In 1994 a Sunnyvale, California, start-up company was trying to coin a term for treating vertebral compression fractures (VCF).

Vertebral compression fractures?

VCF in the 1990s was nowhereville. The bread and butter spine business was either teenage deformity patients or middle aged degenerated or herniated disc patients.

Vertebral compression fracture patients were 70, 80 or 90 years old. And reimbursement was...Medicare.

So few people noticed when little Kyphon coined the term Kyphoplasty. ‘Plasty’ means to mold, graft or form a body part. Hip arthroplasty means to graft an artificial hip joint into a patient. Kyphoplasty refers to using a balloon and cement to fill the gap created by a collapsed spine vertebra and, thereby, restore some measure of kyphosis.

Déjà vu All Over Again

Bunions.

Like VCF in the 1990s, bunion deformity is far from the center of the action in orthopedics. More than 100 methods to treat bunion deformity—poor overall success rates and a general feeling that “that’s just the way bunion surgery goes.”

A small company founded in early 2014—this time from Florida—just coined a ‘plasty’ term to describe a bunion deformity treatment.

Oh...incidentally, the former CEO and Chairman of the Board of Kyphon and the key execs who helped make Kyphon one of the most successful companies in the history of orthopedics sit on this company’s board and are investors.

This company’s CEO, as it turns out, is John T. Treace, formerly Senior Vice President of U.S. Sales and Global Marketing for Wright Medical, Inc. arguably the leader in the reconstructive foot and ankle market.

The company’s name is Treace Medical Concepts, Inc.

Another Corner of Orthopedics About to Break Out?

Why should we care about bunions?

Research in the literature showed that 23% of people aged 18 to 65, and 36% of those older than 65 have bunions.

The Framingham Foot Study, which enrolled 1,400 people whose average age was 66 years and 57% of which were female, found that 31% had bunions. Extrapolating those statistics to the general U.S. population and the number of patients with bunions is in the millions. One government statistic said that 4.4 million patients visit their doctor’s annually complaining about bunions.

Painful bunions. Bunions start slowly. Pressure builds on the big toe joint and the metatarsal bone starts leaning outward, creating the familiar bunion bump. At some point, the bunion deformity becomes so painful that it significantly limits their activity not to mention foot wear options.

Non-surgical treatment, like wider shoes, helps. But the metatarsal bone is deviated outwardly and it can continue to worsen. When it becomes too painful to ignore, surgery is an option, but not necessarily a great option.
As Carol Frey, M.D. an orthopedic surgeon with the foot and ankle division of West Coast Sports Performance in Manhattan Beach, California said: “There is nothing magical about bunion surgery. Results are not always 100%. You will not fit in fashion shoes for six months after surgery.”

Indeed, long term studies of more traditional bunion deformity correction surgery published in the past 10 years suggest that recurrence following metatarsal osteotomy is as high as 25-75% due to inability to align the joint.

Bunion surgery is tricky. It takes a long time to heal and the results may not be ideal.

Until Treace Medical’s Lapiplasty™ that is.

**Lapiplasty™ Surgery**

Lapiplasty™ is a paradigm shift in thinking about bunion deformity and its surgical correction. It allows the surgeon, for the first time, to automate a three-plane (transverse, frontal and sagittal) bunion correction and fuse the tarsal-metatarsal (TMT) joint in the corrected anatomic alignment.

According to founder John T. Treace, correcting the frontal plane deformity is likely the “missing link” in traditional bunion surgery.

“Recent studies indicate that in about 85% of bunion patients the metatarsal bone is rotated valgus (or pronated) in the frontal plane in addition to being translated in the transverse plane. The frontal plane has historically been overlooked and unaddressed in the surgical management of the bunion,” said Treace.

“Numerous scientific studies link MTP (metatarsophalangeal) joint incongruence to recurrence rates of 30 to 50% within a few years of surgery with the “gold standard” metatarsal osteotomy procedure. If the surgeon doesn’t adjust the metatarsal into proper frontal plane alignment, sesamoid position and MTP joint surfaces remain misaligned, then the joint will not be congruent. That, in turn, can keep the bunion growing and, paradoxically, load the MTP joint.”

“A surgical technique that corrects all three planes sounds like a logical solution, but accomplishing this “freehand” surgically, and in a way that is both accurate and reproducible, is extremely challenging.”

**How Does Lapiplasty Work?**

First, Lapiplasty™ has a novel “positioning” instrument that allows the surgeon to quickly and reliably reposition and hold the metatarsals in 3-planes before making any bone cuts. Next, the surgeon uses a guide to make precise and accurate cuts to the joint surfaces. Freehand variability is simply out of the equation.

“This is a very big deal as it allows the surgeon ultimate flexibility in dialing in perfect correction before permanent alterations are made to the bones” said Dr. Paul Dayton, one of the physicians who helped develop the procedure with Treace Medical. “The instruments also make the procedure very consistent and in my experience it reduces the time and frustration of the operation.”

For the first time, with the Lapiplasty™ system, the surgeon can address all three planes concurrently, which provides a method to completely correct the deformity.

