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Options for Toe Arthritis: A Biomedical Engineering Point of View

Abstract

The involvement of Biomedical Engineers in arthritic joint replacement includes, but is not limited to designing improved surgical methods using biomechanical concepts and use of suitable biomaterials for joint implants. Surgical methods used in toe arthritis have been immensely improved by biomedical engineering concepts. They include application of biomechanical concepts in external fixators, total joint replacement designs, improvement of joint replacement implants using biocompatible materials and finally the development of digital arthrodesis. Despite the advancements in this regard, there is still need for further improvement of the efficacy and safety of these techniques, thereby influence the long-term outcome.

Introduction

Deformities at the toes and toe joints are frequent consequences of Osteoarthritis and Rheumatoid arthritis. Hence, '*toe arthritis*' represent a significant clinical delinquent that has been persistent for a long time. Biomedical engineers working in concert with the doctors have led to clinically relevant developments to treat toe arthritis, especially in case of replacement of toe joints. Two of the most commonly seen toe arthritis conditions are Hallux rigidus (HR) and hammer toe, which are generally associated with Rheumatoid arthritis as well as Osteoarthritis (Coughlin et al., 2013). For instance, the prevalence of HR in adults older than 50 years old is ~2.5% (Hamilton et al., 1997).

Toe arthritis conditions are usually characterized by restricted motion, as the mechanical properties of the first metatarsophalangeal joint (MPJ) or lesser toes are severely compromised. In the case of MPJ, when the dorsiflexion is reduced from 40-60° to less than 10°, a treatment approach is required to correct the deformity or reconstruct the toe (Webb et al., 2005). Therefore, many of the surgical treatment strategies were implemented to improve the motion of the joint while restoring the normal foot functions. Biomedical engineering has incorporated biomechanical applications and established biocompatible materials to be used in toe replacement strategies. This mini-review will provide how 'engineering' concepts are being applied to address a clinical problem, in this case the '*toe arthritis*'. Two biomedical engineering aspects are being reviewed here. They include biomechanical engineering aspects and biomaterial biocompatibility aspects.

Literature Review

Non-surgical and surgical techniques for toe arthritis treatment: The non-surgical therapy strategies applied in this situation include pain relievers, anti-inflammatory drugs, heat-cold therapy, non-steroid/cortisone injections to the joint, shoe gear modifications, Morton's extension modified orthotics and carbon fiber inserts. These conservative techniques provide unsatisfactory outcomes in cases of advanced stages of arthritis.

The biomedical engineering aspects are mainly utilized in basic and improved surgical component of the therapy strategies. The most basic surgical methods include but are not limited to cheilectomy, fusion/arthrodesis, interpositional arthroplasty, decompression osteotomies and arthrodesis. The surgical toe replacement options are heavily dependent on the stage of degeneration of the joint. Bioengineering applications used in surgical options to treat progressing levels of HR can be taken for example. Cheilectomy and periarticular decompressive osteomy is used at early stage HR. In mid-stage HR complications, joint sparing techniques such as interpositional grafting and athrodiastasis as well as functional motion-sparing techniques such as total joint replacement are used. The end-stage HR are more degenerative arthritic stages which are difficult to be treated in simple techniques, but total joint replacement along with other joint-destructive procedures are used to alleviate the pain and/or motion difficulties (Perler et al., 2013).

The following sections will discuss examples of Biomedical Engineering applications in toe arthritis.

