CHAPTER **12**

THE CASE AGAINST THE USE OF NEW TECHNOLOGIES FOR HAMMERTOE REPAIR

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INTRODUCTION

Hammertoe repair is one of the most common procedures performed by foot and ankle surgeons. Over the past few years, companies have brought to the marketplace numerous intramedullary implants to be utilized for hammertoe repair and specifically for proximal interphalangeal joint (PIPJ) fusion (1, 2). The object of this discussion is to try and critically evaluate the appropriate use of these devices. Some of the questions that must be answered include: Is there a problem with the traditional approach to hammertoe repair? Are these new technologies really giving us a product that will improve patient outcomes? Does the cost of these new technologies justify their use?

As a foot surgeon who has performed hundreds of hammertoe surgeries yearly for more than 30 years, claims by orthopedic companies regarding the overwhelming success of their devices is viewed with a jaded eye. There is no question that medicine has become commercialized. One only needs to watch the evening news and see continuous commercials for prescription medications and orthopedic implant devices. Medical device companies claim that their implants are superior and often market their product directly to the population. More than one manufacturer has declared that their device is now the standard of care for hammertoe fixation. Certainly, one of the difficulties is that continuing education programs are often supported most enthusiastically by companies who have a new and improved product to market. Medical device companies train their sales people with talking points that emphasize the potential benefits. As a physician utilizing these devices and in the midst of our depressed economic environment, I understand that our healthcare dollars are very precious. Government and private insurance are squeezing physicians and hospitals in an attempt to limit inflationary healthcare costs. As a practicing physician, I can appreciate the current economic environment and hope that my clinical practice takes into account cost versus benefit of the medical devices and technologies that they utilize. Dr. Scot Malay has recently brought this topic of discussion to foot and ankle surgeons in his editorial in the *Journal of Foot and Ankle Surgery* (3).

THE HAMMERTOE DEFORMITY

A hammertoe is often viewed as solely a sagittal plane deformity with flexion of the PIPJ, extension of the metatarsophalangeal (MTP) joint and neutral, flexed, or hyperextented position of the DIPJ. This is probably too simplistic as there is often a component of transverse or coronal plane deformity that must be addressed. Part of patient assessment includes the number of toes involved. Is this a solitary deformity of one toe or are multiple toes involved, possibly with a variety of deformity components, and the degree of severity may vary among the individual toes?

Hammertoe repair must begin with appropriate assessment of the patient and his or her deformities. A hammertoe may be a very simple deformity with a degree of sagittal plane flexion of a single toe PIPJ or a much more complex problem involving multiplanar deformity of the toes and MTP joints or muscular imbalance of the lower leg extrinsic musculature, such as occurs with a cavus deformity with claw toes and MTP joint contractures.

PROCEDURAL OPTIONS

Our procedural options should address the deformities assessed. Toes/deformity may be flexible or rigid and there are certainly advocates of tendon transfer that may be appropriate in selected cases. Rigid PIPJ flexion is usually addressed with osseous procedures such as a Post arthroplasty or PIPJ fusion. The PIPJ fusion may be performed denuding the cartilage, performing end-to-end resection osteotomies or use of reamers or peg-in-hole type resection to provide an interlocking configuration. Deformity at the MTP joint may be addressed with simple extensor tenotomy, dorsal MTP joint capsulotomy, a full MTP joint release, proximal phalangeal base resection or metatarsal osteotomy. Luxatory and transverse plane deformity of the MTP joint may require plantar plate repair or tendon transfer. Individual patient variables may require a combination of osseous and soft tissue procedural options. One toe or ray segment may be involved or the entire forefoot may be deranged such as the case in a patient with pes cavus and a metatarsus equinus, digital adductus, or other multiplanar scenarios.

This article is directed to a sole procedure, PIPJ fusion, but the author does not wish to limit the importance of the remainder of the surgical options that may be performed to repair a hammertoe.

