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Research Article

Distraction Implantation. A New Technique in Total Joint Arthroplasty and Direct Skeletal Attachment

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Abstract

Background: Using the marrow canal of a tubular bone as a holding compartment for implant stems has been the paradigm in total joint arthroplasty for more than a century, and for direct skeletal attachment of limb prostheses for about forty years. Both interventions rely on the osteogenesis in the inner walls of the marrow canal in a direction radially inwards. It so remains despite the frequent aseptic loosening of the implant stems caused by the resorption of the marrow canal's inner walls which increases the canal's diameter and reduces its capacity to hold the implant.

Materials and Methods: To improve the bone-device bond, we suggest an implantation methodology that activates positive osteogenic remodeling in the circular direction rather than radially inwards. The rationale is that circular osteogenesis is a component of natural healing of bone fractures and its activating may mitigate the consequences of resorption caused by stress shielding, bone developmental growth and other factors.

Results: Circular osteogenesis occurs in response to the distraction of slots precut into the bone tube. We call this methodology distraction implantation (DI) because of its debt to Ilizarov type distraction osteogenesis (DO). The methodology is accompanied by a design of an implant stem, and has been investigated in a previous pilot animal study.

Conclusion: Distraction implantation is based on a component of natural healing of bone fractures and therefore has merit to be investigated further.

Keywords: *Total Joint Arthroplasty; Bone Remodeling, Anisotropy, Direct Skeletal Attachment*

Introduction

Since John Charnley's introduction of contemporary hip arthroplasty in 1961 [1], marrow canal of the bone continues to be used as a holder for the implant's stem. The current total joint arthroplasty (TJA) is a successful procedure overall [2]. However, with increasing number of TJA being performed at a younger age and increased life expectancy significant increase in the revision burden has been either documented or predicted [3-6]. Mechanical loosening (19.7%), is one of the most common indications for revision [3,7-9].

Various theories have been introduced to explain the cause of loosening, including the particle disease theory and the stress shielding theory [10]. According to the latter, reduction of stress in the proximal metaphyseal region results in resorption in that region, which can cause the prosthesis to loosen from the bone. Insufficient ossification in the inner walls of the canal may also increase transport of the wear debris to the area between the implant and the bone around the implant. The association between early migration of femoral stems and late aseptic revision was confirmed in a meta-regression analysis on data from 24 studies (with 731 stems), and 56 studies (20,599 stems) [11]. The reviews showed that for every 0.1-mm increase in 2-year subsidence, there was a 4% increase in revision rate for the shape-closed stem designs. Another negative consequence of the prevalence of resorption over remodeling is that patients with loosened femoral components are at higher risk for bone fracture [12].

Beyond the mechanisms mentioned above, an intrinsic cause of the stem loosening, especially in the development age, is a prevalence of resorption of the inner walls of the marrow canal over deposition of the new bone cells on the outer walls of the bone tube. We call these processes negative and positive remodeling correspondingly and will discuss them in detail in the "Methods" section of the paper.

Mechanical loosening is a serious problem in the direct skeletal attachment (DSA) of limb prostheses as well. DSA was introduced by Mooney and colleagues [13] in 1977 and achieved practicality about two decades ago [14,15]. The method also relies on the holding capacity of the marrow canal since the loosening diminishes the functionality of the artificial limb [16]. A special fixture with an abutment is implanted transcutaneously into the distal part of a residuum's bone, allowing the limb prosthesis to be attached to the outer portion of the abutment. The fixture's loosening due to resorption of the bone walls often leads to revision and reimplantation with dramatic shortening of the residuum's bone [17].

To increase holding capacity of the hosting bone and address the issue of loosening in TJA and DSA we developed a methodology called distraction implantation (DI) with a corresponding stem design. The methodology and design pairing activate ossification in a direction which is more physiologically advantageous for bone remodeling [18]. The approach takes inspiration from Dr. Ilizarov's methodology of distraction osteogenesis (DO) [19], specifically the application of DO to bone widening [20]. Further similarities and distinctions between DI and DO will be discussed later.

Methods

Positive and negative remodeling

The sustainability of an implant depends on sufficient bone remodeling. Remodeling is governed by genetic mechanisms of the body's development and is critical for the repair of defects and fractures. Remodeling respects the tubular architecture of bone, with limited remodeling occurring in the radially inward direction in order to preserve the bone canal as a vital volume for the bone marrow [21].