Usage of external fixator: In some of the toe arthritis treatment methods, an external fixator is used for correction of the deformities and reconstruction of toe/foot (DeHeer, 2003). Many of the toe treatments involve unilateral external fixator stability approach which is illustrated in **Fig.1A**. They also provide compression during the post-operative period. In Arthrodiastasis, a monorail mini-external fixator is used to move articular surfaces while facilitating stretch-relax mechanisms of the soft tissue at the MPJ (**Fig.1B**) (Perler et al., 2013). Usually the mini-external fixator creates gradual distraction of the joint space 0.5mm per day until it reaches a space 2-3 times bigger than the normal joint space. Moreover, interphalangeal arthroscopy is used as a corrective procedure for deformities in interphalangeal (IP) joint of the toes (**Fig.1B**) (Lui and Yuen, 2015). For example, in a patient with Hallux valgus and hypermobility, Tarsometatarsal joints (TMTJ) Arthroscopy was used on IP joint of the toes. The 1.9-mm 30 arthroscope provided extension and flexing the joint required for visualization. As an indication of the efficiency of the technique, analysis showed that hallux valgus angle and intermetatarsal angle were improved by 25.6° and 10.6°, respectively (Michels et al., 2011). Collectively, these examples demonstrate the use of external mechanical aspects in toe arthritis is beneficial in achieving functional toe motions.

Total Joint Replacement Designs: Another biomedical engineering advancement was the development of total joint replacement which was initially designed for fingers (Weems and Van Vo, 2013, Weems and Van Vo, 2014). However, as the mechanical properties of the fingers and toes are fairly comparable, these biomedical calculations can be used in toe joint replacement as well (Weems and Van Vo, 2014). These are basically ‘single-piece prosthetic designs’ or implants used for metacarpophalangeal/phalangeal-phalangeal total joint replacements (**Fig.2A**) with varying degrees of peak stress under 50N load at the flexion centers (Example: Sutter design - 5.20 GPa; Swanson design - 8.71 GPa; Neuflex - 0.188 GPa) (**Fig.2B-C**) (Weems and Van Vo, 2014).

Biomaterials in joint replacement implants: The implant material is a critical factor in better performance of the implant *in vivo*, which adapt to the Wolf law of bone remodelling (Bronzino, 2006). The same biomedical group designed one-piece silicone implant device with many similarities to the natural finger/toe motion mechanics (**Fig.3A**) (Weems and Van Vo, 2013). Moreover, the total finger/toe joint replacement assembly (**Fig.3B**) was simulated to adapt similar static and dynamic properties of the natural joint using the equations shown in **Fig.3C**. The silicone implant material used and the biomechanical design comparative to nature toe/finger allowed 3 and 4 MPa of stress tolerance at 10N load, which is equivalent to the maximum stress tolerated by a natural joint. Therefore, these observations highlight the suitability of silicone as a viable biomaterial when employed in concert with biocompatible mechanical simulations. Applying this concept, currently, there are commercially available toe replacement implants such as Integra® Silicone MTP Toe Replacement System where different geometries of implants are utilized based on the affected toe (**Fig.3D**).

However, due to reduced biocompatibility and longevity, the usage of silicone implants in joint replacement techniques have been less successful. For this reason, recent studies have been biased towards bipolar non-constrained Titanium, Polyetheretherketone (PEEK) or Silastic as the biomaterial for arthroplasty of the first metatarsophalangeal joints (Hetherington et al., 1994, Morgan et al., 2012). Computational calculations in (Weems and Van Vo, 2013) suggested solution treated titanium (Ti) alloy (6Ti-4Al-W) or Ultra high molecular weight polyethylene could be acceptable biomaterials to be used in single-piece joint replacement implants. The equation used in building theoretical three-dimensional model of the implant with different materials is as follows.

$$V = k * Fv = \frac{k * F_N * x}{3 * p_{soft}}$$

V - total adhesive wear volume, k- Archard's coefficient, FN- force applied, x- sliding distance and p_{soft} is the Vickers hardness value of the softer material. (Weems and Van Vo, 2013)

Digital arthrodesis and intramedullary fixation devices:

Arthrodesis is a medical procedure during which the bones of the affected joint are held in place with different types of apparatuses including screws, plates and screws, rods and wires. Biomedical engineering advances have brought up the concept of 'Digital Arthrodesis' primarily using a one-piece intramedullary fixation device (Khan et al., 2015, Zelen and Young, 2013). The digital arthrodesis has now more or less replaced the traditional methods of arthrodesis such as the Keller procedure and the buried Kirschner wire technique (Scholl et al., 2013). Two of the most recently developed intramedullary fixation device are the Nitinol-based 'Smart Toe® Implant' (Sandhu et al., 2013) and stainless steel-based Integra® IPP-ON fusion system (Coillard et al., 2014) (**Fig.4A-B**). The Smart Toe® implant is made of body temperature sensitive and adaptive NiTiNol and hence once implanted it get acclimatized into the patient's toe anatomy by shortening and expanding and creating an anchoring force (**Fig.4A**). Many commercially available devices made with different biomaterials and planar angles are detailed in **Table I**.

Biomaterial aspects of intramedullary fixation devices: The biomaterial used in constructing the fixation device is of utmost importance as the motion properties as well as acclimatization to the joint environment is highly dependent on the properties of the biomaterial. For instance, NiTiNol bioengineering material used in Smart Toe® Implants is a Nickel-Titanium Alloy which exhibits more biomechanical behaviors of natural tissue (Shabalovskaya, 1996). Some of the physical and mechanical properties essential for its vascular applications include, specific mass of 6.45 g/cm³, elastic modulus EA of 53.5 and EM of 29.2 GPa, yield stress at 400 MPa, yield strain 9% and ultimate tensile stress and strain 1355 MPa and 14.3%, respectively (Petrini and Migliavacca, 2011). A Comparison of the tensile behavior of the NiTiNol (used in Smart Toe®) and Stainless steel (used in Ipp On®) suggests that NiTiNol holds more elastic and hysteresis properties while supporting its elastic deployment and thermal deployment (**Fig.4C**). Additionally, plantar angle is another important factor and in most cases it ranges from 0°-10° or 0°-10°-17° or 0°-10°-20° (Guelfi et al., 2015). Both NiTiNol and stainless steel-based devices have 0°-10° Plantar angle while PEEK-based devices have higher angles.

Discussion and Future Implications

Arthritis toe deformities such as HR and hammer toe are among the most common clinical complications presented to podiatric surgeons. Surgical replacement or reconstruction of the compromised toe joints is frequently practised to alleviate the pain and motion restrictions associated with toe arthritis. The biomedical engineering techniques incorporated into toe arthritis treatment are rapidly advancing. The employment of more biocompatible materials such as NiTiNol seem to be advantageous in terms of the fusion rate reported (NiTiNol-93% and Stainless steel- 83%: **table II**). As expected, each technique bears its own advantages and disadvantages, thus evaluation of their efficacy, long-term outcomes and developing methods to improve their quality are essential.

Stem-cell based replacement or regenerative medicine approaches have been implicated in many foot deformities. Tendon repair has been achieved in injecting Fibrin and bone marrow-derived mesenchymal stem cells, while this application resulted in improved biomechanical properties (Schmitt et al., 2012). Therefore, stem cell-based regenerative technique may presumably be a future possibility for toe arthritis. The robotic surgery advancements are applied in many joint replacement surgeries (example hip joint) to improve component and positioning and alignment (Elmallah et al., 2015). However, robotic options are so far not available for toe arthritis treatment, yet sounds as a promising option in near future.

Conclusions

There are several surgical options for toe arthritis where biomedical engineering aspects are used in functional and structural recovery of the toe joint. These biomedical engineering approaches can be broadly categorized into two; 1) Biomechanical aspects where mechanical engineering concepts are employed to either support the reconstruction of the toe joint as in the case of external fixators and/or to simulate the implant mechanics to match natural joint mechanics. 2) Biocompatible biomaterial aspects of

biomedical engineering where the knowledge of physical and mechanical properties such as stress, temperature sensitivity is used in developing improved toe replacement implants.

