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Treace Medical Concepts Inc (NASDAQ:TMCI): Screwed

*“The big Treace sin was telling people to bill their Lapidus as a transverse multi-midfoot fusion ...
That’s not unbundling – that’s fraud”*

– Podiatrist 1

*“I have NO problem with the Lapiplasty set. However, it has created a huge increase in billing
fraud.”*

– Podiatrist 2

*“If Medicare comes down on this it’s going to be pursued like a criminal conspiracy ... that will
ultimately be worth pursuing as a fraud.”*

– Podiatrist 3

*“You would never ever have a company advise the physicians on what to do, because you could
go to jail for that. So you give them a paper that shows them the rates ... and doctors ask me all
the time, ‘hey if I throw a screw, would this get additional reimbursement.’ And I’d say ‘yes’. But
I’d never ever tell them to do that ... It’s sort of a gray area...”*

– Former Treace Sales Representative

*“I think the reps are pushing it, but if you put them on a witness stand, I’m sure they’d argue that
the doctor still has their judgement and it’s your choice.”*

– Podiatrist 1

*“Met with Shana [Zink] from the reimbursement specialist for Treace Medical...there are several
additional CPT codes that can increase the reimbursement ... the suggestion was made that ... a
complexity adjustment is made and the reimbursement goes from, in our case, \$5,629.49 to
\$11,258.98 ... If there is not additional reimbursement it does not make sense to bring it in...”*

– Meeting Minutes from The University of Toledo’s Healthcare System

We are short Treace Medical Concepts Inc (“TMCI”, “Treace”, “the Company”). Treace makes itself out to be an innovative MedTech business “driving a fundamental shift in the surgical treatment of Hallux Valgus” (i.e., bunions) through its triplane Lapidus fusion (i.e., “Lapiplasty”) kits. Our view is that Treace’s primary innovation has not been in any sort of medical advancements, but in aggressive reimbursement practices and deceptive DTC marketing. We view these business drivers as problematic and self-defeating, as insurers appear to have begun placing Lapiplasty procedure reimbursements under scrutiny while customer complaints about misleading claims from Treace are mounting. We think Treace’s best days are behind it, and insiders are voting with their wallets: through the Company’s April 2021 IPO and subsequent sales, insiders have cashed out over \$136 million in stock, and continue to sell through 10b-5 plans.

Treace sells its Lapiplasty kits to surgeons at over \$5,700 each, multiples higher than traditional Lapidus fusion kits. The Company line is that these egregious prices are justified by clinical outcomes, but our diligence suggests instead that **physician adoption** is accompanied by implementation of dubious billing tactics such as unnecessary complexity adjustments, unbundling, and billing for procedures which simply never happened. Such tactics

increase reimbursement and appear to justify the high price of Treace's kits for many doctors. According to various podiatrists, Treace sales representatives have in many cases suggested such practices. Podiatrists characterized billing practices among many of their peers as "conspiratorial" and "Treace's big sin". One podiatrist opined that Lapiplasty "has created a huge increase in billing fraud" and another opined that "if Medicare comes down on this it's going to be pursued like a criminal conspiracy." We also uncovered meeting minutes from the University of Toledo – whose health system was a potential buyer of Treace's kits – which suggest Treace's SVP of Reimbursement directed the University on how to find "added reimbursement" via billing for additional codes and complexity adjustments. Tellingly, the minutes concluded that without such adjustments, "it does not make sense to bring it [Lapiplasty kits] in." We also spoke with one former Treace sales representative who described Treace's conversations with doctors regarding billing as "a gray area." Our diligence suggests payors are now pushing back. One podiatrist stated that they are "on retainer with several major insurers" to review such cases. Another podiatrist we spoke with said they are now including all their operating notes in reimbursement requests so as to avoid coverage denials or an audit.

Meanwhile, we believe **patient demand** for Lapiplasty is propped up by Treace's DTC marketing program, whose backbone is a variety of misleading, unsupported, or cherry-picked claims that inflate outcomes and downplay risks. We believe Treace has overstated both the severity of the clinical challenge and the effectiveness of its own high-priced solution. First, Treace claims that Lapiplasty holds just 1% to 3% recurrence rates, but this statistic fails to show the full picture, as complication rates are an order of magnitude higher; it does little good for a patient to have their bunions gone but a metal plate protruding from their foot instead. Patients in Treace's own ALIGN3D study saw 15.0% complication rates, while we think real-world outcomes are far worse: ALIGN3D reported results only for a group of patients treated by the Company's best, highest paid physicians, while patients have only been tracked to 24 months thus far on average. ALIGN3D also excluded patients older than 59 who represent one-third of those with bunions. Our conversations with podiatrists, patient feedback, and the MAUDE adverse events database all suggest to us that long-term issues with Lapiplasty can arise, even such that many patients have their hardware removed entirely.

Treace claims that its competition, namely traditional osteotomy, has "up to 78%" recurrence rates, which we view as a highly disingenuous and cherry-picked figure cited from a single outlier study. More recent and comprehensive meta-studies suggest that patients are overwhelmingly satisfied with competing surgeries, and recurrence rates are just 0% to 10%. Treace also deceptively cites pediatric studies to claim that traditional surgery is often unsuccessful, but it doesn't take a medical degree to realize that worse outcomes are to be expected in children who lack fully grown bones. Treace's data, by contrast, originated in patients aged 14 to 58. We believe this sort of misleading and self-serving approach permeates Treace's marketing to both patients and doctors.

We further believe that Treace's claim that Lapiplasty patients can "get back on their feet sooner" than with competing procedures is bogus. For one, Treace's ALIGN3D study had no specific method to quantify patients' weight bearing status, but even in this study, patients reported a return to normal activity only after 120 days. Multiple doctors have presented evidence disputing Treace's claims, while patient reviews suggest widespread dissatisfaction with Treace's characterizations of speedy recovery times.

Treace's presentation of blended ASPs, which include the effects of incremental products, masks the pricing pressure the Company faces from well capitalized competitors who have brought their own triplane systems to market. Our diligence suggests Stryker is massively undercutting Treace by over 50% per kit, and we think Treace will face further price cuts. Treace is valued at a nosebleed valuation of 10x revenues and supports its cash burn with variable rate debt. We see significant downside to the shares.

We Think Treace’s Physician Uptake Has Been Fueled by Problematic Practices

There are two primary surgical methods to fixing bunions today: Lapidus-type / Lapidus fusion, which fuses the first tarsal/metatarsal (“TMT”) joint (25% of total procedures), and 2D osteotomy, or “cut and shift” procedures (75% of total procedures).¹ Treace claims to be a revolutionary new third option which solves the drawbacks of both Lapidus fusion and 2D osteotomy [by](#) reliably addressing the “root cause” of bunions, an unstable TMT joint. It’s important to first understand that in our view, Treace’s core innovation isn’t scientific or technical: Lapiplasty kits are merely a high-priced aid that helps surgeons perform the same decades old Lapidus fusion procedure. In the words of a medical director at an ankle replacement program:

“[Founder John] Treace is a very smart guy, he’s a terrific marketer. And he essentially took a procedure called the Lapidus, which has been around for 100 years or so and called it Lapiplasty... What Treace has done is come up with a very sort of clever slick little jig that makes the correction a little bit easier.”

