Company Overview

• Founded January 2014, Ponte Vedra Beach, FL
• “Pure Play” Foot & Ankle
• Well-funded
• 10 Employees + 3 part-time, 3,000 sq. ft. office
• First surgeries and revenue in September 2015
  • 150+ cases to date
Our Team

Management / Officers

John T. Treace  
CEO & Board

Kirk A. Brennan  
VP, Corporate Controller

Joe W. Ferguson  
COO

Board

James T. Treace  
Chairman

F. Barry Bays  
Board Member

John R. Treace  
Board Member

Thomas E. Timbie  
Board Member

Richard W. Mott  
Board Member
Bunions = high prevalence

Unsolved problem → mixed reviews on long term outcomes

Lapidus (1st TMT) = fastest growing but <15% procedure volume

Business Thesis assumptions:

• TMT joint affords best location to fix the 3 plane deformity - frontal plane rotation has been essentially unrecognized to date
• Pent up base of surgeons wanting to do Lapidus (or more Lapidus), but lacking technology to do so with confidence
• TMC can deliver the technology & training making Lapidus more precise and reproducible

Market conversion model, not “taking market share”
Bunion Surgery: Symptom Vs. Root Cause

Osteotomy

1st TMT Fusion

86% of Surgeries Treat Symptom

14% of Surgeries Address Root Cause
DPM Survey Results (600 responses)

How interested are you in increasing the percentage of your bunion patients treated by Lapidus (versus osteotomy)?

<table>
<thead>
<tr>
<th>Lapidus Interest</th>
<th></th>
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<tbody>
<tr>
<td>Not Interested</td>
<td>28%</td>
</tr>
<tr>
<td>Somewhat Interested</td>
<td>32%</td>
</tr>
<tr>
<td>Interested</td>
<td>24%</td>
</tr>
<tr>
<td>Very Interested</td>
<td>12%</td>
</tr>
<tr>
<td>Extremely Interested</td>
<td>4%</td>
</tr>
</tbody>
</table>

72% interested in doing more

How would each of the following factors increase the number of bunions you treat with Lapidus?

<table>
<thead>
<tr>
<th>Factors increasing Lapidus utilization</th>
<th>Some to Very High Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Better instruments/implants</td>
<td>67%</td>
</tr>
<tr>
<td>Data: time to weight bearing</td>
<td>74%</td>
</tr>
<tr>
<td>Data: recurrence rates</td>
<td>72%</td>
</tr>
<tr>
<td>Respected peer advocate</td>
<td>52%</td>
</tr>
<tr>
<td>Access to cadaver training</td>
<td>56%</td>
</tr>
</tbody>
</table>
The Product Development Team

Over 100 Issued Patents

Daniel Hatch, DPM
ACFAS Pres. 2007

Paul Dayton, DPM
Prof., Des Moines U.

Bret Smith, DO
Columbia, SC

Robert Santrock, MD
Chief F&A Surgery WVU

Cadaver Lab
August 23, 2014

Joe Ferguson

Carlos Gil

Barry Bays

Lowell Weil Jr., DPM
President, Weil Foot & Ankle Institute

2 U. of North FL Interns
Peer-Reviewed Publications - Past 2 Years:


2. Is our current paradigm for evaluation and management of the bunion deformity flawed? A discussion of procedure philosophy relative to anatomy. 2015.


4. Observed changes in radiographic measurements of the first ray after frontal and transverse plane rotation of the hallux: does the hallux drive the metatarsal in a bunion deformity? 2014.

5. Observed changes in radiographic measurements of the first ray after frontal plane rotation of the first metatarsal in a cadaveric foot model. 2014.

6. Clarification of the anatomic definition of the bunion deformity. 2014.


8. Observed changes in first metatarsal and medial cuneiform positions after first metatarsophalangeal joint arthrodesis. 2014.


Product Presentation
330,000 Bunionectomies Yearly

Does our current paradigm of metatarsal osteotomy with capsular balancing return the patient to normal anatomy?
What is our current HAV Paradigm?

Algorithms for Procedure Selection (120+ choices)

- IM severity
  - <15 degrees vs. > 15 degrees
- HAV severity
- Congruity of joint
  - DMAA
- Tibial Sesamoid Position
- Hypermobility

This evaluation scheme:
- **Assesses only the transverse plane**
- Treats each bunion as unique with literally hundreds of choices for correction possible
Are the long term outcomes of metatarsal osteotomy and capsular balancing as good as we think?