The vectors of bone remodeling in response to different stimuli are shown in figure 1A. Remodeling is not even in all directions, but is instead truly anisotropic [22]. Specifically, bone growth is associated with new matter being deposited on the outside of the bone walls (see vector Y in figure 1A). Since growing bone requires more bone marrow, resorption of the walls of the medullary cavity affords more volume for the marrow (see Figure 1B). We call the resorption *negative remodeling,* and the term *positive remodeling* relates to bone growth apposition, when new layers are added to the outside of the bone walls.

The geometry of the positive and negative types of remodeling is illustrated in figure 1B.

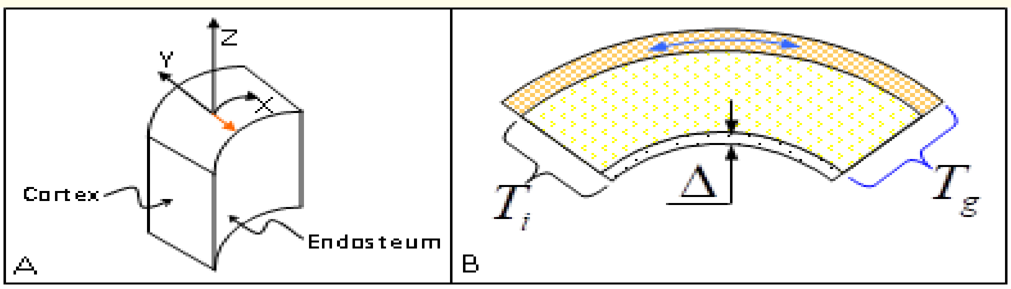

Figure 1: *A: segment of a cortical bone wall. Coordinates x, y, z correspond to ossification in circular (x), radial outward (y black), radial inward (y red) and longitudinal (z) directions. The red arrow points in the radial inward direction relative to the medullary cavity. B: Increased thickness T_g of bone walls compared to the initial thickness T_i following positive radial outward and circular remodeling (blue arrows). Δ –thickness of the layer being resorbed due to negative remodeling.*

A sector of the bone cross section is depicted with initial thickness T_i and thickness T_g following the bone growth. Due to positive remodeling, the thickness of the bone wall is increasing, thus $T_g > T_i$. Concurrently, due to negative remodeling, the internal wall layer of thickness Δ dissolves, resulting in the increase of the volume of the medullary cavity.

If the medullary cavity is the only holding compartment for the stem, the increased radius of the cavity would be a legitimate cause for mechanical loosening or for the loosening enforced by the debris transported to the newly developed space [23].

Other authors have noted this phenomenon as well. Accordingly, porous stems surfaces, various combinations of flutes and non- biological and biological coatings were introduced for improving bone- implant bond. While these measures may show mild positive remodeling in the radially inward direction, the remodeling of the inner walls is limited by the genetically dictated task of preserving the space for bone marrow and may occur only to the extent provided by the reaming of the medullary canal before insertion of the stem [21,23].

Distraction implantation (DI)

The purpose of developing a new stem design and method of implantation [18], was to activate the remodeling in a more advantageous direction compared to the radially inward direction associated with the current art. We selected the circular remodeling of the bone walls, which is a natural component of the process of fixing the bone fractures.

To activate this positive remodeling, we developed a modification to an implant's stem and a technique for its insertion. The implant stem is designed with fins. These fins are pressed into slots that have been precut into the bone walls before implantation [18]. To activate circular bone remodelling, a distraction of the slots is required during implantation. The side fins also create an anti-rotational effect, similar to the role of transverse pins. As to distraction, activating positive remodeling around the fins, that feature is not present in the technology of the transverse pins or intramedullary locked nails. Also, the new technique does not require any guiding jigs, which are necessary for inserting the anti-rotational pins or intramedullary locked nails.

As illustrated in figure 2a, the DI technique [18] includes tight press-fitting of the side fins of the stem to the slots made in the bone walls. The resulted distraction (red arrows) causes a simultaneous compression (blue arrow) due to the elastic resistance of the wall to the widening of the slot. In figure 2b, a CAD model depicts the stem with side fins implanted into the bone. Figure 2c shows Von Mises stress distribution in bone-implant system for cylindrical stem; figure 2d – demonstrates reduction in Von Mises stress distribution in the bone when the stem has side fins compared to the stem without fins (c) [24].

