S-Core® Subchondral Platform Technology Providing Stabilization to the First Metatarsophalangeal Joint Complex in Addition to Cheilectomy Repair for Hallux Limitus/Rigidus

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Abstract:
The S-Core® platform technology is the only intra-osseous stabilizing device with regenerative capabilities to stabilize subchondral insufficiency microfractures. Subchondral disease is often present, yet undiagnosed, in all grades of hallux rigidus. This technology offers a reliable alternative to joint destructive and joint fusion procedures. This is a joint preservation procedure which initiates a physiologic process, allowing the regenerative anabolic healing process to outpace the degenerative catabolic process. This technology was introduced in 2019 and has been implanted in over 200 cases. There have been no reported cases of deep infection or loosening. There have been two reported cases of arthrofibrosis which were addressed by manipulation which restored functional dorsiflexion. Passive range of motion is started immediately following surgery, and a structured postoperative physical therapy program is important to maintain range of motion and favorable outcomes. A prospective, long-term follow-up study is currently underway.

Introduction:
A cheilectomy is popular as the treatment of all grades of hallux limitus/rigidus. The complexity and associated adjunctive procedures are determined by the clinical picture, examination and objective findings, x-ray, MRI, and patient goals and expectations, all of which are open to interpretation by each individual surgeon.

The balance of the hallux flexor-extensor and abductor-adductor mechanisms and the insertion of the plantar aponeurosis into the base of the proximal phalanx are critical to maintain stability of the first metatarsal-phalangeal (MTP) joint.[1,2] The compression and shear stress on the MTP joint during gait is dissipated by dorsal gliding of the hallux on the MTP joint articulation.[3,4] Total joint arthroplasty procedures that replace the metatarsal head are vulnerable to dorsally directed and shearing weight-bearing stresses, which often lead to loosening and implant failure.[5] Total or partial joint destructive procedures that replace the metatarsal head are vulnerable to dorsally directed and shearing weight-bearing stresses, which can lead to loosening and implant failure.[6] In contrast, the S-Core® platform technology maintains a favorable mechanical arrangement through dorsal gliding on the metatarsal head while preserving the sesamoid attachments to the proximal phalanx. This mechanical advantage can occur because the implant is placed intra-osseously and below the articular cartilage within the subchondral space and does not interfere with the external supporting structures involving the first MTP joint.

Problems Associated with Diagnosis and Treatment of Hallux Rigidus with Cheilectomy Bunionectomy:

Hallux rigidus is a common condition with an estimated incidence of 1 in 40 in subjects aged over 50 years. It is the second most common disorder of the first metatarsal-phalangeal joint after hallux valgus. The hallmark traits of hallux rigidus are progressive pain and loss of joint motion of the great toe MTP joint.[7] The patient presents with gradual onset of pain, swelling and stiffness of the first metatarsal-phalangeal joint. There is limited dorsi-flexion due to the formation of osteophytes around the dorsal aspect of the articular margin on the head of the first metatarsal. A fixed plantar flexion deformity may develop, hence, the original name of hallux flexus.[8]

Plain radiographs may show flattening of the distal articular surface of the first metatarsal head, a narrowed joint space, osteophyte formation on the medial, lateral, and dorsal aspects of the metatarsal head and proximal phalanx with sclerosis and cyst formation in the subchondral regions as the condition advances.[9]

Some colleagues feel that the inclusion of MR imaging is unnecessary and ask why it is utilized. Radiographs almost always underestimate the extent of pathology. One of the reasons cheilectomies fail is because subchondral dysfunction and instability issues are not addressed. O thought process for advanced imaging is explained in detail later in the paper.

Non-operative treatment of progressive hallux rigidus/limitius includes the use of non-steroidal anti-inflammatory agents, and orthoses which aim to reduce the movement that produces pain. Surgical treatment includes resection arthroplasty, metal, or ceramic hemiarthroplasty, silastic interposition arthroplasty, soft-tissue interposition arthroplasty, metatarophalangeal joint arthrodesis, phalangeal and metatarsal osteotomy, cheilectomy and arthroscopic debridement.[10-15]

The treatment of choice for this condition for years has been a cheilectomy with a multitude of variations, all with the hope of negating the need for joint realignment and/or joint destructive procedures (e.g., joint resection arthroplasty with or without implant or fusion). These patients clearly have articular defects with subchondral disease seen on MRI, typified with bone marrow edema, insufficiency microfractures, and cystic lesions.