IMPLANT OPTIONS

Our discussion of implant options is obviously directed to the PIPJ fusion. Stabilization of a Post arthroplasty with a transient Kirschner wire (K-wire) is an option, but our examination of implant options is specific to PIPJ fusion. The prevailing standard that all other fixation implants is compared is to the use of K-wires (Figure 1). K-wires are simple and inexpensive, and require limited instrumentation for their insertion. Importantly, in the case of malalignment or infection, the percutaneous wire may be simply removed, generally with very limited patient discomfort and rarely requiring anesthesia. K-wires are generally inserted in a retrograde manner and cross the DIPJ as well as the PIPJ. If the situation dictates, the wire may also be placed across the MTP joint. Segments of a K-wire have also been utilized where the wire is inserted within the proximal phalanx and cut leaving a 5-10 mm segment that may then be pushed within the middle phalanx (4).

Absorbable pins have been utilized for fixation of the PIPJ arthrodesis site. Insertion has been aided with the manufacture of pins with points on either end, which are rigid enough to be placed on power equipment for insertion much like standard K-wires (Figure 2). These pins may be cut subcutaneously at the tip of the distal phalanx. Break-off pins are available that allow placement only in the proximal and middle phalanx without crossing the DIPJ.

Absorbable pins are more expensive than K-wires, and insertion may be somewhat more troublesome. These pins are less rigid than stainless steel and may bend or break. Insertion of an absorbable pin is generally preceded with insertion of a guide pin that actually cuts a tract for the subsequent placement of the absorbable pin. Absorbable pins have an advantage versus K-wires in that the pin remains in place for a much longer period of time. Absorbable pins may be bent inadvertently or intentionally. As a polymer, these pins will retain a plastic deformation of shape but like the intramedullary K-wire does not provide rotary stability of the digit. Introduction of slight digital flexion is possible with the absorbable pin and, this may help avoid "too straight" toes. Absorbable pins, much like K-wires, allow for transverse and sagittal plane stability but do not provide compression (Figure 3).

Screws have been utilized with a variety of insertion configurations, either from the tip of the toe or alternatively

Figure 1A. Kirschner wire fixation of the proximal interphalangeal joint fusion is the generally accepted standard that all other fixation techniques are compared. Preoperative view of a patient before a second toe end-to-end arthrodesis.

Figure 1B. Postoperative view at 6 weeks.

Figure 1C. Postoperative view, 3 months.

Figure 1D. Postoperative view, 6 months.

Figure 1E. Postoperative view at 9 months.

Figure 1F. Postoperative view at 1 year.

through the DIPJ. Specialized screws with small heads or headless varieties have been utilized. Screws may be solid or cannulated with the latter allowing for concomitant use of a K-wire if stabilization of the MTP joint is desired, although the largest cannulated screws usually only allow for a 0.045 inch diameter K-wire. Generally, if a K-wire is placed across an MTP joint, at least a 0.062 inch diameter wire is most appropriate. Smaller diameter wires, particularly 0.045 inch wires will have a greater likelihood of breakage at the MTP joint.

Screws allow for compressive forces across the arthrodesis site and intuitively suggest a greater likelihood for successful fusion (Figure 4). Screws have been associated with toes that are too straight, and screws like any other orthopedic implant may be subjected to excessive forces, yielding fracture of the device.

Figure 2A. Absorbable pins are an alternative to Kirschner wires. Variations of absorbable pins, polymer alone, metallic tip on one end, “break-off” pin.

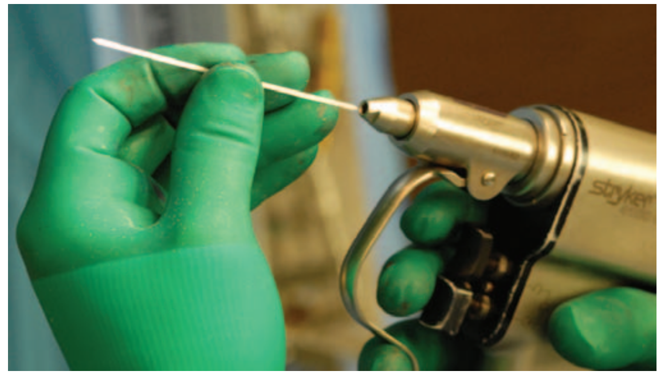

Figure 2B. Placement of absorbable within power driver.