- Bock et al, JBJS 2015
  - 30% recurrence after Scarf
- Iyer S, et al, FAI 2015
  - 64.7% had evidence of recurrence at final
- Raikin et al, Foot & Ankle Clinics NM 2014
  - Complications including recurrence following HV surgery have been reported as high as 50%
- Chong et al, JBJS 2014
  - The long term results were worse than we expected 25.9% dissatisfaction at 5.2 years
- Pentikainen et al, FAI 2014
  - 73% radiographic recurrence of HV deformity of 15 degrees or more at long term follow up after distal chevron
  - 25% recurrence with lateral round sign
- Coetzee JC, et al, FAI 2003
  - 25% recurrence after Scarf

The fact is, Bunion Surgery is unpredictable based on our current Paradigm
If we honestly and critically analyze our current paradigm we know that joint stiffness, degeneration, hallux varus and recurrence occur at a high frequency following osteotomy and soft tissue balancing. **WHY?**
Why do we see recurrence?

Failure to restore the anatomy

*If you don’t…*

1. Correct the deformity at the origin/CORA
2. Correct in all three anatomic planes

*Then you cannot…*

1. Anatomically realign the MPJ
2. Anatomically realign the sesamoid-metatarsal apparatus

recurrence of Hallux Valgus”

- Okuda et al JBJS 2007
  - “A positive metatarsal head round sign after proximal osteotomy can be a risk factor for the recurrence of HAV”
Why do we see recurrence?

Joint congruency DMAA (PASA) & TSP are strongly implicated

- Sravisht et al FAI 2015
  - “Recurrence was associated with a greater preoperative deformity and an increased DMAA”

- Pentikainen et al FAI 2014
  - “Long term hallux valgus recurrence was significantly affected by congruence, DMAA, TSP, HVA and IMA”

- Devici et al JFAS 2013
  - “Incongruity was observed to be a statistically significant risk factor for recurrence”

- Neary et al 2013
  - “We believe that the key components in the magnitude of the hallux valgus correction depend largely on the DMAA”

- Okuda et al JBJS 2009
  - “Postoperative incomplete reduction of the sesamoids can be a risk factor for recurrence of Hallux Valgus”

- Okuda et al JBJS 2007
  - “A positive metatarsal head round sign after proximal osteotomy can be a risk factor for the recurrence of HAV”
Are These Different Deformities?

Despite differences in IMA, all three have the same level of deformity.

All have Transverse, Sagittal and Frontal Plane Components

The first metatarsal is deviated - not deformed.
No matter where we cut the metatarsal we see the same non-anatomic alignment of the MTPJ? The bump is gone but the original tri-plane deformity is not corrected and the MTP is not anatomically aligned.
Common bunion correction methods don’t anatomically realign the bony anatomy - they make a new deformity
FUNDAMENTAL DEFICIENCY: Algorithms for procedure selection are based on 2D radiographic representation of the anatomy

• Transverse plane predominates
  • We focus on the IMA, HVA and DMAA
  • We make procedure choices based on the degree of the deformity rather than the anatomic level of deformity
  • The net result is hundreds of procedure choices and high variability

• Sagittal plane is talked about less
  • Elevation and hypermobility

• What about the frontal plane?
  • Very little attention has been focused
Possible Solution

Valgus metatarsal rotation (pronation) has been shown to be consistent in HAV
(first described by Mizuno in 1956)

• Scranton. CORR 1980
  • Feet with Bunions averaged 14.5 degrees of eversion of the first metatarsal, 3.1 normal

• Talbot & Saltzman, FAI 1998
  • Pronation of metatarsal and subluxation

  • Feet with Bunions have everted first metatarsals

• Okuda, JOS 2009, 2013
  • Supination improved correction of sesamoids

• Dayton, Feilmeier, Kauwe 2013, 2014, 2015
  • Direct correlation of TSP to rotation of the first metatarsal in the frontal plane

• Yejeong, FAI 2015
  • WB CT evaluation showing metatarsal pronation in HAV (87.3%) vs. control
What if the sesamoids are in fact aligned and in their grooves, but they look displaced on the AP X-ray due to pronation of the first metatarsal?