Both Lapidus fusion and “Lapiplasty” procedures – as termed by Treace – fuse the TMT joint using a set of plates and screws; Treace’s kits also include a jig, which the Company claims makes the procedure “replicable” for surgeons who have difficulty doing these procedures by hand. In the [most recent quarter](#), Treace reported ASPs of \$5,794 per kit², a significant premium to competing options on the market today. Per one orthopedic surgeon:

“Now the traditional way to do a Lapidus is two screws, that’s going to cost you about \$175, okay? The Lapiplasty construct is extremely expensive. I think it’s typically about \$6,000.”

And in the words of one medical director:

“... at the end of the day, remember Lapidus is Lapidus, fusion is fusion, that doesn’t make a difference. Whether you use \$5,000 placement screws, or you use South Korea’s generic plate and four screws.”

Treace’s high price tag presents a problem for surgeons, as not only are the kits priced astronomically higher than competing options, but we understand that physicians commonly bill Lapidus fusion procedures [under CPT code 28297](#), which generates a Medicare reimbursement fee of roughly \$6,000. As such, the procedure is not particularly financially attractive for surgeons when using Treace’s high-priced kits.

Our research suggests that Lapiplasty is routinely billed with unnecessary complexity adjustments or unbundling – techniques which inflate reimbursement for physicians and make the use of Treace kits more attractive. Tellingly, multiple physicians and buyers state that without such “additional reimbursement”, Treace kits are not worth using.

Though it doesn’t appear that Treace provides its billing guide publicly as some other medical device companies commonly do (for example, see [Stryker](#) and [Zimmer Biomet](#)’s foot and ankle system coding guides), we obtained a billing guide through public records requests. In it, we see that Treace conveniently lays out for surgeons exactly what combinations of codes will trigger complexity adjustments, which take Medicare payments from \$6,265 to \$12,315. Interestingly, neither the Stryker nor the Zimmer Biomet billing guides linked above mention “triggering complexity adjustments”.

¹ Per the Company.

² Disclosed on the Q3 2022 conference call by CEO John Treace.

OPPS Addendum J Complexity Adjustments for Some Procedures⁵

J1 Procedure Code Pairs that Trigger a Complexity Adjustment⁵ and Adjusted APC Payment – \$12,315

CPT & Primary APC / Medicare Payment

APC Medicare Payment 5114 \$6,265	New APC Medicare Payment 5115 - \$12,315
<p>CPT 28297 Correction, hallux valgus (bunionectomy), with sesamoidectomy when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method</p>	<p>CPT 27687 – Gastrocnemius recession (eg, Strayer procedure) CPT 28270 – Capsulotomy; metatarsophalangeal joint, with or without tenorrhaphy, each joint (separate procedure) CPT 28285 – Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy) CPT 28292 – Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method CPT 28298 – Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method CPT 28300 – Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation CPT 28308 – Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; other than first metatarsal, each CPT 28310 – Osteotomy, shortening, angular or rotational correction; proximal phalanx, first toe (separate procedure) CPT 28313 – Reconstruction, angular deformity of toe, soft tissue procedures only (eg, overlapping second toe, fifth toe, curly toes)</p>
<p>CPT 28740 APC 5114 - \$6,265 Arthrodesis, midtarsal or tarsometatarsal; single joint</p>	<p>CPT 20900 – Bone graft, any donor area; minor or small (eg, dowel or button) CPT 27687 – Gastrocnemius recession (eg, Strayer procedure) CPT 27691 – Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (eg, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot) CPT 28285 – Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy) CPT 28292 – Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method CPT 28297 – Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method CPT 28298 – Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method</p>

To be clear, many patients may in fact need both a Lapidus fusion procedure and an Akin or mid-foot procedure. However, our research leads us to believe that many Lapiplasty cases are billed under completely unnecessary complexity adjustments. For example, one podiatrist stated to us that Treace has “encouraged” surgeons to “throw an extra screw” such that what is typically identified as a Lapidus fusion procedure is instead recognized as a “multi-midfoot fusion” procedure. Such a step would provide the surgeon with additional reimbursement while providing no incremental benefit to the patient. Per the podiatrist:

“The big Treace sin was telling people to bill their Lapidus as a transverse multi-midfoot fusion. This is the code that applies to essentially any multi-tarsal joint fusion i.e., a medial double TN/STJ fusion, a 1-3 TMTJ fusion, a medial column fusion i.e. 1st TMTJ, naviculocuneiform, TN joint. Multi-joint fusions are a thing, but surgeons were routinely being encouraged to place 1 additional crossing screw from one cuneiform to another during the fusion and then identify this as a fusion even though no fusion was prepared, no joint was exposed, etc. That’s not unbundling – that’s fraud. The service isn’t actually being performed.”

“More problematic than the \$6,000 bump on complexity adjustment is that the Treace hardware set is some variation of \$4,000, and were the facility to not receive the additional complexity adjustment, they would likely disallow the use of the Treace set.”

There's something very cringe about the above arrangement - almost conspiratorial. The doctor receives a few hundred extra. The facility receives potentially \$6K extra. Treace gets to be used. And ultimately all

the patient actually received was a single joint fusion but through the magic of throwing one extra screw at the end of the case, the reimbursement of everyone involved increased.”

The podiatrist we spoke with opined that Treace has been pushing these multi-fusion codes both through both their sales representatives and surgeon training courses:

“A friend of mine recently attended one of the Treace Masters courses and was led to believe that a lot of their main speakers use the multi-fusion code. I can't speak to the prevalence but any time you see the words "spot weld fusion" or some variation of that you are likely seeing proof that a screw was placed but that the procedure was not actually performed. I was somewhere a few years ago where a doctor showed me part of their op note (or maybe it was on this forum) and they had changed their wording to suggest that they prepped an intercuneiform interval. There is no way that they did this. I do Lapidus/Lapiplasty ([Code] 28297 like 99-100% of the time) and prepping this interval would be a nightmare. Also - it contains the dorsalis pedis artery.”

“I think the reps are pushing it, but if you put them on a witness stand, I'm sure they'd argue that the doctor still has their judgement and it's your choice. At events I went to they [Treace representatives] talked non-stop about using the 28730 code and the increased reimbursement for you and the facility.”

This encouragement to “throw an extra screw” was also a technique mentioned by another [podiatrist, who stated](#):

“Scrubbed a Lapiplasty with an outside attending this past week and he threw the intercuneiform screw. He told me to make sure I put in my dictation that we prepped the joint when we didn't even touch it...”