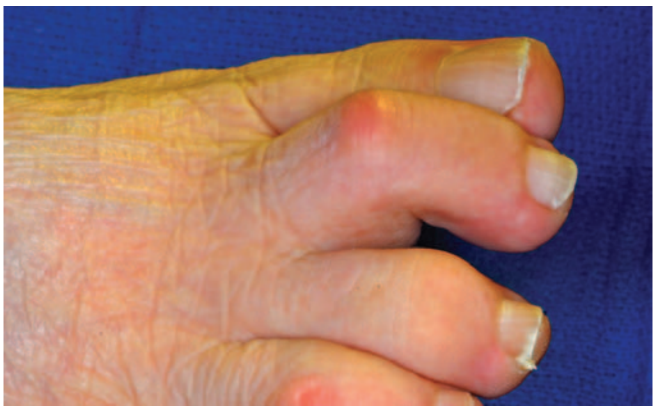

Figure 2C. Clinical view of hammertoe deformity.

Figure 2D. Preoperative radiograph.

Figure 2E. Radiograph at 2 weeks postoperative.

Figure 2F. Postoperative at 6 weeks of hammertoe repair of the second toe with 1.5 mm absorbable pin.

Figure 3A. Absorbable pins are useful in complex deformities such as a patient with divergent second and third toes, where PIPJ fusion was combined with proximal phalangeal base resection. This patient underwent procedures of the 2nd and 3rd toes.

Figure 3B. Radiograph at 2 weeks postoperative.

Figure 3C. View at 3 months postoperative.

Figure 3D. View at 7 months postoperative.

Figure 4A. Preoperative clinical appearance. A 2.4 mm headless screw was utilized in several toes in this patient with claw toe deformities.

Figure 4B. Screws in the second and third toes placed through the DIPJ (DIPJ arthoplasty was also performed) with ancillary Kirschner wire stabilization of the respective metatarsophalangeal joints, radiograph at 2 weeks postoperative.

Figure 4C. Radiograph at 5 weeks postoperative with Kischner wires within second and third toes removed.

Figure 4D. Radiograph at 3 months postoperative.

Thermoplastic staples, fabricated from nitinol, have been utilized generally with a single leg placed on either side of the arthrodesis site, the PIPJ, and placed in a dorsal to plantar orientation. This allows for compression across the arthrodesis site (Figure 5). More recently, several varieties of a nitinol thermoplastic metal implant have been utilized as an intramedullary fixation device. These implants require specialized instrumentation for insertion and certainly a learning curve exists before a surgeon is able to insert the device in a uniform and predictable manner and do so in an efficient amount of time. These implants do allow the surgeon to select an implant that will stabilize the arthrodesis perfectly straight or one that allows for a small degree of flexion, thus allowing for a more anatomic configuration to the toe.

Variations of the above generalized implants have also been advocated. One- and two-piece designs are marketed that incorporate threaded or barded ends. One design incorporates a threaded screw-like portion that is initially inserted within the proximal phalanx. Distally, this implant possesses a barbed spade-like configuration that pierces and maintains position within the middle phalanx.

Certainly, the question comes up of whether compression is necessary for successful hammertoe repair. The Post arthroplasty continues to be popular method of hammertoe repair performed by foot surgeons. The Post arthroplasty allows for resection at the level of the PIPJ with reduction of deformity at that joint followed by a fibrous ankylosis to stabilize the toe. Certainly, most foot surgeons have a good history with this procedure and still perform this with some frequency.

OUTCOMES

All studies are generally compared to the results of that achieved with simple K-wire fixation/stabilization of the toe. Coughlin et al (5) reviewed 79 consecutive patients (118 toes) over a 3-year period; patients with rheumatoid arthritis and diabetes were excluded. Articular resection was performed with hand instrumentation and the toe stabilized with a 0.045" K-wire, 81% achieved radiographic fusion with an 84% overall satisfaction rate. Infection was observed in 3 of the 118 toes and all healed uneventfully following removal of the K-wire. Malalignment was identified in 18 of the 118 toes (15%), with recurrent deformity making up the majority of these. They concluded that fusion was not the objective of the procedure but simply a well-aligned and stable toe whether fused or stiff. Peg-in-hole techniques have been advocated for their increased postoperative stability and fusion rates (6, 7).

Absorbable pins have been advocated including flexible polydioxanone (8) to more rigid polylactide varieties (9). Konkel in 2007 reported on 48 procedures in 35 patients utilizing 2.0 mm polylactide-L pins with more than a 38 month average follow-up (9).