**How does this effect our need for capsular balancing?**

Frontal plane eversion (pronation) of the first metatarsal makes the sesamoids inaccurately appear displaced on the AP x-ray

Supination Endpoint

1. TSP 0-2  2. Reduction of lateral round sign  3. Congruent MTP

Mean of 22.1° (sd 5.15°), Range 12°-30°
De-Rotation reduces the deforming forces applied by the sesamoids at the MTPJ

Sesamoid position in a rectus rather than everted metatarsal head will control deforming forces

(Mortier 2012)
Is rotation the key?
Met Rotation & Sesamoid Subluxation

• Kim et al. 2015 study: 87% of HAV have rotational deformity

Goal: When a surgeon sees a rotated metatarsal, they think LAPIPLASTY™.
New Paradigm

**TRIPLANE TMT ARTHRODESIS**

Indications are **NOT** dependent on IMA / HA / TSP Algorithms

Triplanar correction is at the CORA (TMTJ) in every case
New Paradigm – Lapiplasty™ System
TRIPLANE 1st TMT ARTHRODESIS
Indications are NOT dependent on IMA / HA / TSP Algorithms
Triplanar correction is at the CORA (TMTJ) in every case
Why Lapiplasty™ Triplanar Deformity Correction?

Low Variability

The quality of the outcome is dependent on the amount of variability in the process chosen

→ 130 different bunionectomy procedures is a lot of variability

Correction at the CORA

Analysis of HAV anatomy points to the TMTJ as the root of the problem

Instrumented Correction in 3 Planes

TMTJ Tri -Corrective arthrodesis is the only procedure that provides controlled correction in all three planes simultaneously
Why the Lapiplasty™ Procedure?

Currently two options for triplanar correction…

- Cut then correct (traditional Lapidus)
  - Requires a good “eyeball”
  - Less consistent
  - “Leap of faith”

- Correct then cut (LAPIPLASTY™ System)
  - Triplanar Correction
    - Reduce IMA
    - Correct rotation
    - Maintain sagittal plane
  - More anatomic
  - Two precision cuts
  - No “leap of faith”
CORRECT
Make your correction before you cut

CUT
Perform precision cuts with confidence

FIXATE
Apply multiplanar fixation with tension-side support
Correct Before You Cut

1 – CORRECT

2 - CUT

3 - FIXATE
LAPIPLASTY™ System

LAPIPLASTY™ Instruments
- Fulcrum
- Cut Guides
- Positioner
- Joint Seekers

CONTROL·360™ Anatomic Biplanar™ Fixation

PLANTAR·PYTHON™
Anatomic Tension-Side Plate

BIPLANAR™ Plates
Incision for First TMTJ exposure

- Dorsal midline
- Just medial to the EHL
- No subcutaneous undermining
- Small sensory nerve branches will be there
- Sub-capsular and subperiosteal dissection
Release the Joint

• Saw Technique
  • Run the saw congruously through the joint to release and remove the plantar flare

• Osteotome to ensure plantar ligament fully released

• Check for free metatarsal rotation
  • Tip: insert “joystick” pin
Release the Joint

LAPIPLASTY™ Procedure
Triplanar Deformity Correction

Complete 1\textsuperscript{st} TMT Joint Release for Triplanar Mobilization

Performed by Bret Smith, DO (Lexington, SC)
Joystick Pin to Check Rotation
Fulcrum Placement

• Fulcrum Function
  • Pivot point for IM correction
  • Spacer to prevent metatarsal base translation

• Fulcrum Placement
  • Placed through dorsal TMT incision
  • Placed proximally between the base of 1st and 2nd met
    • Proximal edge of fulcrum at the TMT joint line
Positioner Placement

• Placement on proximal 1/3 of met is critical
  • Placed 5-10mm distal to fulcrum to maintain mechanical advantage

• Positioner Tip - Stab incision over the dorsal-lateral surface of the 2nd metatarsal base

• Positioner Cup – Engage medial ridge of 1st metatarsal
Positioner Placement

Cup “grabs” the medial ridge just distal to flare (ridge moves plantar with metatarsal pronation)

Medial ridge is more plantar with high degrees of metatarsal pronation
LAPIPLASTY™ Positioner

More than a C-clamp!
Positioner Mechanism

“Log rolling up a hill”
Supination Endpoint

1. TSP 0-2  2. Reduction of lateral round sign  3. Congruent MTP

Mean of 22.1° (sd 5.15°), Range 12°-30°
Stabilizing 2 mm wire through positioner
Joint Seeker & Cut Guide

- Direct dorsal placement
- Joint Seeker aligns Cut Guide with TMT joint inclination
  - Avg Inclination: 24 ° - 29° (Doty 2014)
- Cut Guide makes precise cuts
Orthogonal Bone Cuts