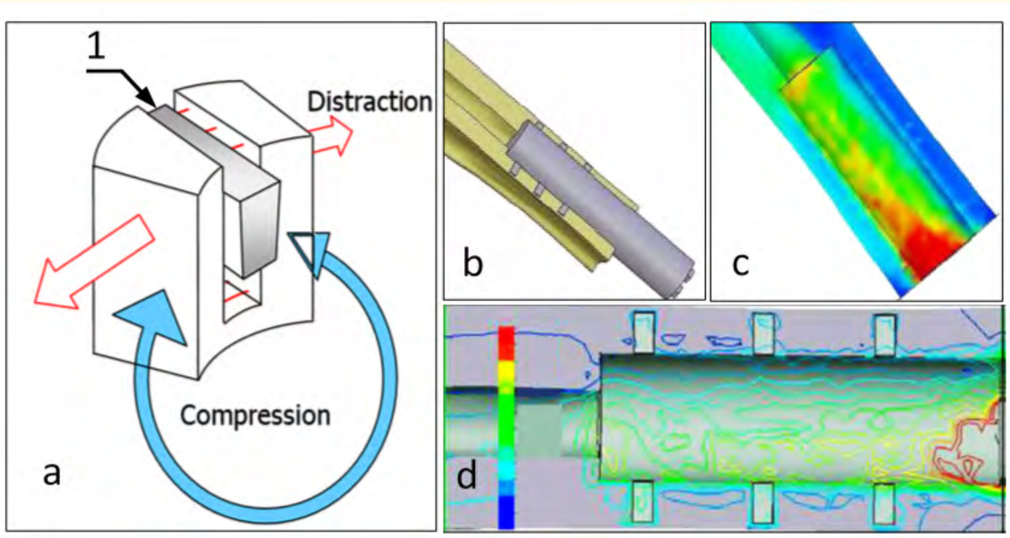

Figure 2: *a: Press-fitting of fin 1 to slot in bone wall results in Ilizavov-type distraction (red arrows) and compression (blue arrow) due to elastic resistance of bone wall to widening [12]; b: 3-d CAD model of SBIP-F implanted in bone; c: Von Mises stress distribution in bone-pylon system for cylindrical SBIP; d: Von Mises stress distribution reduction in bone- SBIP-F compared to the SBIP without fins (c). Adopted from [25].*

Snapshots of the supplemental video illustrating the DI method are shown in figure 3. The stem with side fins (Figure 3.1) is press-fitted into the slots in the bone walls (Figure 3.2). The distraction initiates bone circular remodeling in the slot (Figure 3.3), which fills the gaps around the fins (Figure 3.4-5). That integrates the side fins into the surrounding bone (Figure 3.6). Encapsulating the fins increases the rotational stability of the implant.

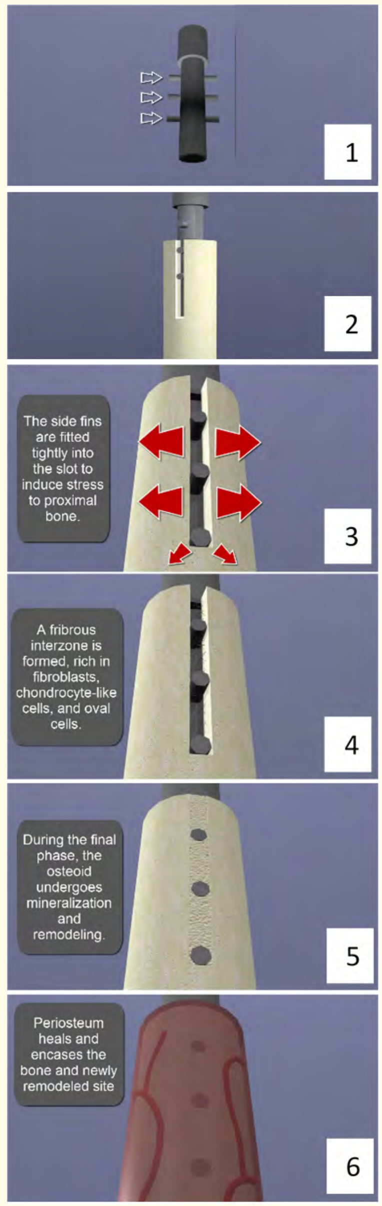

Figure 3: *Illustration of the DI concept. Side fins of the stem are inserted tightly in the precut slots initiating distraction osteogenesis (Supplemental Video).*

Video

Discussion

All current technologies of TJA require remodeling of tubular bone in the radially inward direction, pointing to the bone's central axis. This vector of remodeling is less effective compared to remodeling in the outward, longitudinal and circular directions [23,25].