This becomes a chronic and progressive degenerative process which results in instability of the foundation of the articular surface. This may be the reason why long-term results have been disappointing and resulted in the need for subsequent and even multiple surgeries.[16]

Risk Factors for Subchondral Bone Pathology and Dysfunction:

We have learned that multiple factors play a role in the development of hallux limitus/rigidus. These include but are not limited to trauma, degenerative and inflammatory arthritis, genetics, faulty biomechanics, etc. As we learned the different contributory etiologies, we became proactive as additional procedures were added to deal with those etiological factors, such as realignment osteotomies, arthrodeses, etc.

Peer Questions Regarding Cheilectomy and adjunctive procedures:
Questions have arisen regarding adjunctive surgical procedures which were synergistic with cheilectomies. Cheilectomy, as a stand-alone procedure, does not address the etiology and therefore does not prevent the progression of disease and is rarely a permanent solution to the problem. Oftentimes, micro-drilling of the diseased portion of the articular surface is performed with the hope of stimulating a healing response. However, there is a paucity of evidence as to the efficacity of this procedure, and often the procedure is performed in cases of more extensive disease. These cases more frequently progress to clinical failure. Adjunctive procedures are necessary to not only deal with the sequela but also the etiology of this condition. The failure of reconstructive efforts of a diseased joint, is related to a lack of understanding of the delicate balance and interdependent relationship between the structures of the subchondral bone, cartilaginous surface, and the synovial fluid.

Cheilectomy, with adjunctive procedures, allows surgical intervention to be both reactive and proactive. The reactive portion is the removal of surrounding or adjacent hypertrophic and degenerative bone, with or without joint replacement implant, micro- drilling, etc.

The proactive portion involves additional procedures to alleviate the underlying etiology which leads to hallux rigidus in the first place. These procedures include, but are not limited to, realignment osteotomies of the first ray, joint stabilization, and realignment of the medial cuneiform-first metatarsophalangeal joint (to control arthritic pain and instability), as well as to realign structural deficits.

Another proactive procedure is open reduction with stabilization of non-healing subchondral micro-fractures, cracks, surface defects, and/or cysts of the metatarsal head, well beneath the articular cartilage. These are often not imaged with traditional radiographs but are seen on MR imaging. If not visualized and not addressed, this condition can progress and may necessitate follow-up surgery, such as revision arthrodesis of the first metatarsal-phalangeal joint. This is a separate and distinct procedure as it addresses a diseased and structural entity that is clearly not part of a cheilectomy procedure.

Cheilectomy procedures, with or without implants, are joint destructive procedures.

S-Core®, the internally intra-osseous placed stabilizing “cage-like” platform device, is a joint preservation procedure.

Cheilectomy and stabilization platform technology address different types of pathology and with different surgical objectives, making them two distinct surgical procedures. Although they

are separate procedures, they are synergistic and share goals of attenuating pain, maintaining joint motion, increasing functional capabilities, and reducing the risk for subsequent surgery.

Coughlin Hallux Rigidus Grading System[17] and Scoring Systems Play a Role in Developing a More Complete Surgical Plan

The Coughlin Hallux Rigidus Grading System and Subchondral Bone Fracture Defect Score help to recognize subtle subchondral foundational stability problems present but previously were hard to identify. These systems may provide additional information which is helpful in the formulation of a surgical treatment plan. In dealing with hallux limitus/rigidus, include only those patients with a well-aligned first ray and MTP joint. If additional underlying issues are present, consideration in dealing with these issues is necessary as this can lead to a better prognosis, including reducing the risks of recurrent post-operative pain and deformity. A complete surgical plan may reduce the need for subsequent surgery. These issues can include but are not limited to alignment problems of the first ray, hallux valgus, metatarsal varus primus, first ray hypermobility, and arthritis of the first metatarsal-cuneiform joint. Diagnosis, formulation of a comprehensive treatment plan and management of these conditions are critical in achieving a favorable prognosis for these patients. Regarding hallux limitus/rigidus in this discussion, we limit our focus to surgical procedures in dealing with pathology of the first MTP joint and first ray, both of which are well aligned and stable.