Cannulated screws have been advocated including an Italian study of 37 feet (51 toes) comparing a 3.0 mm lag screw versus a K-wire and a mean follow-up of 2.6 years. Caterini et al (10) placed a long screw from the distal tip across both the DIPJ and PIPJ. They admit that the screw may yield persistent pain at the tip of the toe due to the screw head requiring removal. This occurred in 5 patients, 7 toes while radiographic union occurred in 94% with a 10% patient incomplete pain relief. Lane (11) also reported on successful use of cannulated screws placed through the head of the middle phalanx, utilizing either 2.0 or 3.0 mm depending upon the girth of the phalanges.

A 2012 article from Chile by Fernández et al (12) utilized 2.0, 2.4, and 2.7 mm screws with most frequent use of the 2.4 in 95 of 134 digital fusions. Complications were rare but included nail bed protrusion, malposition, and a broken screw. Patient satisfaction improved and complications reduced with the use of the 2.4 mm screw attributed to a good balance of small size and mechanical strength. They acknowledged that the K-wire is still the most reliable form of fixation.

The use of headless screws has been popular in hand surgery (13, 14) and use in the foot/toes began with Reese and his headless compression screw (15). This screw was ahead of its time and available in a variety of diameters including 2.4 mm. Several varieties of headless screws are available today.

Vitek (16) utilized a unique screw placed in a proximal to distal fashion with oblique joint resection that allowed for physiologic flexion of the toe. He reported a 93.4% fusion rate in 61 toes.

Angirasa et al (17) reviewed the SmartToe implant compared to K-wires in a 2012 study of 28 patients that followed the patient for 6 months posteratively. A total of 13 patients received the SmartToe while 15 underwent a similar procedure but with K-wire fixation. They did not report how many or which toes were operated on. All patients were immobilized in a CAM walker postoperatively and the K-wires removed at 4 weeks postoperative. Return to full activity occurred sooner with the SmartToe group (29 days compared to 37 days postoperative in the K-wire group). Radiographic union of the arthrodesis site generally occurred earlier and in a larger proportion of patients, 100% with the SmartToe versus 60% in the K-wire group. Interestingly, multiple complications were experienced in the

Figure 5A. Clinical appearance of patient with claw toe deformities.

Figure 5B. Preoperative radiograph.

Figure 5C. Small thermoplastic staples were utilized for the PIPJ fusion of the second, third and fourth toes. Radiograph illustrates appearance at 2 weeks postoperative.

Figure 5D. View at 3-months postoperative.

Figure 5E. Intraoperative clinical appearace.

K-wire group while no complications were noted in the patients who had the SmartToe. They concluded that the "The SmartToe implant is a reasonable option providing rigid, reproducible, stable, end-to-end arthrodesis fixation" and it "outperformed the K-wire without being fraught with complications."

Several intramedullary devices are marketed, from single piece to 2 piece interlocking designs. Screw and spade combinations or simple trocar-like designs are available, and are likely modeled after the success with use of a segment of a threaded or smooth K-wire (18).

DISCUSSION

Hammertoes are an ubiquitous deformity and commonly addressed with surgical management. The Post arthroplasty still makes up a good proportion of procedures and surgeons must vary their technique when performing a PIPJ arthrodesis including less bone resection of the proximal phalangeal head, resection of the middle phalangeal articular surface, and then stabilization of the arthrodesis. There are many variations in surgical techniques but pitfalls are encountered. Anatomy may vary from patient to patient as may the actual deformity.

Without question, K-wire fixation of PIPJ fusion is still the standard of care. No one can fault a surgeon for utilizing K-wires. This is a completely satisfactory alternative. K-wires are transient and may be easily removed in the case of infection, malalignment, or loosening. K-wires may be bent to introduce a physiologic flexion to the toe and the wire may cross the MTP joint if required. Some type of guard is recommended at the tip of the toe.

Absorbable pins although similar to K-wires allow for more permanent stabilization and are not generally removed unless necessary. These are either left buried at the tip of the distal phalanx or break-off pins allow for insertion only crossing the PIPJ. Pins may perforate and cross the MTP joint if desired. Both 1.5 and 2.0 mm varieties are available and useful for hammertoe repair. The more rigid 2.0 mm versions are less likely to bend upon insertion but are almost twice the size of the commonly utilized 0.45 inch (1.1 mm) K-wires. Theoretically, these pins will be absorbed as a result of hydrolysis within the body. Occasionally, adjacent bony changes may be encountered typically with a degree of cystic erosion, most commonly encountered within the metatarsal head.