Figures

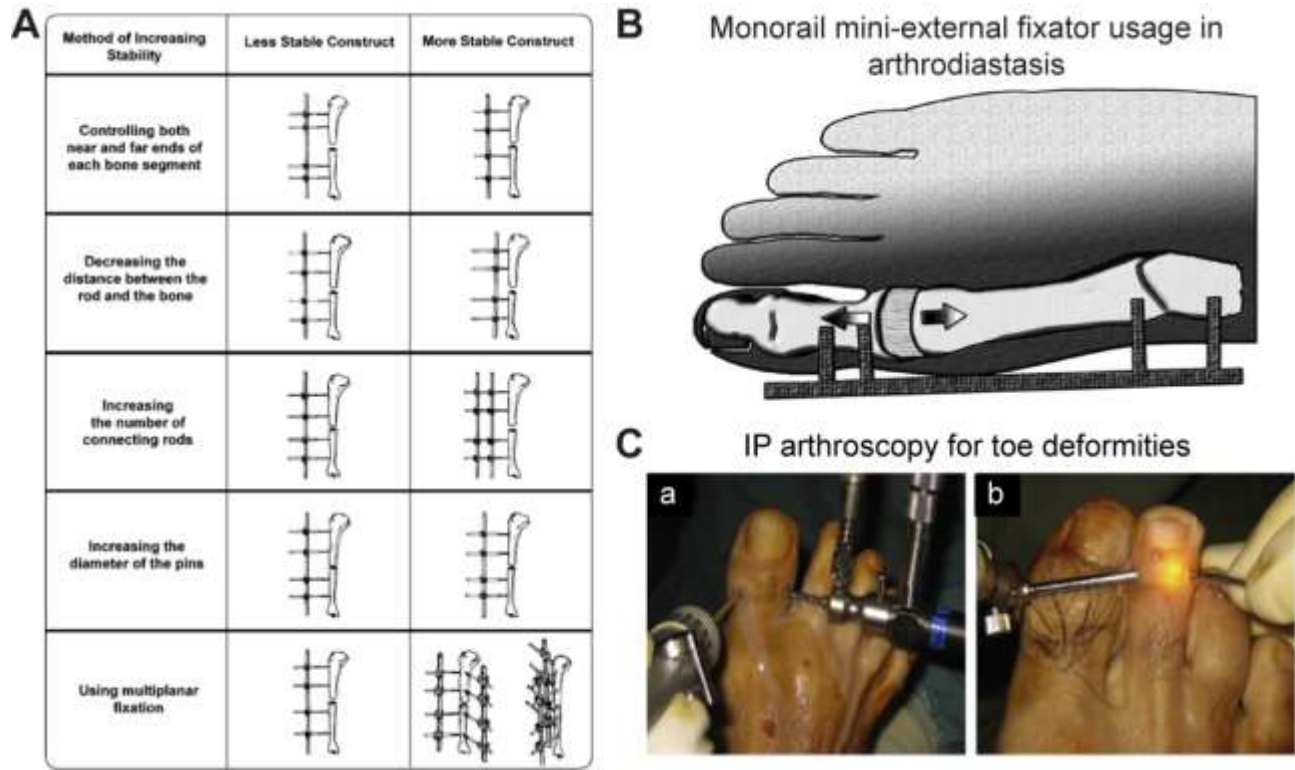


Figure 1. Usage of external fixator to reconstruct toe arthritis deformities. A) Unilateral external fixator stability approaches used for joint corrections. Adapted from (Fragomen and Rozbruch, 2007). B) Using monorail mini-external fixator in arthrodiastasis of the first MPJ. Adapted from (Perler et al., 2013). C) IP arthroscopy of the a) hallux and b) the second toe with deformities. Adapted from (Lui and Yuen, 2015).

