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Thumb basal joint: Utilizing new technology for the treatment of a common problem

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ABSTRACT

New technology has the potential to greatly impact the medical field because it may lead to a greater quality of life, decreased pain, or increased function for our patients. This manuscript will discuss the introduction of one such advance in hand surgery and hand therapy. Utilizing the Mini-Tightrope™ (Arthrex, Naples, FL) for suspension of the thumb metacarpal following trapeziectomy is a new technique for treating thumb carpometacarpal (CMC) arthritis. This technique is described as an example of the advantages of considering new techniques and technologies when treating established problems. This article discusses the responsibility of health professionals in considering the adoption of new technologies over current ones in the context of describing a new type of CMC suspensionplasty procedure. Further, a description of the surgical technique, the hand therapy postoperatively, and a case study to demonstrate some of the features of the Tightrope suspensionplasty procedure is presented. In the author's experience, the reduced healing time, reduced weeks of immobility, and fewer therapy visits following the procedure suggest that the Tightrope procedure should be considered as an option for patients needing thumb CMC arthroplasty.

Considering and assessing new technology

Technological advances in surgical devices and techniques are exciting, with the possible advantages of better patient outcomes, reduced cost or surgical time, and increased interest in research for comparison studies. Salah et al[1] state that "we must continuously seek better methods and techniques for achieving better outcomes. … technology adds dimensions of capability to making improvement real and systematic, as well as providing safer care with fewer errors and better adherence to proven best practices." But the possible advantages must be weighed against the possible disadvantages. What criteria does a surgeon or a therapist use to decide that it is time to look for or embrace a new device or technology over a current, adequately performing one?

One area of decision making is in the arena of morals and ethics around new medical device development and use. Iserson et al[2] of the Arizona Bioethics program state, "Medical technology itself… has no morals; our morality revolves around when and how we use technology." In hand surgery, this includes surgeons and therapists who must assess their own level of skill when implementing these new technologies and introducing these new devices, and providing quality information to the patient to obtain true informed consent. Iserson et al point out that new advances in technology sometimes come with a steep learning curve, there is little agreement on how long a surgeon should be supervised when performing these new procedures, and who is responsible for setting adequate standards for performance and monitoring. For surgeons and therapists adopting new techniques or skills, training often consists of another surgeon or therapist or simply a vendor presenting an in-service. Occasionally, there is a competency check following the in-service, but often no follow-up afterwards. Currently, individual surgeons and therapists, the code of ethics for their professions and employing institutions, and the government are responsible for ensuring various aspects of the ethical use of new devices and technologies, but are inconsistent. Schultz,[3] with the Center for Devices and Radiological Health (CDRH) at the US Food and Drug Administration (FDA), states that "We try to apply a risk-based approach that makes the most sense for patients and for public health. Surgeons probably appreciate this method better than most people do, as they do risk-benefit analyses many times each day." He also states that "it has become increasingly obvious that a surgeon's use of a device affects the performance of that device. For this reason, training in the use of a device must be

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integral not only to early development and clinical investigation but also to eventual use. Until about eight years ago, neither device manufacturers nor the FDA required end-user training." Fogarty, founder of the Fogarty Institute for Innovation and a co-author of the article, states that "device development involves continuous innovation and improvement even after preclinical and clinical testing, and typically requires special expertise and training for proper clinical use," but the type and amount of training is not defined. Work must be done to standardize the training and continued competency assessments for surgeons employing new technologies.

The American Academy of Orthopaedic Surgeons (AAOS) and the Advanced Medical Technology Association (AdvaMed, the association for medical device manufacturers) have both established ethical guidelines prohibiting companies from using gifts or gratuities to encourage surgeons to use their devices.[4] The AAOS also cautions surgeons who consult with medical device companies during the development of a device to make sure that the compensation they receive is of fair market value, and not inflated to promote bias for their product.

In busy hand therapy clinics, the appearance of a variety of vendors who attempt to promote the use of their devices, modalities or prefabricated orthoses increased to the point that most institutions now have policies to discourage the use of a device based on promotions or personal relationships with vendors. Stanford University Medical Center was one of the first institutions to adopt this policy in its strictest form in 2005. As technology advances and devices change, therapists are responsible for ensuring against bias for one particular vendor and critically analyzing all products for best practice. Devices are evaluated on their own merit, compared to similar devices, including cost, amount of training required, and most importantly best and safe practice for patients.

