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Case Study

A Novel Procedure for Type B Pre and Post Axial Polydactyly Removal Using Digi-Clamp®

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Abstract

In humans, most polydactyl digits occur as benign unilateral or bilateral lesions in either the upper or lower extremities. When present, these are generally isolated and not associated with any other genetic abnormality (non-syndromic polydactyly) [1]. Most cases of type B pre or post axial polydactyly are inherited as an autosomal dominant trait [7]. When present in newborns, this condition is noted immediately after birth and is typically addressed by the primary care provider at the request of the parents prior to the patient's discharge. Most of the caretakers will tie a suture at the base of the extra digit with the intention of choking off its blood supply. If done correctly, this procedure leads to dry necrosis of the digit and, thereafter, to spontaneous auto-amputation which typically takes place within 7 - 21 days. The suture ligature method is the current standard of care, and it is used globally. If a suture ligature succeeds in achieving the auto-amputation of the polydactyl digit, the family generally accepts this as the best possible outcome. It is likely however, that in many of these cases (up to 40%), this method will result in the development of a residual bump or "nubbin" at the site where the digit had been implanted [6]. When present, the "nubbin" projects outwardly from the digit's base and is typically extremely sensitive to any incidental contact with surfaces [13]. The nubbin's hypersensitivity is most likely secondary to a neuroma which can result as a sequela of the suture ligature (See figure 3) due to tethering of the digital nerve ends by the purse string effect of the ligature [13]. The true incidence of the neuromas is likely much higher than the 23.5% currently being reported since persons affected feel that auto-amputation of their digit is the best possible outcome that can be achieved [16,17]. In the group of patients in whom the suture ligature has been applied with insufficient tension, auto-amputation will not occur. Instead, the digit becomes engorged and painful. In these instances, the digit's arterial blood supply continues while the venous drainage is impeded which may lead to venous congestion, thrombosis and moderate to severe pain (See figure 2). This group of infants are usually very irritable, and difficult to console; their parents are then challenged trying find an alternative solution to this problem urgently [19].

At the University of Florida, we have been managing patients with type B pre or post axial polydactyly successfully by excising the polydactyl digits at their bedside prior to discharge using the Digi-Clamp®. This novel procedure requires only minutes to perform, does not require ligature or suturing, and allows the patients to be discharged from the hospital with their polydactyl digits permanently excised. We report the use of this method in 25 patients with type B pre and post axial polydactyly. In all instances, we performed primary excision of the digits using the Digi-Clamp® device without complications or subsequent recurrence.

Keywords: *PAPTB; Polydactyly; Extra Digit; Removal of Polydactyly; Digi Clamp*

Background and Case Study

Polydactyly is one of the most common congenital anomalies of the hand and feet [6]. When present, it manifests in humans and animals as one or more extra fingers or toes. The extra digit is usually a small piece of soft tissue which may or may not contain bone, a nail bed, or have an articulation as part of a complete functioning unit. Most type B polydactyly cases are inherited as a dominant trait, so the number of cases is expected to increase worldwide. The condition occurs most frequently in one or two of the upper limbs but, in rare cases, can be present in all 4 limbs (termed as tetra polydactyly) [2].

Based on the location of the extra digit the condition is classified into three major forms. The most common of these is the postaxial or ulnar/fibular polydactyly [4], where the extra digit is located on the ulnar (little finger) side of the hand or the fibular side of the foot (near the small toe). This condition is 10 times more prevalent in African Americans than Caucasians and can occur in up to 1:139 births for that population [4,5]. This phenotype is further sub-classified into two types [6,7]. In type A, the extra digit is fully developed and articulates with the fifth or an additional metacarpal/metatarsal. In type B, the digit is rudimentary and mostly presents as a non-functioning digit closely resembling a skin tag which can vary from a small "nubbin" to small finger or a pedicle on the foot. Figure 1 below presents some examples of ulnar and fibular postaxial polydactyly.