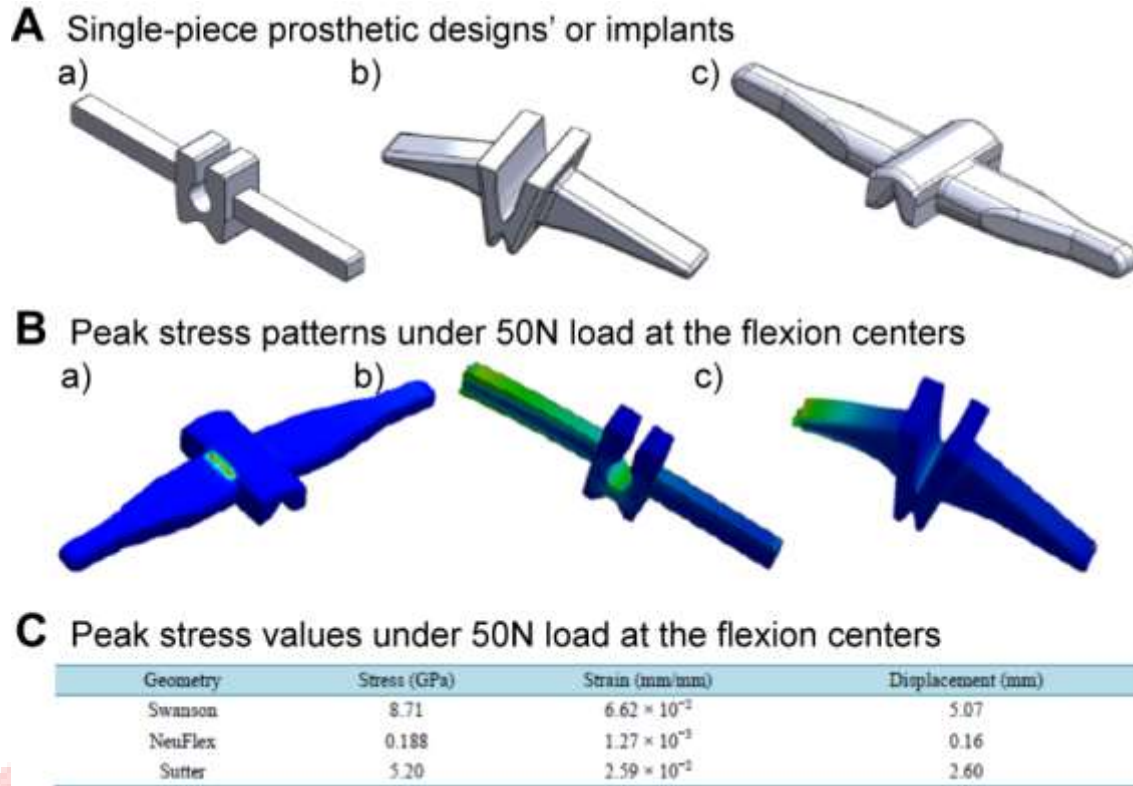


Figure 2. One piece metacarpo-phalangeal/phalangeal-phalangeal total joint replacements. A) Three different types of implants, a) Sutter, b) NeuFlex and c) Swanson. B) The varying degrees of peak stress under 50N load at the flexion centers of the implants, a) Sutter, b) NeuFlex and c) Swanson. C) The stimulated peak stress values. Adapted from (Weems and Van Vo, 2014).