Another area to consider when analyzing new technology is the acceptance and adoption of the technology as best practice. Especially over the past decade, when electronic medical records (EMRs) were implemented in most large medical institutions, even though EMRs were proven to increase safety and best practice,[4A] and decrease costs through standardizing lab and medication ordering, there were early adopters, later adopters, and non-adopters of this technology. Cardiac surgeons[5] in Canada were surveyed for personal perspectives on biomedical innovation, and asked to self-identify into one of three categories: "innovator," "early adopter," or "late adopter." Two key barriers to embracing new technologies in this study were identified as lack of support from colleagues and the culture of innovation within their environment. According to this study, "the majority of surgeons did not perceive themselves as having the necessary knowledge and skills to effectively translate innovative ideas to clinical practice."

New technology for thumb CMC arthritis: considerations

How are developing technologies incorporated in hand surgery? Currently, new surgical techniques and devices are being evaluated for the treatment of thumb basal or carpometacarpal (CMC) joint arthritis. In a recent AAOS symposium chaired by Ladd and colleagues,[6] a discussion of the ideal surgery for CMC arthritis summarized that "trapeziectomy, the root treatment in current CMC arthritis surgery, creates adequate pain relief. The ideal surgery, however, results in versatile mobility with strength and precision in the myriad positions required with fine and gross motor function not currently addressed with just one technique. Surgical options that combine the basic science and clinical relevance of strength, mobility, stability, and proprioception, either through emulation (soft tissue reconstruction), or re-creation (implant arthroplasty) will constitute that ideal procedure." However, in search of this ideal, recent technologic advances have facilitated the introduction of options other than simple trapeziectomy or soft tissue reconstruction or implant arthroplasty in the form of suture button (Tightrope) stabilization.

Meta-analyses have supported simple trapeziectomy with stabilization of the thumb CMC space for 4 weeks with a Kirschner wire (K-wire) to allow a hematoma to form.[10,11] However, many patients complain of pain from the K-wire as it rubs on the orthosis and may become irritated and even result in infection. Recently described techniques coupling a partial or complete trapeziectomy with suture-button suspensionplasty between the first and second metacarpals offers similarly good results when compared to previously described techniques when it comes to pain reduction, restoration of mobility and strength.[12,13] The suture button suspensionplasty provides the added benefit of eliminating the need for the K-wire fixation, and this allows for early mobilization at seven to ten days. The accelerated mobilization may occur because there is no external K-wire holding the joint suspended and there are no soft tissue reconstructions that need to heal (such as seen with the ligament reconstruction tendon interposition (LRTI) or abductor pollicus longus (APL) suspensionplasty techniques).

Stein[7] states that "it is our prediction that future directions for thumb reconstruction will focus on combinations of trapeziectomy with synthetic suspensionplasties between the thumb and index metacarpals, such as the Mini TightRope CMC Fixation system, the first commercial product available for this type of suspensionplasty."

Arthrex Mini TightRope suture button suspensionplasty procedure

Yao[8,9,12] has been utilizing the Mini-Tightrope suture button procedure for approximately four years with good results both with patient-self report questionnaires including the Disabilities of the Arm Shoulder and Hand (DASH) and Patient-Rated Wrist and Hand Evaluation (PRWHE), and physical impairment measures including range of motion and pinch and grip strength recovery. The Mini-Tightrope is used to suspend the thumb metacarpal from the second metacarpal to prevent subsidence into the newly formed CMC space. Study results have shown that this implant achieves similar stability as the k-wire fixation,[9] but allows early motion at seven to ten days postoperatively, which may lead to increased patient satisfaction, and a faster recovery and return to full activity.

The procedure is performed as follows. The 3 cm incision is made just volar to the APL attachment on the base of the metacarpal. This allows for the suture-button to be placed beneath a portion of the radial aspect of the abductor pollicis brevis tendon, thus decreasing the chance of postoperative hardware prominence. The CMC capsule is identified and opened. The trapezium is removed using osteotomes and rongeurs. A ballottement test is performed by placing an axial compression load on the thumb metacarpal to try to subside the metacarpal into the trapeziectomy space and down on to the scaphoid. This is done under live fluoroscopy to demonstrate that without suspension, the thumb will subside down on to the scaphoid. A positive ballottement test confirms that suspension of the thumb metacarpal must be performed. A 1.1 mm guidewire is introduced via this incision. It is oriented from its starting point at the dorsal-radial thumb metacarpal base toward the second metacarpal proximal diaphysis and is subsequently advanced through both cortices of both metacarpals. It is important to orient this guide wire in a path that extends from the thumb metacarpal base slightly distally to the second metacarpal metaphyseal–diaphyseal junction. Orienting the Mini-Tightrope in this oblique fashion provides a vector of tension that is better able to prevent subsidence than if it were transversely oriented. The K-wire is then advanced so that its exit site between the second and third metacarpals may be identified. A small incision is made over this region