The vector of circular bone wall remodeling is advantageous for mitigating the negative outcomes of the resorption in the inner walls of the medullary canal.

Remodeling in the circular direction was first used in Ilizarov's technique of distraction osteogenesis (DO) in its modification for bone widening [20]. The precursor to this technique was an initial application of DO to bone lengthening; bone growth in the longitudinal direction (vector Z in figure 1A) is a major component of self-healing of bone fractures. Bone lengthening requires a cross-sectional bone cut, and bone widening requires a cut along the bone's longitudinal axis. Once the fragments are distracted in a cross sectional plane perpendicularly to the longitudinal axis of the bone and fixed in a frame, ossification is activated [20] (Figure 4). This ossification proceeds in the circular direction of the bone tube (vector X in figure 1A). Such ossification is a remodeling of the positive type and is a component of self-healing of bone fractures as well [23]. The lessons from DO can be readily applied to DI for total joint arthroplasty that can address stem loosening, especially in young and physical active patients.

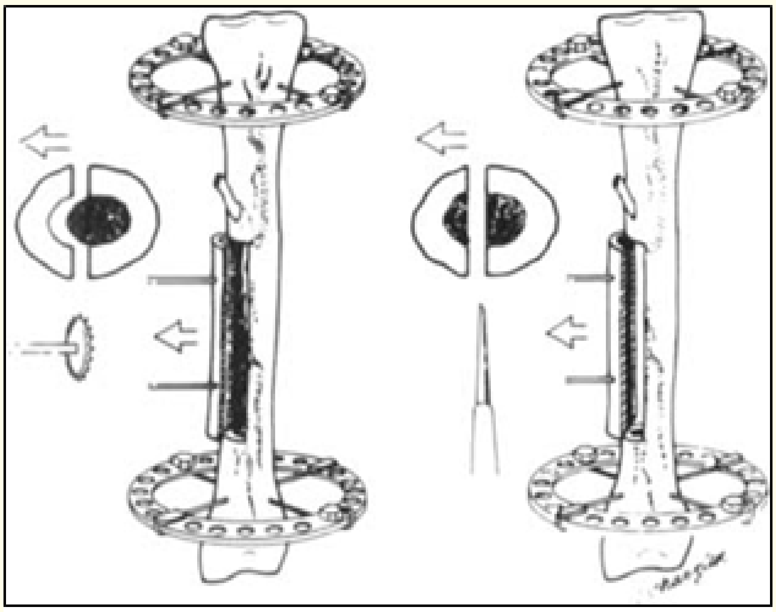

Figure 4: *Ilizarov distraction osteogenesis in bone widening: osteotomy of the cortical segment, and the apparatus to displace the section of tibia1 cortex transversely [20] (with permission from the Wolters Kluwer Health).*

The similarities and distinctions between classical DO and the new DI are summarized in table 1. Classical DO consists of three phases: latency, distraction and consolidation [26]. In the latency phase, the gap is formed following the osteotomy, with no stresses applied to the bone fragments. During this phase, biological processes are basically the same as those in the early stages of fracture repair [27].

Phases	DO	DI
Surgery	Application of the apparatus	N/A
	Osteotomy: transverse for bone lengthening; longitudinal for bone widening	Transverse osteotomy if required by TJA
		Cutting the slots
		Inserting the implant with the stem equipped with side fins
Latency	Lasts 3-10 days after osteotomy	N/A
Distraction	Multiple, applied by apparatus	Single, applied by the implant to the walls of the slots
Consolidation	Within the gap between bone fragments	Within the gaps between the fins in the slots
	Stability provided by the apparatus	Stability provided by the hosting bone

Table 1: *Specifics of Distraction Osteogenesis (DO) and Distraction Implantation (DI).*

Distraction is performed 3 - 10 days after osteotomy and that action stretches the newly developed callus. Acting mechanical forces form a fibrous interzone with active chondrocyte-like cells, osteoblasts, and fibroblasts.

Distraction implantation (DI) is performed by tightly press-fitting the side fins of the stem into the slots made in the bone walls. Following distraction, bone morphogenetic proteins and their signal transduction molecules influence osteoblasts to induce bone formation.

