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Short-term Follow-up of Patients Receiving Bio-integrative Screws for Lisfranc Injuries: A Case Series

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Learning Point of the Article:

This report is the first study evaluating the post-surgical outcomes of patients received bio-integrative screws for their tarsometatarsal (TMT) joint fixation to date.

Abstract

Introduction: Various methods are used for open reduction and internal fixation of Lisfranc injuries, and each shows different post-treatment outcomes. Other than the common post-surgery problems in these patients, including possible non-anatomical reduction, implant loosening, breakage, and arthritis, most of these patients will undergo a second surgery for implant removal which itself might cause further complications. To reduce the need for re-operation, bio-degradable or bio-integrative implants can be promising; however, the short- and long-term outcomes have been scarcely investigated to date.

Case Report: We followed up 10 adult patients who received bio-integrative screws for Lisfranc injuries. The patients were asked to fill out the patient-reported outcome measures (PROMs) surveys during one of the follow-up visits. We gathered variables including the type of injury, pain score, and PROMs including physical function (PF), pain interference, pain intensity, and depression. We evaluated the patients for wound dehiscence, non-union, and hardware failure. The median (interquartile range [IQR]) follow-up time of the patients in this study was 9 (4–11.5) months. Nine out of 10 patients with Lisfranc injuries who received bio-integrative screws showed improvements in their pain scores and started progressive weight-bearing. Among 3 patients who had sport-related Lisfranc injuries, 2 returned to play in <6 months, and one started side-to-side agility work in <3 months. The median (IQR) scores of PROMs representing PF, depression, physical health, mental health, pain interference, and pain intensity were 49.5 (30.1–61.9), 41 (41–49), 50.8 (39.2–57.7), 59 (48.9–63.7), 51.7 (41.6–72.6), and 43.5 (37.8–55.2), respectively.

Conclusion: Our results demonstrated promising short-term outcomes of using bio-integrative screws in patients with Lisfranc injuries based on PROMs and the rate of complications. Future studies on larger populations and more comprehensive variables with longer follow-up duration should be the next step in evaluating the pros and cons of these new implants.

Keywords: Bio-integrative implant, revision surgery, implant removal, Lisfranc complications.

Introduction

Lisfranc injuries, caused by low-energy and high-energy traumas, could vary from ligamentous sprains to complex fractures [1, 2]. The incidence of Lisfranc injuries was estimated to be 9.2/100,000 person-year, and men and young individuals in their third decade of life appeared to be more susceptible to the injury [1, 3]. The treatment method for Lisfranc injuries is decided based on the severity of the injuries as well as the patients' characteristics [4, 5]. The injuries with less than subtle malalignment could be managed nonoperatively while open