Patients with Grade 0 hallux rigidus, have well aligned first ray and first MTP joint and with Grade 0 with range of motion is only 10 to 20% below normal, with normal radiographic findings, and with normal MRI findings, Generally these patients do well with a cheilectomy.

Patients with Grade 1 hallux rigidus, with motion 20 to 50% below normal, with abnormal radiographs exhibiting dorsal osteophytes, mild joint narrowing, flattening of the first metatarsal head, and/or periarticular sclerosis, and abnormal MRI findings (periarticular osteophyte formation and joint space narrowing), bone marrow edema 50% or less of the metatarsal head, flattening of the met head, and articular loss and thinning may be a candidate for one or possibly two procedures. Cheilectomy probably is indicated.. During the procedure, the surgeon should consciously examine the articular surface and if there are no soft spots and no articular deficits, then cheilectomy alone is indicated. However, if there is softening of the articular surface and/or any articular deficits present, then consideration should be adding a secondary procedure. That would include open reduction of subchondral insufficiency, and micro-fracture and stabilization of intra-osseous subchondral bone with platform S-Core technology.

Patients with Grades 2 and 3 hallux rigidus exhibit significant radiographic and MRI changes consistent with degenerative changes and most likely will respond positively to cheilectomy plus open reduction, with subchondral insufficiency micro-fracture and stabilization of intra-osseous subchondral bone with platform S-Core technology.

Patients with Grade 4 hallux rigidus should have fusion of the great toe joint. However, for those individuals who wish to maintain motion, consideration can be given to performing the same

two procedures as in Grade 2 and 3, plus adding a biologic soft interface covering the head of the first metatarsal.

Modified Coughlin et al. Hallux Rigidus Grading System

The gold standard and most used classification of hallux rigidus was developed by Coughlin and Shurnas, which was a modification of a prior classification by Easley et al. This classified the disease into 5 grades (0 to 4) and considered MTP joint range of motion, radiological changes, and clinical manifestations. Since this classification is over two decades old, Drs. Coughlin and Zang have modified the classification system by including MR imaging as radiographs which almost always underestimate the extent of disease.

Modified Coughlin et al. Hallux Rigidus Grading System

Grade	Dorsiflexion	Radiographic Findings	MR Imaging	Clinical Findings
0	40° – 60° (10-20% below normal range of motion)	Normal	Normal	No pain Only stiffness Some loss of motion
1	30° – 40° (20-50% below normal range of motion)	Dorsal osteophytes, Mild joint narrowing, Flattening metatarsal head, and/or Periarticular sclerosis	Joint space narrowing/effusion/ synovitis/cartilage loss	Mild and/or intermittent pain Stiffness at maximal dorsiflexion flexion joint
2	10° – 30° (50-75% below normal range of motion)	Periarticular dorsal osteophytes 1st MTPJ Mild to moderate joint narrowing or sclerosis Flattening metatarsal head	Osteophyte formation with or without marrow edema	Moderate to severe pain and Stiffness with more pronounced Pain evoked near end range of motion of the joint
3	<10° Dorsal and plantar flexion below 10° (75-100% below normal range of motion)	Severe degenerative changes 1st MTPJ Subchondral cystic changes Sesamoid irregularities	Subchondral bone edema	Nearly constant pain and stiffness with pain being with end range of motion, but not midrange motion
4	<10° Dorsal and plantar flexion below 10° (75-100% below normal range of motion)	Severe degenerative changes 1st MTPJ Bone on bone 1st MTPJ Subchondral cystic changes Obliteration 1st MTPJ	Subchondral cyst/erosions/ insufficiency fracture Ankylosis	Same as grade 3 but with pain present at midrange of passive joint motion Crepitus

S-Core* Classification Score

Subchondral Bone Fracture Defect Score - From Science to Diagnosis and Treatment:

Dr. Derek Dee stresses that the S-Core stabilizing platform technology addresses a foundational problem – the role of the subchondral bone in the initiation and progression of degenerative joint disease. Articular cartilage is a highly specialized tissue, but it is not an island unto itself – it serves to convert and transmit tangential joint forces in a compressive manner to the subchondral bone, which absorbs and dissipates stresses further. Bone failure causes pain and progression of disease.

