patient
    - Low: Significant number of opportunities to injure the patient
- Number of procedural steps required
  - Measurement: Number of major steps required to complete the procedure
  - Satisfaction: Lower is better
- Reduced surgical time
  - Measurement: Average time required to complete the procedure
  - Satisfaction: Lower is better
- Level of training required for use
  - Measurement: Skill level of clinician required to complete the procedure
  - Satisfaction:
    - High: Can be completed by an untrained individual based on written instructions
    - Mid: Can be completed by an individual with some medical training - i.e. must be able to handle a scalpel, basic wound care
    - Low: Can only be completed by an individual with a high level of medical training - i.e. must be able to suture, make free hand cuts

Amount Post Operative Care

- Potential for post surgical complications due to the device
  - Measurement: Days device is left on the patient
  - Satisfaction: Lower is better
- Amount of post-operative care
  - Measurement: Amount of post-op care required by the patient
  - Satisfaction:
    - High: No care required. Procedure is done or device can be left alone
    - Mid: Patient must monitor site of surgery for complications
    - Low: Active maintenance required by the patient such as changing dressings every day.
- Prevention of blood borne infection
  - Measurement: Risk of infection to patient and clinician/practitioner
  - Satisfaction:
    - High: No transmission path for blood borne infection
    - Mid: Closed wound
    - Low: Open wound

Cosmetic Acceptability Of Results

- Amount of tissue removed
  - Measurement: Amount of prepuse removed by the procedure
  - Satisfaction:
    - High: Can be adjusted by the clinician
    - Mid: Tight circumcision
    - Low: Loose circumcision
- Potential for scarring
  - Measurement: Risk of scaring after the procedure
  - Satisfaction:
    - High: Minimal risk of scaring
    - Mid: Risk of scaring due to necrotic tissue left on glans
    - Low: High risk of scaring
- Alignment of tissue after foreskin removal
  - Measurement: Ease of alignment of foreskin during removal
  - Satisfaction:
    - High: Device aligns cutline with the glans
    - Mid: Device provides some features to assist in alignment
    - Low: Alignment is done freehand

Cost of the Device Per Use

- Unit manufacturing cost of device
  - Measurement: Manufacturing cost of device
  - Satisfaction: Lower is better
- Cost of other consumables
  - Measurement: Cost of other consumables (gauze, sutures, etc.)
  - Satisfaction: Lower is better
- Preparation and re-processing costs for reusable components
  - Measurement: Cost to reprocess non-disposable devices (sterilization, etc.)
  - Satisfaction: Lower is better