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Patient	Age	Gender	Mechanism of Injury	Diagnosis	Post-operation visit	Last follow-up visit	Follow-up duration
Case 1	44	Female	Fall	Laterally displaced fractures of the bases of the right second, third, and fourth metatarsal.	-Pain score: 0/10. -Plan: Progressive weight -bearing adding 25 pounds every 3 to 5 days until week 6 when she can wean from the post -op boot.	-Pain score: No report of pain in foot. -Radiographs: Complete bone healing. -Returned to activity.	15
Case 2	45	Male	Sports injury (Basketball)	Widening of the left Lisfranc interval, and non -displaced fracture of second metatarsal bone.	-Patient felt better (Pain score decreased from 7/10 to 3/10) Plan: Touchdown weight -bearing (weeks 2 –4), then progressive weight -bearing. Wean boot at 8 weeks post-op.	-Pain score: No report of pain in foot. -Radiographs: Stable alignment -Returned to sport (biking).	11
Case 3	80	Male	Workplace injury	Avulsion fracture of the base of fifth metatarsal, and fracture of the first proximal phalanx shaft.	-Pain score: 8/10. -Plan: Touchdown weight -bearing (weeks 2 –4), then progressive weight -bearing. -Complication: Patient had significant amount of swelling up to knee. -Management: Ultrasound examination ruled out DVT, and PT was prescribed.	-Pain score: 8/10. -Radiographs: Improved alignment of Lisfranc space, unchanged alignment of fifth metatarsal base. -Plan: Cortisone injection if pain persists .	9
Case 4	34	Female	Fall	Avulsion fracture at first and second metatarsal interval.	-Pain score: 3/10. -Plan: Non-weight-bearing for 4 weeks, then progressive weight -bearing. Wean the boot at week 9–10 post-op. Start PT at week 4 post -op.	-Plan: Continue progress activities. -Radiographs: Stable alignment.	3
Case 5	33	Male	Fall	Fractures of medial cuneiform, lateral cuneiform, second, third, and fourth metatarsal bases, and widening of second/third tarsometatarsal joint.	-Pain score: 2/10. -Complication: Swelling over the midfoot sutures. -Management: Ultrasound ruled out DVT. -Plan: NWB for 4 weeks, and start progressive WB at week 4. Wean boot at week 8 –10.	-Pain score: 1/10. -Radiographs: Stable alignment. -Plan: Continue progress activity as tolerated.	7
Case 6	39	Male	Motor vehicle accident	Fractures of navicular, first and second tarsometatarsal.	-Pain score: 4/10. -Plan: NWB for 6 weeks, then start progressive WB. Wean boot at week 12.	-Pain score: 4/10. -Complication: Symptomatic hardware. -Management: Removal of hardware.	12
Case 7	40	Male	Fall	Fractures of second and third metatarsals, and widening between first and second metatarsals.	Pain score: 2/10. Plan: NWB for 4 weeks, then progressive WB. Weaning boot at 9 –10 weeks postoperatively.	-Pain score: 7/10. -Complication: Pain in lateral midfoot. -Radiographs: Staple securing TMT is fractured. -Plan: Nonoperative treatment options for midfoot arthritis, custom molded orthotics and pain medication.	11
Case 8	18	Female	Sports injury (Squash)	High-grade partial tear of Lisfranc ligament.	Pain score: 2/10. Plan: NWB until 2 weeks, then TDWB until week 4 postoperatively. Start progressive WB from weeks 4–6, then WBAT and wean boot at week 8. Start PT at week 2.	-Pain score: 0/10. -Radiographs: Interval fractures of screws without any widening of joints. -Plan: Continue to progress with activity and return to sports.	9
Case 9	18	Female	Sports injury (Football)	Increased space between first and second metatarsals.	Pain score: 0/10. Plan: NWB for 4 weeks, then begin progressive WB. Wean boot at 6 –8 weeks postoperatively. Start PT at week 2.	-Pain score: 0/10. -Radiographs: Stable alignment. -Plan: Return to sports.	4
Case 10	41	Female	Fall	Multiple fractures at bases of metatarsals, and widening of Lisfranc interval.	Pain score: 6/10. Plan: NWB for 4 weeks, then progressive WB. Wean boot at 8 –10 week postoperatively.	-Pain score: No report of pain in foot.	2

TMT: Tarsometatarsal

Table 1: Patient characteristics, procedures, and post-surgical outcomes.

reduction and internal fixation (ORIF) and arthrodesis might be indicated for more severe cases [5].

Different instruments and implants are used for both ORIF and arthrodesis including plates, screws, K-wires, staples, and flexible fixation [6, 7]. Most of these implants are metallic and impose the need for second removal surgery on the patients aside from other complications such as loosening and breakage that can cause further psychosomatic and economic burden on the patients and the health-care system [8, 9]. Thus, resolving the need for a second operation that is provided by bio-absorbable and bio-integrative implants has become a focus of various research in orthopedic surgery [10]. A preclinical study on rabbit models with cylindrical bone defects in the femur showed that using bio-absorbable screws could lead to higher rates of bone healing by increasing vascularization and bone regeneration [10, 11]. While the application of bio-integrative implants is still limited, this could revolutionize the care of patients with orthopedic injuries if the implants' built-in properties ensure a functionally stable connection between the bones and the implant surface [11].

The current study is a case series of 10 patients receiving bio-integrative screws for their Lisfranc injuries. Herein, we report the patient-reported outcome measures (PROMs) and the complications in these patients over at least 3 months of follow-up.