We spoke with one former Treace sales representative who referred to billing conversations between Treace representatives and surgeons as a “gray area”. The rep told us that podiatrists ask “all the time” about this very tactic of throwing an extra screw with the idea of obtaining additional reimbursement:

“They [surgeons] want to wrap up as many – in terms of reimbursement, and I'm not talking about terms of what's best for the patient but those are always going – you're usually going to look for a bunch of codes to put on there. You could do an akin, or a bone graft ... **It'll always go to a multiple joint fusion** to capture the biggest and best reimbursement.”

“You would never ever have a company advise the physicians on what to do, because you could go to jail for that. So you give them a paper that shows them the rates – and the doctors know this – so doctors ask me all the time, ‘hey if I throw a screw, would this get additional reimbursement.’ And I'd say ‘yes’. But I'd never ever tell them to do that ... It's sort of a gray area where you give them an example of what other doctors have done.”

“But everybody knows – the doctors know – if you want to keep doing these expensive procedures, then you want to get these billing procedures figured out.”

In addition to the “extra screw” tactic, one podiatrist on a [public forum](#) stated that Treace representatives have also suggested billing a combination of additional codes for a lateral release, which is already commonly part of the Lapidus fusion procedure:

"I feel like these pages [referencing a billing guide] used to be on their website but aren't anymore. Anyway, they want you to bill either 28297 or 28740 + 28270 for the lateral release. I almost laughed out loud when my rep suggested this."

We think this suggestion could be particularly problematic. We spoke with the podiatrist, who further explained the Company's pitch for what appears to be overbilling:

"A Treace rep semi-recently did suggest to me that I could use a 'capsulotomy' code with either the midfoot fusion or Lapidus code (probably the fusion code) to address the lateral release of the 1st MPJ. That would be unbundling; i.e., the 1st MPJ release is inherent in the Lapidus. However, the reason he suggested it though is because it is associated with the complexity adjustment."

We also uncovered March 2021 [meeting minutes](#) from the University of Toledo's Surgical Procedural Value Analysis group, in which it was noted that a Treace representative suggested to the University how they could find "additional reimbursement" via complexity adjustments. Tellingly, the notes conclude that "without additional reimbursement, it does not make sense to bring it [Lapiplasty kits] in."

Follow up: Met with Shana from the reimbursement specialist for Treace Medical... there are several additional CPT codes that can increase the reimbursement... I communicated that to Dr. Elattar... See communication and response below.

Dr. Elattar,

In looking at the paper... the suggestion made was when we have a J1 procedure code in pairs that a complexity adjustment is made and the reimbursement goes from, in our case, \$5,629.49 to \$11,258.98. As an example below:

CPT	Description	APC	UTMC Payment Rate
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint	5115	\$5,629.49
28298	Correction, hallux valgus, with sesamoidectomy, when performed ; with proximal phalanx osteotomy... any method		\$5,629.49 Complexity adjustment
		Total reimbursement :	\$11,258.98

Lapiplasty:

Dr. Osman... CPT codes follow up and work with Treace... Meet with Reimbursement specialist for added reimbursement... Follow up with Dr Elattar... and communicate to the committee. If there is not additional reimbursement it does not make sense to bring it in...

Insurers Appear to be Cracking Down on Unsustainable Billing Practices

Our diligence suggests that insurers are pushing back on the techniques employed by many physicians. [One podiatrist commenter describes](#) Treace's precarious position as "roadblocked" by the high costs of the kit relative to the standard reimbursement. He claims Lapiplasty "has created a huge increase in billing fraud" and added that

he's been consulted [by insurers] to review these cases. We suspect that as Treace has grown, it has placed a target on its back with insurers:

"That's the roadblock they [Treace] are running into. Surgical centers are not allowing this set due to cost. Unlike hospitals, the surgery centers can't bill for these sets. They want to use the least expensive stuff out there. The surgeons panic, since the insurance company wants the surgery done at an ASC vs hospital due to cost savings, but the ASCs won't allow the set. The panic starts when these surgeons realize that they have no idea how to perform a free hand Lapidus. I have NO problem with the Lapiplasty set. However, it has created a huge increase in billing fraud. I've been consulted to review more of these cases than any other product with the exception of the thieves who bill a STJ arthroereisis or ORIF of a talotarsal dislocation for performing an arthroereisis ... I was contacted last week by an insurer to review 3 op[erating] reports from a provider who is doing Lapiplasty. He unbundled the procedures to a 28292 and 28740 AND billed for an ORIF of a tarsal metatarsal joint (for the metatarsocuneiform joint). This guy will be paying back big bucks because he's billed this way for his last 32 cases."

"I know a lot of young docs who are paying back big bucks for listening to reps ... the biggest offenders are the reps for these newer Lapidus systems. Do not listen to these reps. No matter how you slice it, you've performed one procedure. A 28297. I'm on retainer with several major insurers specifically to review these claims. It's become an issue and it's high up on their radar."

"The orthopedic surgeons are very aggressive billers and have billed a Lapidus as a 28292/28740 for years.³ DPMs have now jumped on that bandwagon. However, it's aggressive and 'creative' reps who "sell" the idea to docs regarding how to make more money. That's when all this BS come up with billing 28730 for throwing that intercuneiform screw or billing for an ORIF of a tarsal-metatarsal dislocation. By the way, you can't get paid for fusing the same joint that is dislocated (even though in this case it's not a dislocation anyway). You need to reduce a dislocation to fuse the involved joint so the reduction is a component procedure of the fusion. You can't get paid for 2 procedures when in essence, you've only performed one procedure. Bill honestly, understand the rules and do not look for quick schemes. And do not taking billing advice from reps."

[Another podiatrist opined](#) that Lapiplasty overbilling could "be pursued like a criminal conspiracy":

"Commercial insurance aside - if Medicare comes down on this it's going to be pursued like a criminal conspiracy. Surgery centers/hospitals etc. aren't going to let you perform Lapiplasty on Medicare patients because the cost of the set is almost the value of the Medicare reimbursement to the facility. There's a reason they (Treace) are desperately pointing us to additional procedures - some of which are inclusive, some of which are fictional. When the doctor bills the 28740 they bump their reimbursement up a few hundred dollars, but the facility picks up an extra \$6000 allowing the whole event to occur but also creating a much more massive expenditure that will ultimately be worth pursuing as a fraud."

The podiatrist we spoke with earlier also corroborated that insurance has "cracked down" on doctors submitting certain code combinations, adding that he is now submitting operation notes for each procedure:

"Insurance has also cracked down on some of the combinations of codes; i.e., I think you are highly likely to be denied if you bill 28740 and 28292. A friend of mine contacted me telling me that they 'weren't

³ See [here for additional context](#) on the reference to billing 28292 and 28740; i.e., unbundling, rather than billing the sole code, 28297.

getting paid for Lapiplasty'. I said 'are you billing 28297' - they didn't know the code existed which means they were likely billing 28740/28292. Whoever they had billed it to had denied it."