5° Cut Guide (resection of cuneiform obliquity)
Remove Bone Slices

- Pituitary rongeur helpful for removing slices and cleaning up joint
Aggressive Fenestration

• Fenestrate bone surfaces with drill
  • Ensure that lateral side is adequately fenestrated to assist with angular correction

• Leave bone debris in the fusion site
Provisional Fixation

- Olive wires are threaded for pre-compression and temporary stability
- 2mm (0.078) wires are superior to 0.062 k-wires
- One or two olives
  - First one placed from distal-lateral direction
- Take Positioner off and confirm correction before plating
**Fixation: Biplanar™ “Internal Fixator”**

- Surfaces touch, but not relying on compression for stability (no inter-fragmentary screw)
- Bridge fixation with small flexible locking plates at 90 degrees
  - Not relying on compression fixation, therefore the sub-chondral plate is not needed for stability
  - Standard-length unicortical screws – no measuring
  - Contourable to fit the bone surface - “Universally Anatomic”
  - Non strain state of bone surfaces
  - Does not require “Stress Strain Relieving” bone grafting
  - Early loading **stimulates biological healing** and callus formation
- Stability in multiple planes
  - I.e. multiplanar external-fixator, locked IM nail
Biological Internal Fixation Principles

- AO shift from absolute stability (compression) to relative stability
  - *Evolution of Internal Fixation* (Perren 2002 AO Institute)
    - “The new technique of internal fixation, however, seems to tolerate and even require some degree of mobility of the interface of the fracture.”
    - “More flexible fixation should encourage the formation of callus.”
    - “Even non-visible, instability may be deleterious for rigidly fixed small fracture gaps”
  - *AO Principles of Fracture Management* (Ruedi 2007)
    - “Fixation with relative stability aims to maintain the reduction and still keep the mechanical stimulation for fracture repair by callus formation”

Increase in radius from callus greatly increases moment of inertia and stiffness.
Biplanar™ Biomechanics

- Comparison of Biplanar™ Plating construct to WMT Lapidus plate + compression screw construct
  - Biplanar™ screws all unicortical
  - WMT screws all bicortical, including inter-fragmentary screw

- Loaded cyclically with increasing cantilever load every 50k cycles (simulated weightbearing)

- Results - Biplanar™ Plating superior
  - Significantly greater cycles to failure
  - Significantly greater load at failure
PLANTAR PYTHON™ Plate
M1 – M2 Screw

• Improved stability in the transverse and coronal planes (Dayton et al. - in process)
  • Better than:
    • Cuneiform to Cuneiform
    • Metatarsal to Cuneiform

• Try to position on the dorsal medial aspect of 1st metatarsal, proximal to bone plate screws

• Lapidus’ original article included base of second metatarsal in the arthrodesis by removing the lateral portion of the metatarsal
Distal Release

• Lateral release needed in some cases
  • Goal is to perform after correcting metatarsal alignment
  • Perform conservative lateral release earlier in case if not obtaining free rotation and/or sesamoid alignment

• Capsular thinning often needed
• No traditional medial eminence resection
• No capsulorrhaphy

"Stab" Lateral Release

Intra-capsular release through medial incision
Medial Eminence Resection
Rarely Needed (capsular thinning more common)
Post-Operative Care

- 2 weeks of non-weight bearing with crutches to allow soft tissue stabilization
- 2-4 weeks of protected weight bearing with CAM boot
- Normal shoe at 6-8 weeks
- Resume sports at 4-6 months
Other CONTROL 360™ Application: 1st MTP Fusion
2016 Reimbursement Changes

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2015 OPPS*</th>
<th>2016 OPPS*</th>
<th>% Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>28292</td>
<td>Correction, hallux valgus (bunion), w/ or w/out sesamoidectomy; Keller, McBride, or Mayo type procedure</td>
<td>$2,676</td>
<td>$2,395</td>
<td>-11%</td>
</tr>
<tr>
<td>28297</td>
<td>Correction, hallux valgus (bunion), with or without sesamoidectomy; Lapidus-type procedure</td>
<td>$2,676</td>
<td>$7,064</td>
<td>164%</td>
</tr>
<tr>
<td>28740</td>
<td>Arthrodesis, midtarsal or tarsometatarsal, single joint</td>
<td>$5,219</td>
<td>$7,064</td>
<td>35%</td>
</tr>
</tbody>
</table>

Note: Comprehensive APCs – only payment for primary procedure

2016 Pricing Strategy

*OPPS: Outpatient Prospective Payment System (Medicare hospital outpatient facility reimbursement)