Bone is in a constant state of repair and remodeling. When the rate of damage exceeds the rate of repair, failure or defects occur – i.e., trabecular stress fracture, insufficiency fracture, osteochondrosis, and/or bone hypertrophy. Bone is both a mechanical foundation and metabolic support for cartilage and when this physiologic balance is upset, joint disease ensues. This is a result of both mechanical and biologic failure of the subchondral bone.

The SUB Score – Subchondral Bone Fracture Defect Score - is a radiographic diagnostic inclusion score for subchondral bone failure, fracture, and osteochondrosis. The following simple "ABCD" inclusion criteria forms the basis for the SUB Score:

A. Bone edema / bone marrow lesion / bone contusion – MRI T2 or STIR
   1. [ ] Less than 5mm [ ] More than 5mm
   2. Bone structure – subchondral plate or trabecular fracture / insufficiency fracture / osteochondral fracture-defect – MRI T1 Images, CT, XR
   3. [ ] Less than 5mm [ ] More than 5mm

B. Cystic changes

C. Defective – bone hypertrophy, architectural changes – MRI, CT, XR
   1. [ ] Intralesional Osteophyte

      Generalized upward migration subchondral bone plate – loss of continuity with surrounding plate/curvature, often subtle
   2. [ ] Sclerosis

      Typically associated with thinned or fibrillated overlying cartilage, as the bone is encroaching on the space of the articular cartilage and pushing it out.

Patients who meet at least one of these criteria (A, B, C, or D) are candidates for repair and reconstruction of the subchondral bone with platform stabilizing intra-osseous technology, S-Core. Patients can be graded with single or multiple inclusion scores, i.e. SUB Score A, or SUB Score C, D2.

The Problem - An Unhealthy and Unstable Subchondral Bone Complex is Subtly Present and Difficult to Identify - Examining What is Occurring on a Molecular Level:

Osteoarthritis (OA) is a degenerative joint disease involving all joint related structures including the articular cartilage, subchondral bone, synovium, bone marrow, ligaments, muscles, nerves, and the blood supply. The bone-cartilage interface has been described as a "functioning synergistic unit." Biomechanical insults and the biologic consequences they induce, that disrupts this synergistic unit, is just beginning to be recognized and understood. This deviation from the normal healthy biologic process that occurs leads to abnormal remodeling and joint failure.[18,19]

It has also been hypothesized that there is a line of signaling pathways or "crosstalk" both biochemically and molecularly that suggests there is a close synergistic relationship between the subchondral bone and cartilage[20].

Once this "crosstalk" is disrupted, degeneration of the structural integrity of the bone cartilage interface ensues. Articular chondrocytes, contribute to their own destruction by producing proinflammatory cytokines including interleukin 1, and matrix metalloproteinases (MMPs) that facilitate destruction of the local tissues, including cracks that can extend down into the subchondral bone[21].

In healthy bones there is a balance between resorption and formation. Both mechanical forces "outside-in" (e.g., wear and tear/microtrauma) and/or autoimmune inflammatory responses "inside–out" (e.g., lymphocytic infiltrates, pannus and increase vascularization), affect stability of the subchondral bone complex is paramount in the presence of bone marrow lesions (trabecular fracture/nonunion).[21]

Treatment and Prognosis is Dependent on a Complete Diagnosis:
Hallux rigidus is associated with the onset of pain and diminishing motion in the first MTP joint. The extent of pathology is often obscured as plain radiographs of the subchondral space of the first metatarsal head remain unremarkable throughout the period of subchondral fracture initiation.
MR imaging is important diagnostically as it enables early detection of fractures and can differentiate repetitive stress fractures and insufficiency fractures.

Subchondral insufficiency fractures (SIF) are a type of stress fracture that occurs below the articular cartilage, on the weight bearing surface of the underlying bone, in this context, the first metatarsal head. SIF occur when normal physiological forces are repeatedly applied to an area of bone compromised by metabolic disease, resulting in fracture.