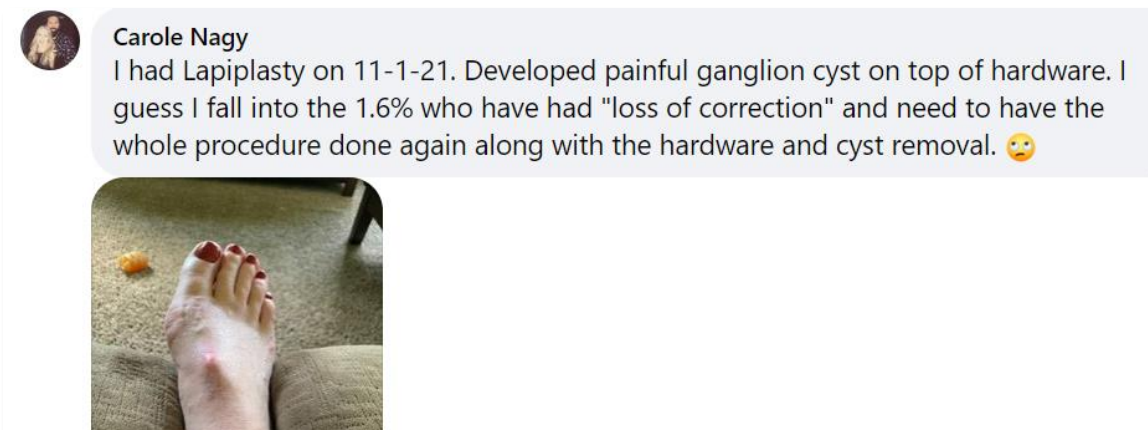
"I am essentially now submitting all of my op notes for everything I do, because insurance almost always asks for them."

Treace's Dubious DTC Pitch: Lapiplasty is No Silver Bullet

We think Treace massively oversells Lapiplasty to patients under a variety of misleading or unsupported claims, namely that current bunion treatment methods are overwhelmingly ineffective, and Lapiplasty is the silver bullet.

Treace Trumpets "Low Recurrence" but Downplays High Complication Rates

Treace continually claims that Lapiplasty patients experience low recurrence rates of 1% to 3%. However, we view this as a red herring statistic when considering that complication rates are an order of magnitude higher. In short, it does patients little good to lose their bunions but instead have a cyst or a metal plate protruding from their foot. Our concerns arise from an analysis of the Company's own clinical data, patient reviews, and podiatrist feedback. For example, see the [following patient](#), who mistakenly believes that their painful ganglion cyst would be considered "recurrence" and that they are merely among the 1.6% with recurrence (per Treace's marketing), when instead this cyst would be an example of a far more prevalent complication:



At the Company's September 21, 2022, [Surgeon Advisor event](#), Treace's paid advisor Paul Dayton glossed over the issue of complications, claiming – without any hard figures – that complications are "very low...extremely low":

"Complications [are] very low, you guys, I'm sure, will have access to this information, so I'm not going to belabor it. With any procedure, there's going to be complications, sometimes hardware needs to come out. Sometimes hardware is uncomfortable in my practice, our hardware removal rate because of the design of the implants and the way they work and the way they fit, it's extremely low. I would argue, again, in my practice, lower than anything else I've used. And very, very low recurrence rate."

However, just days earlier, on September 13, 2022, Treace [released the latest round of interim data](#)⁴ on its ALIGN3D trial, which disclosed that a total of 26 of 173 (15.0%) patients experienced complications, not including the 2 additional patients who experienced recurrence:

Culper Summary of ALIGN3D Reported Complications	Patients (Rate)
Hardware breakage	5 of 173 (2.9%)
Hardware removal (all-causes)	12 of 173 (6.9%)
Non-hardware related complications (since resolved)	5 of 173 (2.9%)
Non-hardware related complications (unresolved)	4 of 173 (2.3%)
TOTAL	26 of 173 (15.0%)

We think real-world complication rates are likely to be substantially higher than those reported in ALIGN3D for three reasons: physician bias, heavy exclusion criteria, and a short follow-up time.

First, Treace’s ALIGN3D data was generated through procedures done by many of the Company’s most experienced, [highest paid physicians](#), while the success of any procedure is largely dependent on the skill of the operator. We thus find it altogether more concerning that Treace pitches its kits to podiatrists as a tool to make the Lapidus procedure easier; this pitch naturally resonates with less skilled podiatrists, and we suspect that this could naturally lead to worsening outcomes. In the words of one 20-plus-year podiatrist we spoke with:

“If you’re not comfortable with the surgery, it [Lapiplasty kits] can help ... But if you’re comfortable, then you don’t need it ... I don’t have to go out and worry about using this system.”

Second, ALIGN3D’s [exclusion criteria](#) for the trial were particularly limiting, excluding patients with prior HV (hallux valgus i.e., bunion) surgeries, a BMI over 40, diabetics, evidence of peripheral neuropathy, metatarsus adductus $\geq 23^\circ$, moderate to severe osteoarthritis of the first metatarsophalangeal (MTP) joint complex evidenced by radiographic signs of joint space narrowing, peripheral osteophytosis, subchondral cyst formation and absence of intersesamoid ridge (crista) or clinically positive grind test, and current use of nicotine products.

ALIGN3D also excluded anyone over the age of 59, which represents [more than a third](#) of the population of those with bunions. We think it stands to reason that older populations are more likely to both hold longer recovery times and see higher complication rates.

Finally, [this data](#) has only been reported to 24 months on average thus far. The Company has recorded and presented safety data for all 173 patients so as “to prevent an undercount of safety events.” However, of these 173 patients, we estimate only two-thirds have reached 24 months of follow up, and less than 15% have reached 36 months of follow up. Treace does not disclose these figures explicitly, but later tables disclose the number of patients measured at certain endpoints at 24 and 36 months, summarized by us in the table below:

⁴ The ALIGN3D audio poster [can be found here](#). We also note that Treace’s [press release](#) announcing the updated interim data stated that “the updated data is also available on the Treace Medical website.” However, as of the time of writing, we could not find where this data was located. We find it telling that it seems easier to find Treace’s patient testimonials than the actual study data.