Materials and Methods

This is a retrospective case-series study on 10 adult patients with Lisfranc injury who underwent tarsometatarsal (TMT) fixation using bio-integrative screws (OSSIOfiber™). The inclusion criteria were: (1) patients with Lisfranc injury with documented instability on weight-bearing computed

Patient	Physical function score*	Depression score*	Physical score*	Mental score*	Pain interference score*	Pain intensity Score*	Time of survey (months after surgery)
Case 1	61.9	41	44.9	50.8	41.6	30.7	3
Case 2	53.4	41	57.7	59	41.6	43.5	3
Case 3	20.9	41	39.8	62.5	75.6	52.1	2
Case 4	23.1	49	37.4	56	75.6	57.5	3
Case 5	61.9	41	54.1	59	41.6	43.5	6
Case 6	40.1	41	50.8	59	65.2	65.2	12
Case 7	47.9	41	57.7	67.6	53.9	43.5	3
Case 8	51.2	55.7	50.8	38.8	49.6	40.2	5
Case 9	61.9	41	67.7	67.6	41.6	30.7	4
Case 10	32.5	49	34.9	43.5	71.6	54.5	1
Median	49.5	41	50.8	59	51.7	43.5	3
IQR	30.1–61.9	41–49	39.2–57.7	48.9–63.7	41.6–72.6	37.8–55.2	2.75–5.25

*Surveys utilized to assess the PROMs in patients were acquired from the PROMIS program. The surveys were PROMIS physical function short form 10a, PROMIS short form 4a (depression), PROMIS Global Health Short Form Score (Physical), PROMIS global health short form score (Mental), PROMIS short form 4a score (pain interference), and PROMIS pain intensity short form 3a sco.
IQR: Interquartile range, PROMIS: Patient-reported outcomes measurement information system

Table 2: Patient-reported outcome measures in the patients received bio-integrative screws for Lisfranc fixation.

tomography scan when compared to the contralateral side, (2) receiving surgical fixation of TMT joint, (3) using bio-integrative implant, (4) being ≥18 years old, and (5) having at least 2 months of follow-up. The exclusion criteria were (1) patients who received metal implants, (2) concomitant injuries that affect the PROMs reported by the patient during the follow-up visits, and (3) patients who have not filled out PROMs surveys. The study protocol was approved by the institutional review board (IRB no. 2015P000464).

Patients' charts were reviewed to gather information about the treatment method, pain score (Visual Analog Scale), and reported complications in the postoperative follow-up visits. The complications we investigated were nonunion, wound dehiscence, and hardware failure (loosening or breakage). The PROMs, which were obtained during one of the patients' follow-up visits that happened during 6-month post-surgery, were gathered from the charts. The PROMs surveys used in the current study were patient-reported outcomes measures information system (PROMIS®) short forms for PF, depression, physical health, mental health, pain interference, and pain intensity (PF-SF-10a, global health, SF-4a, and SF-3a) [12, 13]. PROMIS utilizes T-score maps to compare the patients' scores to the general United States' population [14, 15]. Median and IQR were used to depict the data. Statistical analysis was done using SPSS (ver. 28, IBM™) and P-value of significance was set at 0.05 where needed.

Results

The patients' demographic data, diagnosis, mechanism of injury, procedure, pain scores, and complications in follow-up visits are presented in Table 1. The median (IQR) age of patients with Lisfranc injury who received bio-integrative screws was 39.5 (29.2–44.2), ranging from 18 years old to 80 years old. Of these 10 patients, five were female (50%), and five were male (50%). The median (IQR) of body mass index of patients was 27.76 (24.9–37.3), with the minimum and maximum being 23.9 and 68.3, respectively. The mechanisms of injury included fall (n = 5), sports injury (n = 3), motor vehicle accident (MVA) (n = 1), and work-related injury (n = 1). All patients had TMT ORIF for Lisfranc injury. The median (IQR) of patients' follow-up duration was 9 (4–11.5).

Among the patients, nine showed promising outcomes as their pain scores evaluated in follow-up visits decreased. These patients began progressive weight-bearing, and two returned to sports (case no. 8 after 5 months and case no. 9 after 4 months).