Again, Dr. Paul Dayton: “In a Lapiplasty™ procedure the surgeon can correct reliably in three planes at the same time. The first metatarsal bone is deviated not deformed in a bunion deformity. Bunion deformity includes transverse, sagittal and coronal plane components.”

“Coronal eversion or pronation of the first metatarsal in a bunion was described by Mizuno in 1956. Over the past few decades pronatory rotation has been described by other surgeons. The concept, however, has not been popularized with respect to correction.”

“Recently several groups of researchers have described the pronation of the metatarsal using clinical observations, radiographs and weight bearing CAT scans. It is becoming evident that this pronation is a component in up to 85% of bunions. Traditional osteotomies cannot correct this frontal plane of the deformity and provide correction for the most part in the transverse plane.”

Finally, Lapiplasty™ is both an instrumentation and fixation systematic approach to bunion surgery. To fuse the joint in its corrected position, the system relies on “biplanar plating,” which is a low profile but highly stable fixation construct designed to facilitate fast weight bearing for the patient.

Treace tested the biplanar fixation construct in a controlled biomechanical study—the results of which were recently published in the *Journal of Foot and Ankle Surgery*. That study showed that biplanar fixation was superior to plate and inter-fragmentary compression screw construct.

**It Began in 2014 in Memphis**

In mid-2014 John T. Treace invited a group of five surgeon designers to discuss opportunities to improve foot and ankle surgery. The group, which met in Memphis, went to work identifying areas of foot and ankle surgery that were frustrating, had less than desirable outcomes or lacked consistency.
They unanimously identified bunion surgery as a procedure that lacked reliability and was universally frustrating. It had an unacceptably high recurrence and complication rates associated with many of the popular osteotomy procedures.

A couple of years prior to Treace’s meeting a number of researchers, including Dr. Dayton, had been intensively studying the published studies on metatarsal rotation. Through their own clinical and cadaver research, and studying the published research, they felt that they were beginning to better understand the problem.

Dayton and others at the Treace meeting presented the idea of attacking bunion deformity by way of a “three plane” correctional procedure. And, in the tradition of such revolutionary and disruptive approaches as Kyphoplasty, Treace’s team developed an instrumentation and fixation system to make the procedure reproducibly successful in any foot and ankle surgeon’s hands.

**Treace Medical**

Two year old Treace Medical Concepts, Inc. is based in Ponte Vedra Beach, Florida. In addition to John, the board of directors is a who’s who of some of the most successful medical device entrepreneurs in America. Looking at this team and its surgeon advisory board, Treace Medical Concepts, Inc. may have more in common with Kyphon than simply using “plasty” to describe its innovative solution to a tough surgical problem.

Below are the heavy weights who serve on Treace Medical’s board of directors:

- **James T. Treace** (Chairman of the Board), former President of Medtronic Xomed and ConMed Linvatec, Executive Vice President of Richards Medical (now Smith & Nephew), Chairman of the Board of Kyphon and Wright Medical.
- **John R. Treace**, (CEO) former Executive Vice President of North American Sales at Wright Medical, Vice President of Sales at Medtronic Xomed, Vice President of Sales and Marketing at Richards Medical.
- **F. Barry Bays**, former CEO, President and Chairman of the Board of Wright Medical, Chief Operating Officer of Xomed Surgical Products, Chief Operating Officer of Concept, Inc. and VP of R&D of Richards Medical.
- **Rich Mott**, Executive in Residence for Warburg Pincus, former President, CEO and Director of Kyphon, Inc., Chief Operating Officer at Wilson Greatbatch Technologies and currently serves on numerous boards of directors.
- **Thomas Timbie**, previously CFO for ev3, Inc, CFO for Xomed Surgical, and Director of Accounting for Concept, Inc. and served on the board of Wright Medical, Acclarent and American Medical Systems, Inc.
- **Daniel J. Hatch**, DPM, FACFAS, is a fellow and past president of the American College of Foot and Ankle Surgery. He is also a section editor in reconstructive rear foot and ankle surgery for the Journal of Foot and Ankle Surgery. He is a surgical director of the North Colorado Podiatric Surgical Residency program.
- **Robert D. Santrock**, MD, Chief of Foot and Ankle Surgery at West Virginia University School of Medicine in Morgantown, West Virginia.
- **W. Bret Smith**, DO, Director of the Foot and Ankle Division of the Moore Center of Orthopedics. He currently serves as a member of the education committee of the American Orthopaedic Foot and Ankle Society. He is the recent past-President of the Foot and Ankle Section of the American Osteopathic Academy of Orthopedics.
- **Lowell Weil Jr.**, DPM, MBA, President and Fellowship Director of the Weil Foot & Ankle Institute. He is the Editor of Foot and Ankle Specialist the only combined orthopedic and podiatric peer reviewed journal in the world.

With a team and an instrumented system like this, there appears little doubt that in addition to such routine medical procedure terms as ‘Arthroplasty,’ ‘Rhinoplasty,’ ‘Kyphoplasty’…we’ll be routinely discussing ‘Lapiplasty™’. ♦