Endpoint	Patients Measured at 24 Months (Rate)	Patients Measured at 36 Months (Rate)
Radiographic measures	105 of 159 (66.0%)	19 of 159 (11.9%)
MOxFQ Scores	107 of 159 (67.3%)	19 of 159 (11.9%)
PROMIS Scores	104 of 149 (69.8%)	20 of 149 (13.4%)

As such, we expect to see more complications as more patients come into the 24-month and 36-month post-op measurement periods. Said plainly by one podiatrist we spoke with: “Complications from an arthrodesis [joint fusion] to a distal or proximal joint can take years to develop.” And indeed, various data points suggest long-term complications do arise. Consider the following from the MAUDE Adverse Events database:

- [One patient](#) had an initial surgery in 2020 yet had a revision surgery done in 2022. This was reported to MAUDE in June 2022.
- [Another patient](#) had surgery in 2018, then had a revision/removal surgery in 2019. This was again only reported to the MAUDE database in June 2022.
- [Another patient](#) had an initial surgery in 2019, yet as of April 2021, the event log indicates that “the screws are pulling out and the plate is loose” and “the patient is experiencing pain.”
- [Another patient](#) had an initial surgery in 2017, then had all hardware removed in 2022 due to “internal issues” as claimed by the patient.

See further from various patient support groups, physician pages, and forums in which patients describe complications arising many months and years after their operations, again in some cases leading patients to have their hardware removed entirely:

 **Christina Dews**
17h · 🌐

It's been over 5 yrs now and my foot is hurting like a feel the pin moving. It's causing my foot to cramp so bad i can't put pressure on my foot. Yes this is years later. Not my toe but more up my foot. Is anyone on here that has issues years later?

 **Ashlee Matthews**

Had procedure 4 years ago and run a ton. Hardware held up fine until this year and then i had swelling in the foot after every run. Hardware coming out Dec 7

 **Kaylee Danuta**

I regret it. I'm 4 years post op. Got the surgery when I was 24 with a severe bunion. I had no prior treatments done on my foot. I have pain and numbness in my foot whenever I walk and my foot is noticeably weaker. My doctor thinks removing hardware will help so we'll see. I just wish I got a second opinion.

Like Reply 29w   2

 **Jennifer Swinney Vinson**
Yesterday at 1:08 PM · 🌐

Has anyone had screws move after surgery. I'm over a year and a half out, and now have something sticking up that feels like a screw trying to bust thru the top of my foot 🙄🙄

 **Lisa Anker**
September 13 at 5:45 PM · 🌐

Be very diligent in your research and question everything. Get several opinions. Especially, ask how the rest of the foot and ankle will adjust after changing the mechanics of the foot post-Lapiplasty. Even a well-done Lapiplasty will leave you with ramifications that can be negative. My Lapiplasty healed well and the after X-Rays look great to the doctors. However, I have more residual pain on a constant basis than I ever had with that huge bunion. And, don't let anyone add other procedures to the Lapiplasty. My surgeon so nonchalantly tossed into the consultation the slight possibility of performing an akin osteotomy along with the Lapiplasty that I thought it was no big deal if he had to do it. The Lapiplasty ads all made sense and led me to believe it was a straight-forward correction that my whole foot would welcome. IT'S DEFINITELY NOT. I'm not saying not to have the surgery but I won't deny REGRETTING changing anything with my foot now that I have lived through two whole years with this disappointing outcome and trying to reconcile myself with living like this forever.


🙄👍🙄 16 17 Comments

👍 Like 💬 Comment 📧 Send

View 5 previous comments All comments ▾

 **Linda Champion**
I can SO relate to this. I had Lapiplasty 1/25/22, and refuse to ever let any Dr cut on my feet again! I am waiting until a year post op to really even consider walking back into a foot Dr.s office. Even then...doubtful

Like Reply 4d 🙄

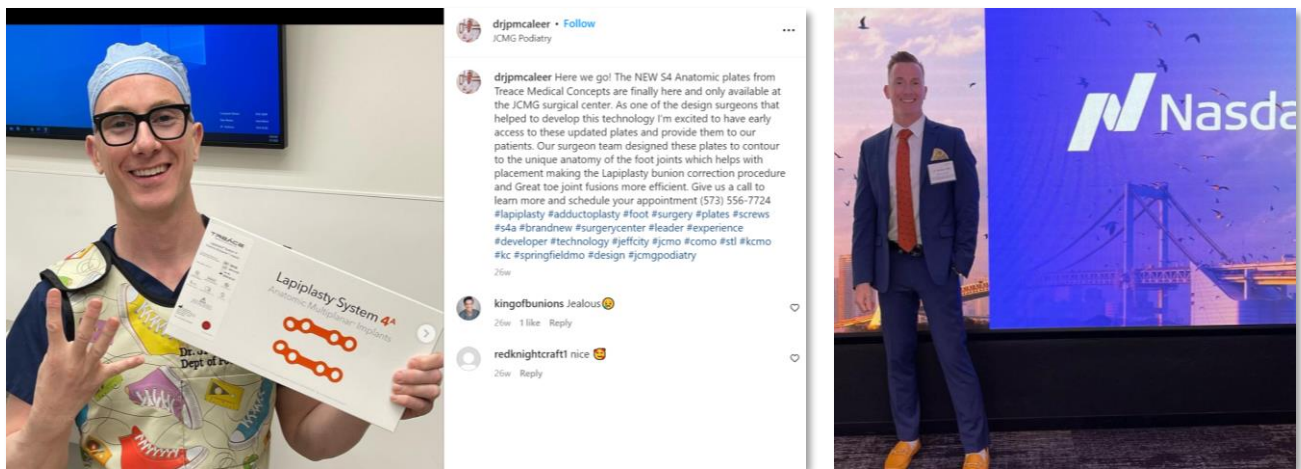
 **Jenny Garden**
Thank you for writing this. You are not alone. I am experiencing this as well status post 2 years of lapiplasty. I'm an operating room nurse too, so I know exactly how this procedure is done. Mine was done on point, foot is perfectly aligned, and buni...
See more

Like Reply 4d Edited 👍

See a [July 2022 review](#) of Dr. Jody Peter McAleer, a physician [who was paid \\$255,784 by Treace](#) in 2021 and frequently touts the procedure to both other physicians and patients. Reviews such as these frequently mention how patients were oversold regarding how quickly they could “get back on their feet.”



Meanwhile, Dr. McAleer [touts Treace products](#) to potential patients via Instagram and brags of his travels with the Company:



Treace’s Claims to Faster Recovery Times

Treace’s DTC marketing also frequently touts that patients can “get back on their feet sooner” with Lapiplasty than with competing procedures. We feel the Company has little scientific basis to make these claims. For example, one Treace “Patient Education” [video](#) claims that Lapiplasty “allows you to walk within days of surgery.” Various providers then trumpet similar lines. For example, see a few we’ve seen on Twitter below:

Source	Marketing Claims
Ray County Hospital	“Benefits are an instrumented approach to a 3-plan correction, rapid weight bearing, back to work & normal activities sooner.”
Eaton Rapids Medical	“David Mansky, DPM performs Lapiplasty® 3D Bunion Correction™ at ERMCM! Call 517.999.4500 to schedule an appointment with Dr. Mansky and quickly get back on your feet.”
Dr. Faraz Haque	“WATCH: Excellent patient education information on a new bunion surgical technique I specialize in to help patient’s return to activity sooner than traditional surgery!”