Staples placed within the midline of the toe in a dorsal to plantar direction across the PIPJ for arthrodesis have been utilized, but were never really that popular. The staple does allow for compression across the PIPJ fusion, but malalignment may occur, the staple may be prominent dorsally, particularly if it backs out, and fracture from one of the legs may occur in soft bone.

Screws utilized for PIPJ arthrodesis may be placed in from the tip of the toe or from the head of the middle phalanx through the DIPJ. The latter requires arthrotomy of the DIPJ while the latter requires exposure at the tip of the toe. Screws must be slender enough to allow for intramedullary passage yet of sufficient diameter to avoid breakage. Screws have been associated with toes that are too straight as well as residual pain at the tip of the toe (in screws that have been placed through the tip of the toe). Both headed as well as headless designs have been implicated in latent distal tip toe pain. This has not been a frequent complication but may require screw removal at a later date. Infection and malalignment are a concern of any completely buried intramedullary device in that additional surgery may be required for its removal.

The intramedullary implants have been widely marketed and most foot surgeons now have some experience with these devices (Figure 6). These devices require special instrumentation and generally stored at cold temperatures prior to insertion. Insertion within the proximal phalanx is generally simple enough although malposition or extrusion of the device outside of bone has been encountered. Insertion within the body of the middle phalanx may be somewhat more difficult as the size and in particular the length of the middle phalanx varies considerably from individual to individual and possibly from toe to toe in the same individual patient. The surgery may be augmented

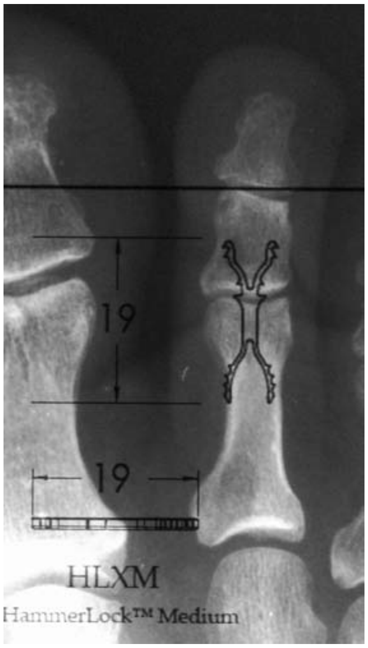

Figure 6A. Preoperative anterio-posterior radiograph of patient illustrating use of sizing template.

Figure 6B. Postoperative radiograph of patient undergoing PIPJ fusion of the second and third toes.

Figure 6C. Adequate placement of the proximal portion of the implant but lack of complete insertion into a short middle phalanx. Length of the middle phalanx is an important determinate of sizing.

Figure 6D. Intraoperatve appearance of insertion of proximal stem into proximal phalanx.

Figure 6E. Distal stem prior to insertion into middle phalanx.

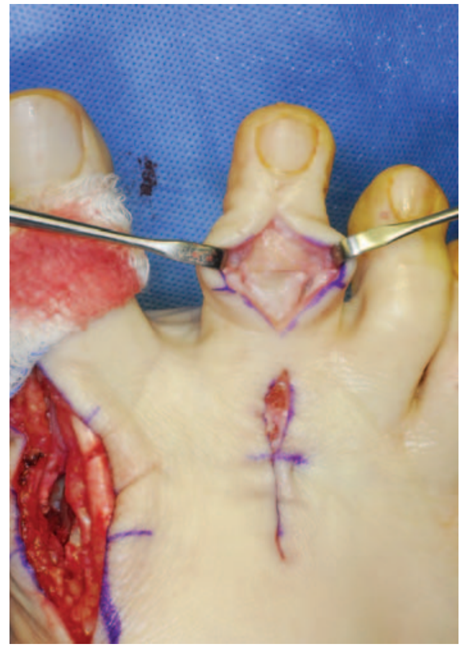

Figure 6F. Reduced arthrodesis site.

with the use of intraoperative radiographic imaging that should improve surgical technique and limit complications. This is certainly a consideration during the learning curve portion for new surgeon but it adds to surgery time as well as the overall expense of the surgery.