Stress fractures and insufficiency fractures can result in serious complications, including destruction of the first MTP joint, therefore. It's important to obtain a definitive diagnosis before a reconstructive plan is completed. It is important to understand the difference between stress fractures and insufficiency fractures, even though the results are often similar. Stress fractures result from abnormal stress on normal bone and are called fatigue fractures, resulting from repetitive stress associated with uncontrolled biomechanical imbalances. Insufficiency fractures are a type of stress fractures which result from normal stresses on abnormal bone.

Those occurring in abnormal bone are insufficiency fractures and occur in patients with underlying metabolic syndromes and bone disease, including osteoporosis, which is the most common cause of insufficiency fracture.[22] Oftentimes repetitive stress, faulty biomechanics and metabolic issues are all present, and increase the risk of progressive destructive joint dysfunction and disease.

What Differentiates S-Core® from Any Other Procedure?

This platform technology produces a circular, decompression osteotomy and provides internal cage-like support to the unstable micro-cracks (fractures) in the subchondral bone space, which provides support for the articular surface. The S-Core® hydroxyapatite coated titanium implant is fenestrated with 800-micron openings that allow for an optimal penetration of whole blood. We believe the increased blood volume increases the amounts of biologic products contained in whole blood and therefore plays a significant role in enabling the regenerative process to overtake the degenerative process in areas where standard healing is disrupted.[24,25] This allows for the nutrient carrying blood vessels to initiate and maintain an angiogenic regenerative healing response that directly targets the microcracks and insufficiency trabecular fractures in the subarticular bone, an area that was previously left untreated, or at best inadequately treated.

When the physiologic metabolic balance is interfered with by disease and/or targeted by repetitive stress, the healthy balance is upset, and the degenerative process may outpace the regenerative process. Historically, surgical joint sparing efforts involved a cheilectomy and then adjunctive procedures were then added to hopefully improve long term results. These efforts included but were not limited to a multitude of procedures: resection of the base of proximal phalanx, micro-drilling of articular defects, re-alignment, and decompression/plantarflexing osteotomies of the first metatarsal or proximal phalanx or both, partial or complete joint replacement procedures, OATS procedures, and more. Post-surgical efforts included physical therapy and control of biomechanical imbalances.

Surgeons have made great strides in dealing with these issues and outcomes continue to improve. However, for us, it appeared that something was missing and our efforts were often insufficient. Initially, efforts were reactive to the abnormal structural components of hallux rigidus, and these efforts then morphed to both reactive and proactive. As technology has progressed, surgeons may now expand their efforts to be more inclusive; reactive, proactive, and regenerative.

The goal is to re-establish a healthy environment so the regenerative process can again outpace the degenerative process. This device provides a space for platelets to congregate and dispence the necessary growth factors to initiate the regenerative process.

Contents of Whole Blood Containing Platelets:

These biologic proteins and other substances necessary to initiate the tissue and the restorative processes are contained in granules located with the platelets.[27]

Platelet a-granule content:[27.]

Type	**Examples**
Adhesive proteins	Von Willebrand factor, fibrinogen, trombospondi-1, trombospondin-2, laminin-8
Growth factors	Epidermal growth factor (EGF), insulin-like growth factor 1 (IGF-1), hepatocyte growth factor (HGF), transforming growth factor ß (TGF-ß)
Angiogenic factors	Vascular endothelium growth factor (VEGF), platelet-derived growth factor (PDGF), fibroblast growth factor (FGF)
Chemokines	CCL5 (RANTES), CCL-3 (MIP-1a), CCL-2 (MCP-1), CCL-7 (MCP-3), CXCL8 (IL-8), CXCL2 (MIP-2), CXCL6 (LIX), CXCL-1 (GRO-a), CXCL5 (ENA-78), CXCL-12 (SDF-1a), CXCL4 (PF4)
Clotting factors and their inhibitors	Factor V, factor IX, antithrombin, factor S, protease nexin-1, protease nexin-2, tissue factor pathway inhibitor,
Integral membrane proteins	aIIb3, GPIba-IX-V, GPVI, TLT-1, p-selectin
Immune mediators	Complement C3 precursor, complement C4 precursor, factor D, factor H, C1 inhibitor, IgG

Growth factors and their biological functions:[27]