Marshall Orthopaedics	“A new bunion treatment option that can get you back on your feet in days!”
---------------------------------------	---

However, Treace’s own study had no method of quantifying early weight bearing. Indeed, ALIGN3D’s principal investigator and presenter, Robert Santrock, acknowledged this fact in his [September 2022 presentation](#):

“...there are some limitations to the study. Study sites are considered to be surgeons who are experienced with this technique, and there is no specific method to quantify the early weight bearing status.”

The ankle program director aired these same concerns:

“I understand that Treace tells you that their procedure lets you walk sooner. There's no data, and there's no papers that I know of that compares using the Lapiplasty plates versus ACME plates and seen which has a quicker return to walking. So I think that the data that the people who work for Treace, I mean, those guys, Bob Santrock and all the surgeons who publish papers on behalf of Treace, all these guys are consultants. I'm not saying they're biased. But I can just tell you that, that data as far as I've seen, has not been reproduced by other people. There's no papers comparing that Treace plate versus ACME plates.”

See from Steve Kominsky, a [podiatrist at Johns Hopkins](#) who founded and directs the surgical podiatry training program, in [response](#) to a [local news promotion](#) in which a podiatrist claimed Lapiplasty would get patients back on their feet sooner. Kominsky reiterates:

“Any time that a surgeon makes a comment like ‘it allows for a faster healing time’ typically means that up against a more traditional approach to the “same procedure”, the procedure being touted is the better of the two for the reasons listed. Unfortunately, in too many cases, this is mis-information being touted as either for monetary gain (either paid by the manufacturer, OR direct marketing to consumer) or it is simply because the surgeon has ‘drunk the Kool-Aid’.

The Lapiplasty procedure, of which I have done several, is a place looking for a home for well-designed surgical instrumentation. I am not speaking against the concept, nor the instrumentation in terms of its function. It works well. It does, however, add substantial cost to the procedure. Does one NEED to use it - well I see it similar to riding a bike with training wheels, or skiing with poles. It may be helpful during the initial phase to learn the Lapidus technique, but in NO WAY do patients heals faster and return to shoes and activities faster with this technique vs. the more traditional Lapidus procedure.”

Our review of comments on [patient Facebook groups](#) suggests that numerous patients are fed up with Treace’s marketing claims, even confused, as their experience was not what they were sold. Note the torrential pace of these comments:

Date Posted	Comment
November 7, 2022	Sadly, yes. 6 months out and in far more pain than I was when I first went to my doctor. I’m hopeful that it will get better with time.
November 7, 2022	I definitely traded one pain for another. In fact, several others. I regret the surgery. However, there are undeniable success stories, too.
November 7, 2022	Almost 1 year out and will be having hardware removed soon. Different & more severe pain now than ever before surgery. Take your time, do your research on both the Lapiplasty procedure AND the surgeon doing it.

November 7, 2022	My doctor is very experienced in Lapiplasty, (over 100 procedures) he said ZERO WB for 6 weeks. Reason? It's a broken bone. SOME people do ok with early WB and others pay a painful consequence.
November 6, 2022	I am 3 and a half months PO and yes, I'll admit as of right now... yes I regret getting this surgery. I had and still have help and a wonderful support system. Mentally it's killing me. I was in PT for 2 months and it helped a little but I still have zero movement in my big toe. Honestly the stairs were and are easy to navigate. I would say after the first week though when I could shower (I got a shower seat, 100% recommend) it helped Mentally ...
November 1, 2022	I'm 12 weeks po and I regret having this surgery so much! I have an incision that still isn't healed, I am walking with a limp, I can't bend my big toe! PT twice a week. Please tell me this gets better! I was walking 4-5 miles a day pre surgery. I can't walk to mailbox and back with aching now!
November 1, 2022	I had mine June, 2021. My experience was much like yours, except my incisions healed well. I eventually had the hardware removed (last February), which finally cured my limp! Big toe still has very limited ROM. I'm sorry you're dealing with this, it's awful.
October 18, 2022	I had my surgery done in April of 2021. I am still having problems with numbness, pain, and an inability to bend my foot ...
October 17, 2022	Has anyone been to a pain Dr? I had Lapiplasty & hammertoe correction 12/30/21, hardware removal & pin in hammertoe to straighten 7/28/22. I am still in pain & my Dr cut a tendon that he never told me about...
October 16, 2022	It's been over 5 yrs now and my foot is hurting like a feel the pin moving. It's causing my foot to cramp so bad i can't put pressure on my foot. Yes this is years later. Not my toe but more up my foot. Is anyone on here that has issues years later?
October 13, 2022	I'm 22 days post op from lapiplasty, adductoplasty, and I have 4 pins in my toes for hammertoes. Saw dr last week and he wants me to start heel walking. At 2 weeks? I can not at 3 weeks. How long did it take you to walk? I'm feeling so depressed and defeated
October 12, 2022	For those who are about a year or over PO. Do you still get pink/redness over hardware site and slight swelling? I'm not in pain and it's slight. Dr says it's normal for a year PO. Curious of others healing progress at this stage.
October 12, 2022	I had cheilectomy after lapiplasty. Had lapiplasty on both feet in 2020. Developed hallux rigidus on the L big toe about a year later. Had cheilectomy in May 2022. Things are settling and I'm about 90 - 95%.
October 12, 2022	First surgery was lapiplasty by a Treace trained surgeon who had done 300 surgeries and did online and in person training of other podiatrists. He really made a mess of my foot. The incisions were crooked, didn't heal well, tendons were cut that shouldn't have been, it was all sooo painful and i had massive swelling that never completely went away. I ended up with a broken staple and a non union of the first and second metatarsals. Had my revision surgery 4 weeks ago with a different surgeon who used lapidus hardware and it's healing beautifully. It has never been very swollen. The incisions have never bled and they are straight fine lines that are already 90% healed. Pain has been minimal. I'm non weight bearing for at least 6 weeks. First two weeks I had a splint and ace wraps and now I have a boot but cannot weight bear for another 2-3 weeks depending on the healing. Next x-ray scheduled for 10/25. I have seen 5 podiatrists total, three before first surgery and 2 after. I did my research and still had a bad outcome. I was convinced by the misleading Treace marketing that lapiplasty was the only way to go. Do not discount experienced surgeons who use lapidus hardware. It's essentially the same procedure. Best of luck to you!
October 11, 2022	Hello. I am 6 weeks post op. 4 weeks in the boot. Physical Therapy at 11:30 then appointment with surgeon at 1:30. Can't wait to see what X rays show. Fingers crossed. I'll post the X-rays . My big toe is still very stiff. And can't bear full weight yet. Too uncomfortable. But feel I'm getting closer
October 11, 2022	I felt Lapiplasty was a better way to address a bunion. Move the metatarsal back to the correct position and fuse the T1 which keeps it there. Older surgeries deform this bone and imo preform a cosmetic procedure. Now after getting 6 opinions finding who I felt was the doctor for me I am partially disabled. Worse off considerably worse off than originally. My guess is he botched the 2nd & 3rd metatarsal shorting. It's been 10 months - 40 weeks. Additionally he did a 2nd surgery to remove the hardware but totally forgot about the bones sticking out of the bottom of my foot. So I am in constant pain and often limp. My point is nothing can be for sure. Lapiplasty was good but the doctor's judgement bad? The additional 3 doctors I had consults with sure don't feel he was right. I believe most people have better results than I did. I have other opinions about all of this but each of us have to find our own way.
October 11, 2022	Day 17 post op. The stitches were removed today. I was given antibiotics for the blister and put in a boot. Was told I could shower tomorrow and to walk on my foot at 25% right now and progress to 100% by November when I will see the Dr again
October 9, 2022	I will be 4 weeks po on Tuesday. I still keep my foot elevated much of the time and ice at least 4 times a day. I still walk with crutches and am not able to put all my weight on my foot. Is this normal! I feel like I should be be able to walk around without my crutches. I just sat down which is why it's red and swollen like that
October 8, 2022	Hello. I've whined and cried enough. Today is day 38 post op. I am feeling so much better mentally and physically. Past 3-4 days have seen an improvement. Pretty much ditched the walker 2 days ago. Mostly using crutches. Purchased a knee scooter but not ready for it yet. The heavy boot makes it uncomfortable. Hoping I will graduate to a smaller type