Figure 1: *(A) Bilateral occurrence of an incompletely formed or rudimentary digit attached to each foot through a thin stalk or pedicle [10]. (B) Same abnormality but on the ulnar side of the infant's right hand [10].*

A less common variation is the pre-axial or radial polydactyly, where an extra digit is present on the radial (thumb or great toe) side. This form is more prevalent in Caucasians than African Americans, with the total incidence varying from 1:1500 to 1: 3000 births [8]. Preaxial polydactyly varies from barely a visible skin tag to a full duplication of the thumb. The third and rarest, of all forms is the central polydactyly, which involves the 3 central digits.

All these conditions are usually detected at birth and, whenever possible, traditionally addressed by "suture ligature," which involves tying off a thread at the base of the digit. This procedure winds up restricting blood flow and causing the tissue to subsequently blacken and "die" (dry necrosis) over a period of 7 - 21 days. On occasion, removing the extra digit will require a referral to a surgeon, general anesthesia and thus becomes associated with increased risks. Other complications which may also be associated with the "standard of

care" currently used include: 1) arterial bleeding; 2) infection of the surgical site; 3) an infected ligated or necrotic digit which may have remained attached after ligature, instead of falling off as expected; 4) accidental avulsion; and 5) "neuroma" formation (swelling of the nerve) at the ligation site (this results in pain, discomfort and tingling as well as possible intermittent bleeding or ulceration) [10-12].

Figure 2 and 3 below show examples of some of the possible complications of polydactyl ligature failure. Occasionally, an initially successful ligature procedure fails and can develop into a thrombotic and painful polydactyl digit (Figure 2), or incomplete necrosis of the base develops into a residual nubbin, which can then become a neuroma (Figure 3). Both are examples of negative long-term outcomes.

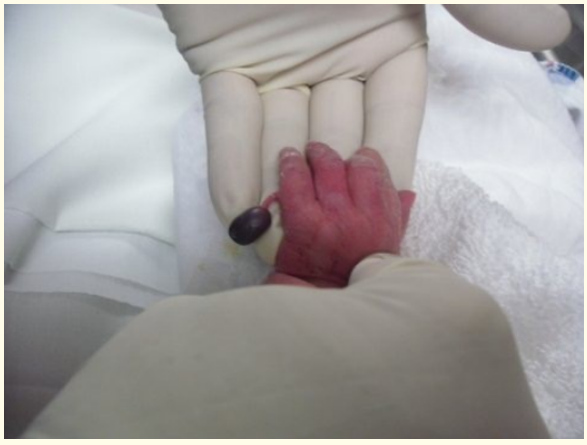

Figure 2: *Example of a typical complication of a failed suture ligature performed on an infant with post axial ulnar polydactyly type B with a thrombosis of the digit 14 days after a failed suture ligation [15].*

Figure 3: *Residual neuroma that has resulted from suture ligature [14].*

The concept of the science of our novel procedure revolves around excision and removal of the type B post axial digits or toes instead of suturing the polydactyl digit after birth, which is based instead on the concept of "choking off" the blood supply and allowing the digit to develop dry necrosis and fall off after discharge home in the space of 7 - 21 days later. In our practice, during the past 15 years, we had begun compressing the digits of these infants; initially with hemostats or needle-holders and excising them on the spot. However, when using those instruments, some of the patients had post procedural bleeding which then required other types of "rescue" interventions, such as cautery with silver nitrate or aluminum chloride to resolve the bleeding. The need for a specific type of smaller size clamp able to generate sufficient compression of the lesion's base to disrupt the arterial blood supply to these small digits at their base and flush with the skin became obvious. The clamp would have to be small enough to allow its operator to squeeze into very small spaces such as that in the pedicle base of extra digit in premature infants. In these patients the pedicle base of the digit may measure as little as 1 - 5 mm in width and be as short as 1 - 2 mm in height (as is the case in instances where a "nubbin" has formed, usually as result of suture ligature or autoamputation in utero). This clinical need prompted the development of the Digi-Clamp^{R} (See figure 4).