Consolidation follows with mineralization and remodeling, resulting in osseous union of the distraction gap.

The DI method was tested in two pilot animal studies described in detail elsewhere [25]. The studies were simultaneously conducted by teams at the Tufts University School of Medicine, Boston, MA, USA, and the I.P. Pavlov Medical University, St. Petersburg, Russia, while working on the development of porous composite skin and bone integrated pylon (SBIP) for direct skeletal attachment (DSA) of limb prostheses [28]. All procedures were carried out in accordance with relevant guidelines and regulations after the protocol approval by the responsible IACUCs.

The purpose of the project was to demonstrate ossification in the precut slots and around the side fins of the pylon that was implanted transcutaneously into the residuum bone of three rabbits. The procedure of implanting a pylon with side fins is shown in figure 5.

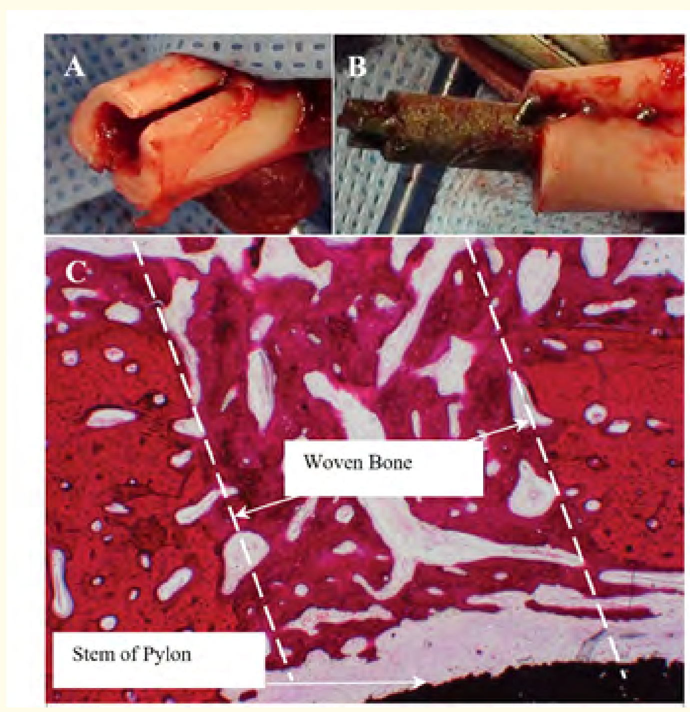

Figure 5: *A: Precut slot before implanting the pylon; B: Press-fitting of te pylon with side fins; C: cross section showing healed precut slot (between dashed lines) in the bone wall in 26 weeks after implantation; H&E 0.5 X [25].*

The distraction required for inducing circular ossification was provided by press-fitting the side fins into the precut slots (Figure 4A, 4B). A concurrent compression was provided by the self- resistances to distraction of the slot walls. Twenty-six weeks after implantation of the pylons, sound and sustainable remodeling was observed (Figure 4C). The space between the fins and the bone into which they were fitted was filled with fibrovascular tissue and woven bone [29], signaling the presence of distraction osteogenesis. The highest values of bone-implant contact were recorded along the distal edge of the pylon.

In the method of distraction implantation (DI), the latency and distraction phases are combined, since the implantation occurs concomitantly with when the slots are cut into the bone walls.

Another distinction is that distraction in DI is developed not by the apparatus as in the classical method, but by the stresses in the bone tube moving apart the sides of the slots. Finally, in contrast to the rhythmic consecutive distractions of the newly formed calluses in the classical method, we perform a single initial distraction of the existing cortical bone followed by a single consolidation phase.

At this stage of the methodology development, it is not known yet to what level the distraction of the slots should be administered in order to maximize the osteogenesis, but not to compromise the integrity of the bone. That is planned for future investigation.

Conclusion

Similarities to the classical method of distraction osteogenesis and the new method of distraction implantation lie in inducing the processes of natural bone remodelling in the circular direction. Their distinctions may allow for application of the new method in total joint replacement and direct skeletal attachment of limb prostheses.

Total joint arthroplasty utilizing fundamental advantages of classical distraction osteogenesis, if properly developed and tested with the new method of distraction implantation, has the potential to improve the long-term bond between the bone and the implant and therefore decrease aseptic loosening and revision rate.

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Competing Financial Interests

The author declares no competing financial interests.

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