	shoe boot. Then use the toot and scoot. Anyway my point of this post is to say hang in there. There is a light at the end of this loooong tunnel. PT has been a huge help too. Emotionally as well as physically.
October 7, 2022	Just chiming in to say that the marketing that Treace does on their website is extremely misleading. I had a FAST recovery with "the real Lapiplasty", but it was not the walk in the park that the advertising depicts and takes upwards of a year for 100% healing. All that being said, I'm very happy with my results at 9 months post op.
October 7, 2022	Lapiplasty marketing makes it look like recovery is a breeze. Reality is way different. Even those who are allowed to 'walk' right after surgery are in reality barely hobbling to the bathroom. Most of us will be non weight bearing for weeks and swelling for months.
October 2, 2022	Did most people on this thread technically get THE Lapiplasty? Sounds like so many had a traditional bunionectomy with several weeks and/or months of recovery. That is not what the Lapiplasty site advertises.

Treace Cherry-Picks Data to Cast Doubt on Traditional Procedures

Treace claims that Lapiplasty holds low recurrence rates (i.e., the return of bunions) of 1-3% vs. "up to 78%" for traditional 2D osteotomy. We've already shown how Treace's complication rates are far higher than 1-3%, but we also think Treace's claim that traditional osteotomy leads to a 70% plus chance of recurrence is also blatant cherry-picking and self-serving. We think osteotomy recurrence rates are nowhere near 78%, but well under 10%.

This 78% figure is constantly trumpeted by Treace. The Company's 2018 [materials](#) claimed Osteotomy recurrence rates "could be as high as 50-78 percent..."; the Company's [IPO prospectus](#) and recent annual reports claim "...complication rates as high as 78% following 2D Osteotomy surgery and 46% following Lapidus Fusion surgery..."; management claimed on the most recent Q2 2022 conference call that "recurrence rates...have been shown to be as high as 78%." Finally, a [patient education video](#) reiterates the 70% claim:



Treace is even pushing this 78% figure in patient testimonials. See from "First for Women" Magazine ([published October 11, 2021](#)), in which the patient claims:

"The Lapiplasty technique realigns and secures the joint with titanium plates at mid-foot, where the toe actually begins, so patients get back on their feet faster. Also, traditional surgery has a bunion recurrence rate up to 78%. With Lapiplasty, the rate of recurrence is only 1% to 3%!"

This magazine has also touted so-called "cures" to its readers such as "the water cure", the "Keto thyroid cure, and "the over-50 fat cure":



Finally, Treace’s physician roster also parrots the 78% line. See from the [Kansas Foot Center](#) which claims, “Less than 10% of Lapiplasty patients need another procedure, as opposed to 30%-78% of traditional bunion cases.”

Treace’s oft-touted 78% figure originates from a single [2016 study \(Jeuken, et al.\)](#) which cited just 73 patients. We regard this study as an outlier in the scientific literature; others have also [acknowledged](#) the strangely high recurrence rate in this study, stating, “Raikin et al summarized the risk factors for recurrence, including anatomic, nonanatomic (systemic), social, and surgical factors. It is conceivable that a combination of these reasons was responsible for the high recurrence level in our study.” The Jeuken study also tracked patients for a mean of 168 months, with a max follow-up of 180 months, as compared to just 17 to 24 months for Treace’s self-reported data. As such, we’d naturally expect to see additional complications arise over in Lapiplasty patients over the incremental 12+ years.

Treace’s blatant cherry-picking of data extends not only to the message given to patients, but also to surgeons. In a Fall 2022 [surgeon webinar](#), for example, Treace presented a series of studies in support of the Company’s claim that osteotomy holds high recurrence rates. However, a deeper look at Treace’s selections reveals that 3 of the studies were conducted in pediatric populations, where a child’s bones are still growing and thus bunions naturally show higher recurrence. In contrast, the ALIGN3D study was conducted in ages 14 to 58. Treace also included studies which measured results in only a handful of patients (n=17, n=20, etc.) in procedures done by a single surgeon. Interested readers can look to our addendum for our full opinions on these studies.

Treace has also pointed to so-called “dissatisfaction rates” of 2D osteotomy. The Company’s Form 10-K claims “traditional surgical treatment approaches are characterized by an approximately 30% patient dissatisfaction rate for 2D Osteotomy surgery...” As far as we can tell, Treace does not source this claim in its 10-K, though we found materials from 2016 that again make this claim while referencing the Jeuken study. We further note that in a [2021 paper](#) published by Jody McAleer – a paid consultant for Treace – McAleer claims “40% patient dissatisfaction” with Osteotomy, and cites a study of just 15 patients.

In contrast to Treace’s cherry-picked data, our review of the scientific literature suggests that the vast majority of patients are satisfied with existing procedures. Two recent meta-studies ([2018](#) and [2021](#)) which each found that traditional bunion surgeries hold low recurrence rates of 10% or less and are overwhelmingly effective. In direct contrast to Treace’s narrative, the 2018 study added that, “Hallux valgus surgery has been reported to have fairly consistent results and rates of complications or unfavorable outcomes.”