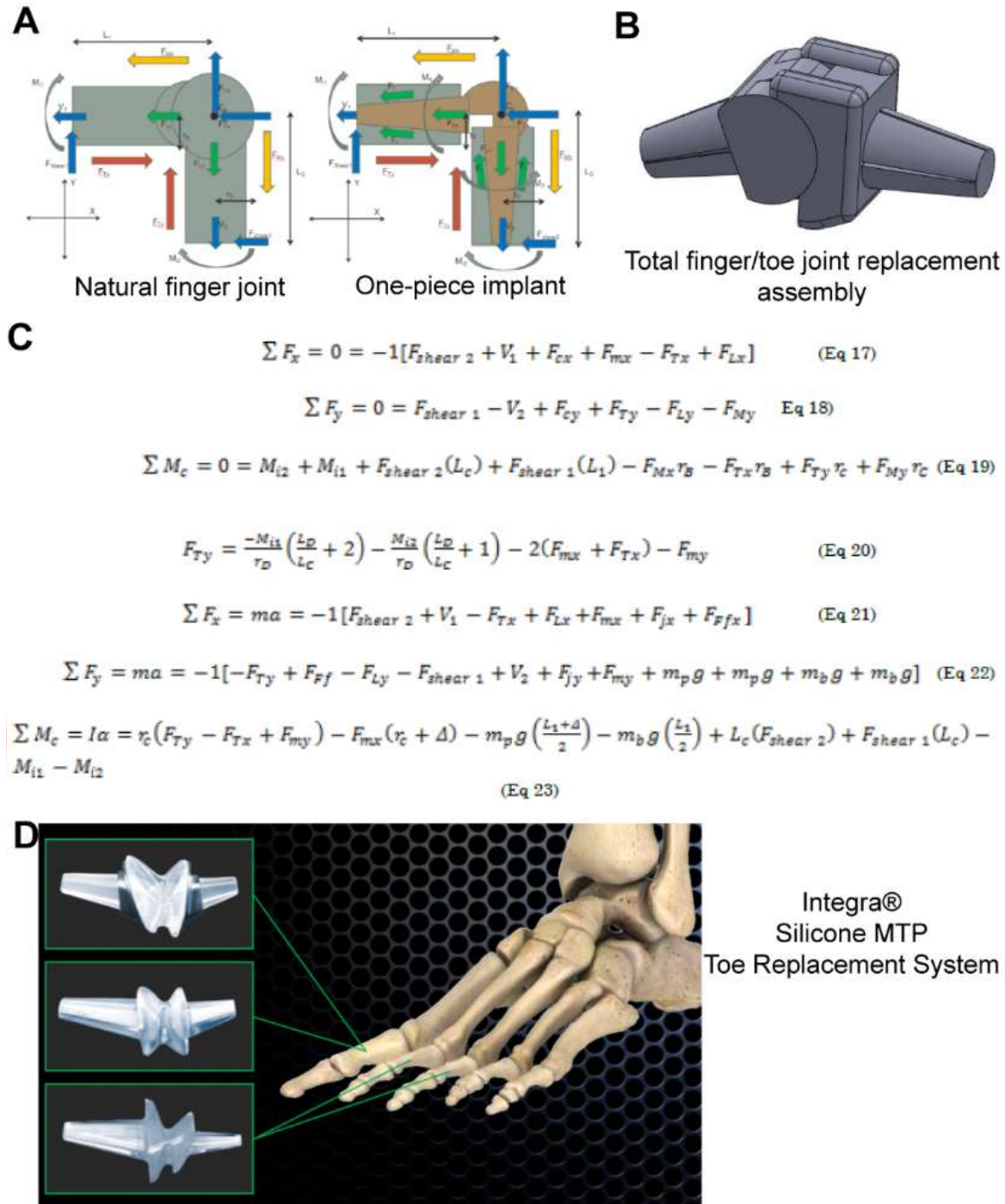


Figure 3. On-piece total finger/toe joint replacement implant – the engineering parameters.

wing the comparison of mechanical properties of the natural joint and the implant. B) A representative schematic of the total finger/toe joint replacement assembly. C) Simulation equations used to apply static and dynamic mechanical properties of the natural joint to the implant assembly. Adapted from (Weems and Van Vo, 2013). D) Representation of the silicone toe replacement implant systems available at Integra®. Adapted from Integra® Silicone Forefoot Arthroplasty Products catalog available at the following link, assessed on February 12th 2016.

<http://integralife.com/products%2Fpdfs%2Fsilicone%20forefoot%20arthroplasty%20%28pgt%2C%20cgt%20%26%20imp%29%20surgical%20technique.pdf>

