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Title: Research on current prototypes of the Digiclamp. Short term and long term outcomes of treating adults with achrocordons (skin tags)

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Protocol

Project Title:

"Research on current prototypes of the Digiclamp. Short term and long term outcomes of treating adults with achrocordons (Skin tags)"

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Abstract:

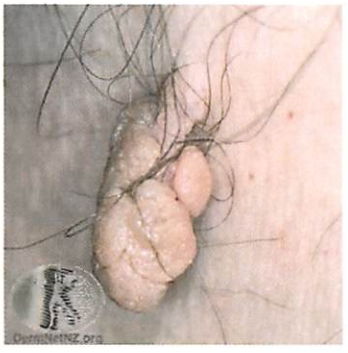
Dr. Juan C. Roig and XDG Technologies LLC have developed a proprietary, hand-held medical device (the "Digiclamp" or "device") for the treatment of both a genetic medical condition called polydactyly (i.e. extra fingers or toes) and the removal of skin tags. The current standard of care for both conditions requires a thin thread (i.e. a "suture") to be tied very tightly at the base of the extra finger/toe or the skin tag, restricting blood flow and causing the tissue to subsequently blacken and "die" (necrose) over a period of 7-14 days, then fall off. For the purpose of this study in particular we propose instead that the Digclamp can be used to change the current standard of care for these conditions (and others) by resolving them in 10 MINUTES. This proposed project will help validate the short-term and long-term clinical efficacy of the Digiclamp specifically for treating adults who are affected by achrocordons. The use of the Digiclamp device to treat adults who suffer from this condition will demonstrate its clinical superiority over the currently accepted "standard of care" - and may lead to the clamp becoming the most common method in the U.S. The clamp procedure is the more comfortable, less costly, and more desirable option for these patients.

The patients who undergo removal of the achrocordons, will subsequently be followed after the removal at 3-6 months to determine if any recurrence, scarring, or discoloration of the skin has occurred. At that time, the patients will be asked to answer a simple survey of satisfaction to determine their opinion of the method used. Pictures of the skin tags before and after its removal will be obtained, in order to demonstrate the resolution of the lesion, or to document any secondary finding that may have taken place. Since discoloration, and scarring are complications associated with the other methods used to remove skin tags such as suture ligature, cryotherapy or cautery documentation of how these lesions progress after their removal with the Digiclamp is essential.

Background:

Achrocordons or skin tags are superficial cutaneous lesions (ICD 10: Skin tags L91.8; Congenital: Q82.8). These skin growths are generally clinically benign and occur most frequently in middle age adults who are 45 years of age or older. Generally, achrocordons are non cancerous, and characteristically protrude from normal underlying skin in the neck, axillae, groin or skin folds attached by a narrow "stalk like" pedicle. Histologically skin tags are made up of loosely arranged collagen fibers and blood vessels surrounded by a thickened thinned out epidermic layer as its cover. They affect men and women similarly, and cosmetically appear darker in color than the underlying normal skin in the area. Obese persons and those who sufferType 2 diabetes are affected by these growths more frequently than other persons.

Appearance of typical achrocordon or skin tag:



In most cases it is not necessary to treat or to remove skin tags, and usually these lesions are not bothersome. The person affected by these lesions most often would choose to remove them for cosmetic reasons if a reasonably priced, safe and effective option was available. There are instances when these growths become infected or irritated due to friction and can change in appearance, and may swell, bleed or become infected and their removal may become necessary. In these situations, as in the elective cases, there are several treatment options available to the patient. The patient may undergo suture ligature by tying a band, or a suture string at the base of the skin tag and choking off the circulation to the lesion. The patient may opt to freeze the lesions with a refrigerant such as Liquid Nitrogen or Nitrous Oxide. The lesion can also be burned off by means of an electro cautery device. Finally, the lesion can be excised using scissors or scalpel. There are no topical creams currently recommended as a medical option to remove achrocordons. The use of a topical anesthetic prior to the removal of these lesions is recommended for most of the options mentioned, however anesthesia isn't necessary. Usually, the procedure is performed by a Dermatologist in an office. Most insurance companies designate the removal of skin tags as a cosmetic procedure therefore, in most instances, their removal represents an "out of pocket" cost to the patient.

Approximately 50% of adults over the age of 45 are affected by one or more of these lesions, thereafter the risk increases with the patient's age. In most instances, a person has multiple lesions and if they desire the lesion(s) removed, the cost of removal can range anywhere from $100 to $300 per intervention

depending on what method is used. Currently, there is a great need for an effective and inexpensive disposable device to remove these lesions that can be readily accessible to the primary care clinicians to use in their office. At this time, clinicians have had to rely on ligature which takes 7-14 days to resolve if successful; cryotherapy which requires expensive equipment, may be painful, and may leave an area of discoloration after the removal; cautery which is associated with pain, blistering, scarring, and also requires special equipment. Because of these associated complications, and the costs to the primary physician, they very frequently refer the patient to a sub-specialist such as a Dermatologist for this procedure. The primary caregivers have not had a reliable and inexpensive tool for removing and resolving these lesions. The Digiclamp represents a new option that when placed in the hands of these clinicians, will allow them to retain this very substantial group of patients, and to treat them without having to purchase expensive devices or to refer them to a Dermatologist. The study we are hoping to conduct will demonstrate that the Digiclamp is easy to use, quick and definitive in the removal of such lesions with less complications associated. The device is disposable, and relatively painless when used correctly, and requires minimal training. There is no need for cautery, suturing of any sort associated with the use of the Digiclamp. The procedure takes approximately 10 minutes to complete. As such, we feel that the Digiclamp is a very logical step in the management of patients with skin tags. Most importantly, in cases where the lesion requires a biopsy excision for pathologic evaluation, the Digiclamp represents a very logical option since cautery or cryotherapy may be precluded due to the effect on the tissue being removed for analysis.