Name	**Abbreviation**	**Function**
Platelet derived growth factor	PDGF	Enhances collagen synthesis, proliferation of bone cells, fibroblast chemotaxis and proliferative activity, macrophage activation
Transforming growth factor ß	TGF-ß	Enhances synthesis of type I collagen, promotes angiogenesis, stimulates chemotaxis of immune cells, inhibits osteoclast formation and bone resorption
Vascular endothelial growth factor	VEGF	Stimulates angiogenesis, migration, and mitosis of endothelial cells, increases permeability of the vessels, stimulates chemotaxis of macrophages and neutrophils
Epidermal growth factor	EGF	Stimulates cellular proliferation, differentiation of epithelial cells, promotes cytokine secretion by mesenchymal and epithelial cells
Insulin-like growth factor	IGF	Promotes cell growth, differentiation, recruitment in bone, blood vessel, skin and other tissues, stimulates collagen synthesis together with PDGF

Name	Abbreviation	Function
Fibroblast growth factor	FGF	Promotes proliferation of mesenchymal cells, chondrocytes, and osteoblasts, stimulates the growth and differentiation of chondrocytes and osteoblasts

The functional properties of the components contained within whole blood are activated with injury, surgery, and these factors are essentially stored in thrombocyte a-granules which play a key role in regulating the cellular process, including chemotaxis, mitogenesis and differentiation.[28,29] This is the only technology with FDA clearance to address this pathology. This is accomplished as an adjunctive yet distinctly separate procedure.

We believe that this technology is unique in that it addresses a different type of fracture that most patients are not familiar with and is not often discussed with patients. Most patients understand long bone fractures that utilize plate and screw fixation devices, a strut on the outside of the bone held in place with screws, or a rod placed in the shaft, like rebar. Patients have difficulty understanding that insufficiency fractures are like an island of quicksand and will not hold screws or plates.

Dee added that the S-Core is the only available cage-like stabilizing and totally buried intraosseous internal fixation device. The circular designed osteotomy not only encircles the unstable area of subchondral micro-fractures, but also allows a space for growth factor rich platelet containing plasma and blood to congregate. The device has openings measuring 800-micron which allow blood to collect inside the cage. This not only provides growth factors and nutrients but the increased volume of blood which is drawn into the area provides a measure of compression to stabilize the targeted area of insufficiency, both of which are necessary to jumpstart and maintain a regenerative healing environment. This provides a protective shield around the area of the subchondral space that is undergoing repetitive injury and stress.

The S-Core technology accomplishes several issues:

1. Circular decompression osteotomy creates a unique opportunity for the device to fully encompass and therefore create an island of security within the area of instability.
2. Provides internal cage-like stabilization platform support to the unstable insufficiency fractures within the subchondral bone space.
3. Provides an area which attracts and stores whole blood which contains the growth factors and proteins necessary to initiate and maintain a regenerative process.
4. Provides a stable foundation under the articular surface which helps to prevent further degeneration of this structure.
5. The articular surface of the S-core allows for the placement of a dermal graft to help maintain an anatomic interface between the implant and the proximal phalanx.

6. Fenestrations in the S-core articular surface provides a consistent and secure site for suturing the dermal graft and allows vascular in-budding between the subchondral bone and the dermal graft.

Summary:
The S-Core® subchondral stabilizing device was designed to deal with a foundational problem that was difficult to identify and when identified, difficult to adequately address. The dysfunctional status of the subchondral unit is often not recognized as standard diagnostic x-ray evaluation is often inadequate and unable to capture subchondral disease and therefore did not lead surgeons to suspect pathology within the subchondral space. Also, platform technology has only been available for a short time and, prior treatment was not specific and therefore not adequate which ultimately led to unsatisfactory results.

We believe that MR imaging is underutilized when a diagnosis of hallux limitus/rigidus is made and treatment plans are formulated without having a complete knowledge of the total metatarsal-phalangeal joint complex. Having complete knowledge of the structural pathology and insufficiencies, plus having additional tools to deal with these deficiencies, will enable surgeons to have a more inclusive surgical plan.

This technology is a joint preservation procedure which allows initiation of an anabolic response. This changes the healing dynamics in that the regenerative process has now been given the necessary tools and ingredients to reverse the ongoing progressive catabolic problem whereby the degenerative process outpaced the regenerative process.

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