Which are the most appropriate deformities wherein to utilize this new technology? In more complex and multiple planar deformities, the K-wire still provides the greatest advantage allowing stabilization of the entire ray with a single device. Our intramedullary implants may offer advantage in less complex deformities where only 1 or 2 toes are involved. One difficulty is that once inserted, there is no return. With a K-wire if the position of the toes is not optimal, the wire and toe may be manipulated to improve position or simply removed and reinserted. With intramedullary implants, there are "no returns, no refunds." Malalignment following insertion of the implant requires removal and usually stabilization with a K-wire. Intramedullary implants do offer the patient more rapid return to regular shoes in that the typical K-wire is usually left in place 4-6 weeks preventing return to standard shoes.

Now, back to my original query. Question #1, is there a problem with the traditional approach to hammertoe repair? Any knowledgeable foot surgeon would probably answer that all procedures have their pros and cons and a properly performed PIPJ fusion with K-wire stabilization is an entirely acceptable procedure. Of course as with any surgical procedure complications are possible but predictably good results may be expected.

Question #2, are these new technologies really giving us a product that will improve patient outcomes? Theoretically, these devices impart a degree of compression at the PIPJ arthrodesis that we do not achieve with simple K-wire stabilization. There have been reports of improved bony consolidation and rate of fusion; but this begs the question, is bony consolidation a requirement for successful hammertoe repair or is simply a well aligned, stable toe the desired result? The contrarian view may also include: does a successful boney fusion result in a successful hammertoe repair? Although intramedullary implants impart rotational stability not achieved with axial K-wires, malalignment of the toe and arthrodesis site certainly may occur. Malalignment of a K-wire stabilized toe may often be rectified with removal of the wire. Infection although uncommon with a K-wire will generally resolve with simple removal of the implant and a course of antibiotics. Deep infection of an intramedullary implant arthrodesis may require revisionary surgery for removal of the implant and probably more likely to develop a chronic osteomyelitis. Non-reconstructible deformity has been observed with an intramedullary implant requiring amputation of the involved toe (Figure 7).

Question #3, Does the cost of these new technologies justify their use? Cost is certainly an important consideration as there is a tremendous diversity between the potential fixation implants. K-wires are very cheap while screws and intramedullary implants may be quite costly particularly considering that 2 or 3 of these devices may be utilized in a solitary surgical case. Hammertoe deformities are probably

Figure 7A. Complications may occur with any fixation implant. Here is a patient who later underwent amputation of the second toe due to nonreconstructible deformity, dislocation of the itramedullary implant.

Figure 7B. A patient who returned at 3 months postoperative with a portion of an absorbable pin retrograding out the distal tip of the toe.

Figure 7C. A radiograph at 1-year postoperative showing radiolucent changes within the second metatarsal head in a patient who had undergone PIPJ fusion and proximal phalangeal base resection with the ray stabilized with an absorbable pin driven within the metatarsal head.

Figure 7D. An intramedullary implant that fractured.

Figure 7E. Extra osseous placement of an intramedullary device.

Figure 7F. Less than ideal placement of an intramedullary implant with the implant too far distal in the middle phalanx.

Figure 7G. Malalignment of arthrodesis and fracture of implant (patient in 7F) due to stress imposed at weak area of implant.

one of the most common surgeries performed by foot surgeons and have likely been targeted for new implants due to their surgical frequency.

This author has personal experience with the majority of implants discussed in this paper. Like my colleagues, I also look for how I may perform better surgery and improve patient outcomes. I also believe that as a foot surgeon and provider of health care that I should independently evaluate my results and strive to spend our health care dollars in an ethical and efficient manner.

CONCLUSION

Hammertoe repair is most frequently performed through PIPJ fusion. Fixation of the arthrodesis site may be performed with a variety of implant options. K-wire remains the most common and the most predictable choice. K-wires are the least expensive form of fixation. Outcomes with more expensive fixation implants show promise but contribute to the complexity of the surgical procedure and time required to complete the operation impacting both operating room time, tourniquet time, and overall cost of the procedure. Complications associated with the use K-wires are generally limited and generally easily resolved. Complications involving intramedullary devices are more complex and difficult to deal with, requiring additional surgery if removal of the implant is necessary. Amputation of a toe is also a real potential for nonreconstructible deformity or complication associated with permanent intramedullary implants.

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