Figure 4: *Disposable Digi-Clamp^{R}.*

Method for the novel procedure for polydactyly excision

It is necessary for the clinician caretaker to correctly identify the type of polydactyly. The patients with type B pre or postaxial polydactyly are suitable candidates for excision using the Digi-Clamp^{R} (See figure 5 below).

The provider should consider providing oral sucrose solution to the patient prior to the procedure to promote analgesia. After consent for excision was obtained from the legal guardians of the patient, those with a family history of bleeding disorder were excluded. A "time out" procedure to identify the patient should be performed at the bedside prior to proceeding with the clamping.

Aseptic preparation of the immediate area around the polydactyl digit was performed using a Chloraprep (2% CHG and 70% IPA) swab stick or betadine and isopropyl alcohol solution was performed around the extra digit, its base as well as the lateral surface of the 5th digit (See figure 6 below).

Figure 5: *Example of type B post axial or ulnar polydactyly [18].*

Figure 6: *Example of preparing the polydactyl for resection [18].*

The provider performs the aseptic preparation of the operative site, and the site is ready for topical infiltration with the local anesthetic. The topical anesthetic effect of the polydactyl digit is achieved by injecting approximately 0.2 ml of 1% lidocaine solution subcutaneously to the lateral digital nerve just proximal to pedicle of digit and distal to the metacarpophalangeal joint (See figure 7 below) [18].

After adequate time has elapsed for the anesthetic to take effect, approximately 1 to 2 minutes, the Digi-Clamp^{R} is applied making sure the inferior surface of the instrument is flush with lateral aspect of digit. Mild traction is then applied to the polydactyl digit before closing the clamp over the pedicle while paying attention to keep the clamp as flush with the lateral aspect of the normal digit as possible and noting that the clamping surface is not compressing any normal skin beyond the base of the pedicle of the polydactyl digit but is flush against the lateral aspect of the affected digit (See figure 7 and 8).

Figure 7: *Example of local anesthetic block to the lateral aspect or the ulnar side of the hand of the patient [18].*

Figure 8: *Example of clamp application and closure at base of pedicle [18].*

Once applied, the Digi-Clamp[R] is left locked compressing the digit for minimum of 5 minutes. During this time the base of the polydactyl digit may blanch slightly (See figure 9).

After the clamp has been closed over the base of the digit for minimum 5 (minimum time recommended), the polydactyl digit is excised using a disposable scalpel that can be inserted into one of the lateral ports present on either side of the Digi-Clamp[R]. Attention should be taken to oversee that the cut made excises the digit flush with clamp surface, and this process should be completed while the clamp maintained closed and in place over the base of the digit (See figure 10).

Figure 9: *Example of clamp closure and blanching of pedicle [18].*

Figure 10: *Example of the actual excision of the polydactyl digit [18].*

After the device has been left closed in place for the minimum recommended period, the device can be safely unclamped and removed. Once the clamp has been removed, there should be an obvious translucent flap of skin apparent where the base of the pedicle had been. The flap should be present and flush to the lateral aspect of the fifth digit (See figure 11).

It is important to point out that there should not be any post-operative bleeding noted after the clamp has been removed. The translucent flap of skin that remains after the Digi-Clamp^{R} has been opened, is simply covered with a spot adhesive bandage. The caretaker is instructed to allow the bandage to remain in place until it falls off (See figure 12), but to look out for bleeding, erythema of the site, discharge of any type, or foul odor. There is no suturing required for this procedure, nor is there a need for cautery or cryotherapy.

Figure 11: *Example of the translucent fused skin flap apparent after clamp removal where the base of the pedicle had previously been [18].*

Figure 12: *Example of covered removal site after Digi-ClampR excision [18].*

Conclusion

We report the use of this method in 25 patients with type B pre and post axial polydactyly. In all instances, we performed primary excision of the digits using the Digi-Clamp[R] device without complications or subsequent recurrence.

Conflict of Interest Declaration

Dr. Juan C. Roig declares that he is the inventor of the medical device with the University of Florida. He is the founder of XDG Technologies LLC.

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