	2018 Systematic Review (Barg et al)	2021 Systematic Review (Clarke et al)	Treace's Marketing Claims
Method	Surgical treatment (various methods)	Treatment by Scarf osteotomy	"Traditional surgery" or "2D osteotomy"
Sources	229 studies, thousands of patients	15 studies spanning 946 operations	Single study in 73 patients
Recurrence Rate	4.9%	"expected to range from 0% to 10%..."	"up to 78%"
Dissatisfaction Rate	10.6%	Not measured	"up to 30%"

We Think Treace's Best Days are Behind It

A Case Study: We Think Lapiplasty Could Become Cartiva 2.0

Treace's Lapiplasty kits remind us of Wright Medical's Cartiva implants, which aimed to fix osteoarthritis in the big toe ("Hallux rigidus") with a synthetic cartilage implant ("SCI").⁵ Note that even Cartiva supported its claims regarding long-term outcomes with studies holding a mean follow-up time of 5.8 years – far longer than any data Treace has disclosed to date. Nevertheless, sales of the implant [floundered](#) after independently-generated data and real-world [physician feedback](#) alleged it to be less safe and effective than claimed. Wright became embroiled in [lawsuits](#), and in 2019, Cartiva implants generated just \$26 million in revenues vs. the \$47 million that Wright called for at the start of the year. Coincidentally, many current Treace insiders have previous experience at Wright, including current Treace SVP of Sales, Aaron Berutti, who was previously VP of Business Development at Cartiva from February to October 2018.

We think a similar scenario could unfold at Treace as patients and physicians come to grips with the vast differences between what Treace has pitched and the real-world outcomes of the procedure.

Insiders Have Sold Over \$136 Million in Stock, and Continue Selling by the Day

It seems Treace insiders have seen the writing on the wall: we estimate insiders have collectively [sold over \\$136 million](#) in stock through the IPO and subsequent adoption of 10b5-1 trading plans:

- CEO John T. Treace has sold a net \$97.4 million in stock, cashing out 5.25 million shares through the conversion and immediate sale of preferred stock after the Company's April 2021 IPO.
- Director James T. Treace has sold \$11.8 million in stock, most recently selling 50,000 shares on October 21, 2022, as part of a Rule 10b5-1 trading plan.
- Director Barry Bays has sold \$5.1 million in stock, most recently selling 26,523 shares just 4 trading days ago on November 9, 2022, as part of a Rule 10b5-1 trading plan.
- Director Thomas Timbie has sold \$4.1 million in stock, most recently selling 50,000 shares on August 16, 2022, as part of a Rule 10b5-1 trading plan.

⁵ Cartiva was acquired by Wright in August 2018.

- Director Richard Mott sold \$2.2 million in stock, or 95,000 shares, on October 31, 2022, as part of a Rule 10b5-1 trading plan.



Appendix: Surgeon Webinar Studies

In Treace's September 2022 surgeon [webinar](#), Dr. Paul Dayton, a paid consultant, listed several studies which seemingly found high recurrence rates for osteotomy:

Bunion surgery has a bad reputation for a reason... recurrence rates are high for osteotomy procedures

- Jeuken FAI 2016: **78%/73% recurrence** (Scarf/Chevron)
- Agrawal et al J Ped Orth 2015: **29.8% recurrence, 21% revision**
- Bock et al, JBJS 2015: **30% recurrence** (Scarf)
- Iyer S, et al, FAI 2015: **64.7% recurrence**
- Edmunds 2015: **<50% obtained correction** (Distal/Proximal/Double)
- Raikin et al, Foot & Ankle Clinics 2014: **50% complications**
- Chong et al, JBJS 2014 : **25.9% dissatisfaction** at 5.2 years
- Pentikainen et al, FAI 2014: **73% recurrence** (Distal Chevron)
- George 2009: **37% recurrence** (Scarf)
- Okuda R, et al, JBJS 2007, 2009: **25% recurrence** (Crescentic)
- Coetzee JC, et al, FAI 2002: **25% recurrence** (Scarf)
- Gali et al, AOFAS 2020: **46% recurrence** (Lapidus)

6:48 / 1:07:04
Confidential and Proprietary Information

We again see these studies as cherry-picked, exemplary of Treace's shoddy approach to science. Dayton – who helped develop the Lapiplasty instrumentation and [has earned at least \\$1.3 million from Treace](#) over the past 5 years – commented on the slide that:

“This is just a very abbreviated list of the literature on long-term bunion correction, and the results honestly are not what I was told they should be when I was a student, when I was a resident.”

However, Dayton's feigned dumbfoundedness is a lame gimmick. Just as the case for Jeuken, we again find many of these cited studies to be cherry-picked. Most egregiously, three of these studies were conducted in pediatric populations. One needn't hold a Ph.D. to recognize that children have bones that are still growing, and thus naturally face a higher risk of recurrence. We note that in comparison, Treace's ALIGN3D study was conducted adults only – Treace is not only cherry-picking, but comparing apples to oranges.

- In [the Agrawal study](#), where Treace points out “29.8% recurrence”, the authors studied 47 feet in 29 patients who underwent a Scarf osteotomy. These patients were just 11.7 years old, on average. Indeed, the Agrawal authors stated that “we recommend postponement of correction until skeletal maturity”; their contention was not with the nature of the procedure, but with its use in children.
- Treace then cites the [Edmonds 2015 study](#) which found that less than 50% of patients maintained correction, but again the Edmonds study was conducted in children, and thus faces the same limitations.
- Finally, Treace then cites a [third pediatric study in George 2009](#), which again faces the same limitations as Agrawal and Edmonds. We note that coincidentally, Treace's presentation chose not to cite in which

journals the Edmunds and George studies were published (The Journal of Pediatric Orthopaedics, and The Journal of Children's Orthopaedics, respectively). Naming them might have given the gimmick away.

Treace also cites the [Raikin 2014 study](#) to claim "50% complications" for osteotomy, even though the slide is meant to speak to recurrence, an entirely different endpoint. Nevertheless, if we look at the actual words written in the paper by the study authors, we find that the authors only make a passing mention that "complications have been reported [via other sources] to be as high as 50%". The Raikin study then states that recurrence is far lower at 2.7% to 16%, while revision rates were just 1.85% to 2.94%.

Finally, the presentation cites studies conducted with extremely small sample sizes and/or by a single surgeon. We find it reckless for Treace to imply widespread conclusions about 2D osteotomy on the basis of these studies.

- In the [Pentikainen study](#), just 77 feet were included. Nevertheless, even with high recurrence, the study found that "all recurrences were painless, and thus no revision surgery was required."
- Similarly, [the Iyer study](#) measured results of just 17 patients who were operated on by a single surgeon.
- Finally, the [Coetzee study](#), published 25 years ago, examined the results of just 20 patients treated by a single doctor.