VIEWS OF DIGICLAMP

Specific Aims:

The objective of the study is to treat adults with skin tags or achrocordons who wish to have these lesions removed permanently, using the Digiclamp. After removal of their lesion, these patients will be reassessed after a period of no less than 3 months and, during that visit, pictorial documentation of the lesion site will be collected to demonstrate the effectivity of the Digiclamp in removing the lesion. The patients will then be asked to complete of a questionnaire of their satisfaction.

Our aim is to demonstrate that the lesions removed using the Digiclamp will be resolved permanently. Also, that the site of the lesion will demonstrate minimal or no scarring, discoloration, recurrence or discomfort.

Research Plan:

We propose to enroll 25 adult patients with achrocordons to the study. These patients will have their skin tags removed by using the Digiclamp. The diagnosis the achrocordons will take place on the initial visit, and will be based on their clinical appearance of being an outgrowth of normal appearing skin attached to the underlying area by a narrow stalk. The initial visit of the study will also include photographing the lesion as well as measuring the dimensions of the skin tag (height, width).

The patients will also be asked if they have any allergy to topical anesthetic prior to removal of the skin tag. The area of the skin tag will be photographed and measured. The skin tag as well as the skin in the immediate area will then be cleaned and prepped in a sterile fashion using Chlorhexidine solution or Betadyne plus alcohol and a topical anesthetic such as Lidocaine 1% solution will be used subcutaneously or a topical cream such as Emla placed on the skin tag. The Digiclamp will then be fitted over the lesion and clamped and held in place until the lesions blanches. After 3-5 minutes, the lesion will be excised using a scalpel (#15 blade) and the clamp will be removed showing a translucent skin flap present at the base of where the skin tag had been. The area will then be covered using a small band aid, and the patient will be instructed to keep the band aid on until it naturally falls off. The patients will be asked to report any presence of post procedure bleeding, erythema, edema to the clinical coordinator after the removal.

The patients will be re-evaluated after a period of approximately 3 months for the presence of any secondary effects such as reoccurrence of the lesion, presence of scar tissue at the removal site, discoloration of the area, hyper-pigmentation, and hyper- or hypo- sensitivity.

The inclusion criteria will be adults over the age of 18 years of age with simple achrocordons up to 1 centimeter width at the base. The exclusion criteria will include minors (less than 18 years of age), patients with lesions that are too large for adequate removal (> 1 cm a the base), whose lesions appear infected, or that are located in the genital areas or the eyelids. Also excluded are be patients that have lesions that are not achrocordons and or may need their lesions evaluated by pathology, and patients with bleeding disorders.

Possible Discomforts and risks:

The potential risks in this study are minimal, but could include: (1) allergic reaction to Chlorhexidine or Betadyne solution, (2) reaction to the local anesthetic, (3) pain when compressing the base of the skin tag, (4) bleeding from the site after removal of the skin tag, (5) site infection after removal. However, during this study we will observe safeguards to mitigate potential risks. The mitigation of the risks will occur by: (1) using either Chlorhexidine or Betadyne if the patient is sensitive to either solution. (2) reaction to local anesthetic or diminution of pain will be reduced by using topical anesthetic or no anesthetic in patients whom may be sensitive to "-caine" anesthetics or have Methemoglobinemia. (3) bleeding post removal will be mitigated by excluding patients with a bleeding diathesis. (4) risk for infection at the removal site will be decreased by observing strict sterile procedure for the removal also, a sterile disposable clamp will be used for each individual procedure.

Possible Benefits:

The direct benefits to the patients will be mainly esthetic in nature. The patient will have the lesion rapidly and permanently removed when using this procedure. This procedure does not require stitch removal as would be required if excised with scalpel, without the risk of burning, or blistering as can occur with the cautery or freezing these lesions. In situations where a clinical indication to remove the skin tag exist, as is the case when these lesions become inflamed due to friction with clothing or with jewelry, the Digiclamp procedure represents an effective, less costly option readily available for use by the Primary Care personnel precluding the need for referral to a specialist. Commercially, the Digiclamp represents a new standard of care in the removal of benign skin lesions, easy to use, disposable, and inexpensive.

Conflict of Interest:

The Digiclamp (TM) is a patent pending, FDA Class 1 device which was invented by Dr. Juan C. Roig who is currently an Associate Professor at University of Florida, Department of Pediatrics, Division of Neonatology. Dr. Roig and the University of Florida wish to disclose that they stand to profit from the Commercialization of the device.