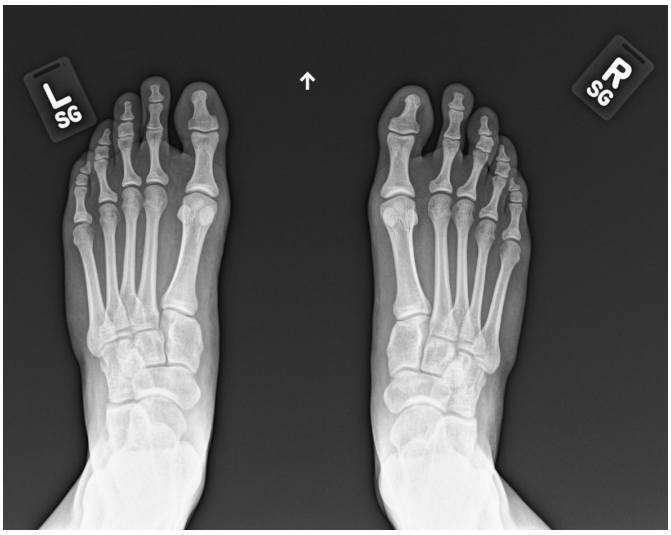

Figure 1: Left and right foot X-ray, anteroposterior view, case no. 8, pre-operation.

Case no. 8 was a young female squash player who came to the clinic after a twisting injury, leading to a high-grade partial Lisfranc ligament tear with 2nd TMT subluxation (Fig. 1). The procedures done for the patient were Lisfranc ORIF, 1st TMT ORIF, and inter-cuneiform ORIF (Figs. 2 and 3). Another patient (case no. 9) who returned to playing 4 months after the surgical procedure was an 18-year-old girl with increased space between her first and second metatarsal bones who received Lisfranc ORIF, 2nd TMT ORIF, and inter-cuneiform ORIF.

The symptoms of one patient (case no. 6) who had MVA did not improve, leading to a second surgical intervention. Case no. 6 was a patient MVA leading to multiple fractures, including metatarsal bones. First and second TMT fusions and inter-cuneiform fixation were done for the patients. However, the patient remained symptomatic and needed a second surgical intervention to remove the hardware.

Table 2 represents the PROMs in patients who received Lisfranc fixation using bio-integrative screws. The median (IQR) scores of PROMs representing PF, depression, physical health, mental health, pain interference, and pain intensity were 49.5 (30.1–61.9), 41 (41–49), 50.8 (39.2–57.7), 59 (48.9–63.7), 51.7 (41.6–72.6), and 43.5 (37.8–55.2), respectively. The surveys were done in one of the patients' post-operation follow-up visits with the median (IQR) of 3 (2.75–5.25) months.

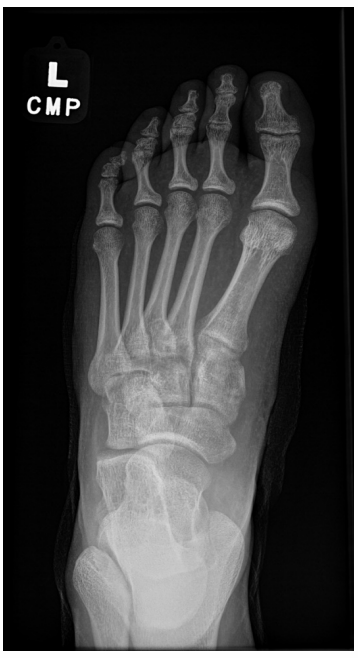

Figure 2: Left foot X-ray, anteroposterior view, case no. 8, 2 weeks after Lisfranc fixation.

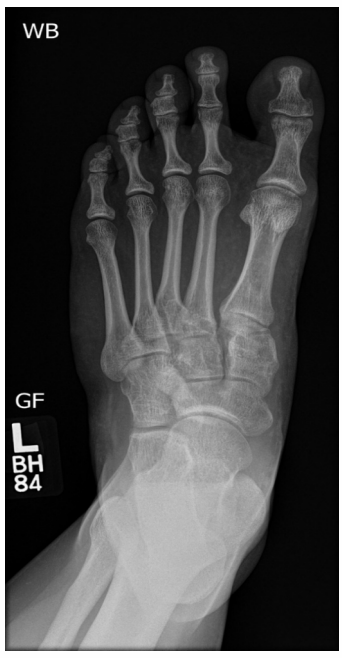

Figure 3: Left foot weight-bearing X-ray, anteroposterior view, case no.9, 6 weeks after Lisfranc fixation..