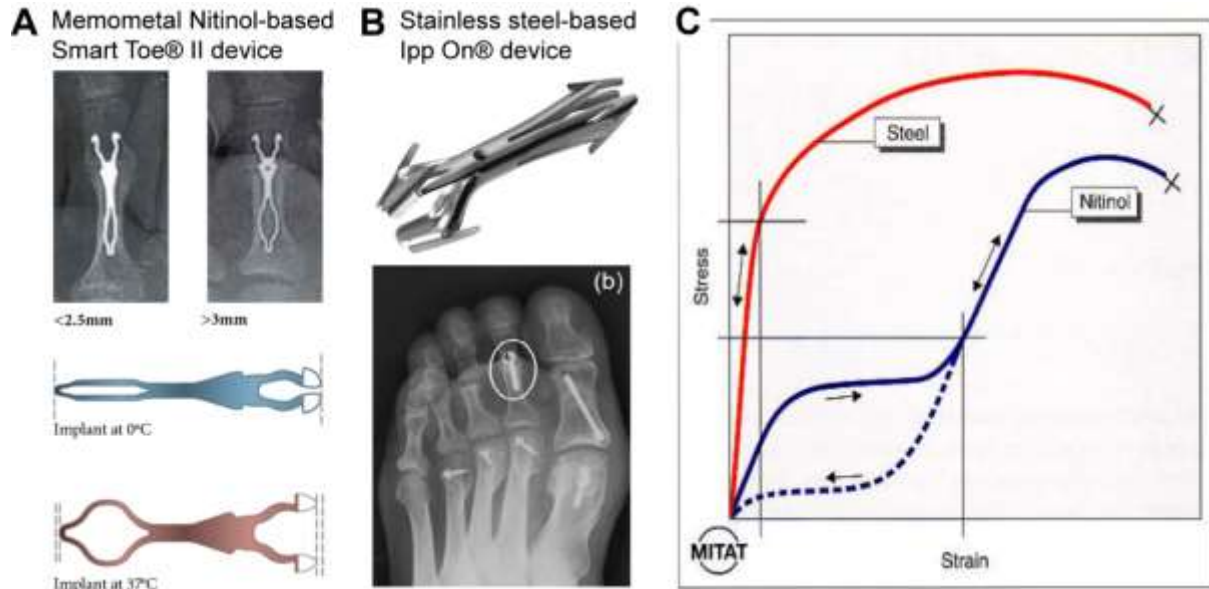


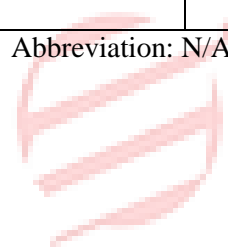
Figure 4. Intramedullary fixation devices used in digital arthrodesis. A) Memometal Nitinol-based temperature adaptive Smart Toe® II. Adapted from Smart Toe® II Intramedullary implant, operative techniques manual available at <https://strykermeded.com/media/1601/smart-toe-ii-intramedullary-implant.pdf> assessed on February 12th 2016. B) Stainless steel-based Ipp On® device and its application in a patient (X-ray). Adapted from (Coillard et al., 2014). C) Comparative tensile behavior of different biomaterials used in implants, NiTiNol and stainless steel. Adapted from (Stoeckel, 2000).

Tables

Table I. Biocompatible biomaterials used in Intramedullary fixation devices

Biomaterial	Commercial name of the device	Plantar angle	Special Properties	Bone fusion rate
Memometal NiTiInol	Smart Toe [®] II	0°–10°	Shape memory	93% (Roukis, 2009)
	Hammerlock [®]	0°–10°	Shape memory and super-elasticity	N/A
Stainless steel	ProToe VO [®]	0°–10°	N/A	N/A
	Arrow-lok [™]	0°–10°		N/A
	Ipp On [®]	0°–10°		83.8% (Coillard et al., 2014)
Titanium	Stayfuse [™]	0°–10°	N/A	60.5% (Ellington et al., 2010)
	Digifuse [™]	0°–10°		N/A
PEEK	DuaFit [®]	0°–10°–17°a	Tissue reaction to metallic ions is reduced, Improved fatigue properties (Green and Schlegel, 2001)	N/A
	Toegrip [®]	0°–10°–20°		
	HammerFix [®]	0°		

Abbreviation: N/A: Not available. The information on devices was extracted from (Guelfi et al., 2015)



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