Discussion

Several complications, including progressive pain and arthritis, and loss of function, might transpire after surgical interventions in Lisfranc injuries [16]. Clinicians and researchers have evaluated the outcomes of different surgical techniques for Lisfranc injuries; each of these techniques has shown several pros and cons with no definite consensus on superiority for one among others [17]. A recent meta-analysis by Levy et al. suggests that arthrodesis could be a better surgical intervention for patients with Lisfranc injuries, resulting in improved outcomes measured by the American Orthopaedic Foot and Ankle Society ankle-hindfoot score and lower complication rates compared to ORIF [18]. Furthermore, Buda et al. showed that Lisfranc patients treated with ORIF had significantly higher reoperation rates in comparison with those who received PA [19]. These results were also confirmed by a systematic review and meta-analysis demonstrating patients who underwent ORIF showed higher rates of a second surgery, aiming to remove the hardware than those treated with arthrodesis [20]. While these pieces of evidence imply that primary arthrodesis could decrease postoperative complications, this might not be a good option for all patients with Lisfranc injuries, particularly young and active ones. Patients with Lisfranc injuries treated with ORIF are commonly required to undergo a second surgery to remove the hardware 3–6 months postoperatively. This second surgery for hardware removal might lead to morbidity and injury per se. A retrospective cohort study on 57 patients with a mean age of 29.8 years old showed that hardware removal surgery could increase the injury rate to deep peroneal nerve from 11% to 23% [21]. Furthermore, Reith et al. reported that this surgery might be associated with higher rates of bone healing complications and infections [22]. Additionally, the surgery and all the

morbidities the patients might need to deal with are not without cost and could increase the financial burden on patients and the health-care systems.

In contrast to the conventional metal screws, the bio-integrative and bio-absorbable implants do not require a second removal surgery. Furthermore, bio-integrative implants, capable of establishing a direct mechanical and functional connection between the implant and tissue, could presumably increase bone healing rates. The current report showed that using bio-integrative screws for patients with Lisfranc injuries could eliminate the need for hardware removal, in most cases. We observed that 9 out of 10 (90%) patients treated with this novel technology showed progressive improvement and did not require a second surgery; one patient underwent a second surgery due to persistent pain.

In addition, we reported the PROMs of the Lisfranc patients who received bio-integrative screws and monitored the complications that occurred at least 2 months' postoperatively. According to the T-score maps and the PROMs, the patients could conduct daily activities and never felt depressed during the study period. In addition, PROMIS global health scores in patients who received bio-integrative screws for Lisfranc injury shows that they were as healthy as the general population, both physically and mentally. Although with a median (IQR) Pain interference score of 51.7 (41.6–72.6), the patients had slight pain during daily and social activities, the pain intensity scores were within the normal range.

In conclusion, this report is the first study evaluating the post-surgical outcomes of patients received bio-integrative screws for their TMT joint fixation. We observed that the patients who received the treatment as part of their primary Lisfranc fixation did not require any further intervention. However, as the implants are made of radiolucent materials, we needed to examine anatomical landmarks to assess the joint alignments after the surgery and during the follow-up period. Further studies with a longer-term follow-up are needed to evaluate these results.

Conclusion

The incidence of Lisfranc Injury is estimated to be 9.2/100,000 person-year, and young individuals in their third decade of life appeared to be more susceptible to the injury. Various methods are used for ORIF of Lisfranc injuries, and each shows different post-treatment outcomes.

In the current study, 9 out of 10 patients receiving bio-integrative screw showed promising outcomes as their pain scores decreased in follow-up visits. These patients began progressive weight-bearing, and two returned to sports in <6 months.

The PROMs representing of PF, depression, physical health, mental health, and pain intensity were within normal ranges during the follow-up period.

Clinical Message

Most of the implants used for ORIF are metallic and impose the need for second removal surgery on the patients aside from other complications such as loosening and breakage that can cause further psychosomatic and economic burdens on the patients and the healthcare system. Resolving the need for a second operation that is provided by bio-absorbable and bio-integrative implants has become a focus of various research in orthopedic surgery. The current study reported the treatment outcomes of 10 patients receiving bio-integrative screws for their Lisfranc injuries.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given the consent for his/ her images and other clinical information to be reported in the journal. The patient understands that his/ her names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflict of interest: Nil **Source of support:** None

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