RESEARCH ARTICLE

Use of Bio-integrative Screws for Fixation of Lisfranc Instability; Pros and Cons from Surgeons' Point of View in a Cadaver Study

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Abstract

Objectives: Majority of Lisfranc fracture-dislocations require anatomic reduction and rigid internal fixation to prevent debilitating sequelae. Current methods include solid screws and flexible fixations which have been in use for many years. Biointegrative screw is a newer option that has not yet been thoroughly investigated for its effectiveness for Lisfranc injuries.

Methods: The ligaments of the Lisfranc complex were resected in eight lower-leg cadaveric specimens. This was done by eight foot and ankle surgeons individually. Distraction forces were applied from opposite sides at the joint to replicate weight bearing conditions. Three methods of fixation – flexible fixation, metal, and biointegrative screws- were evaluated. The diastasis and area at the level of the ligament were measured at four conditions (replicated injury and each type of fixation) in neutral and distraction conditions using fluoroscopy images. The Wilcoxon test and Kruskal Wallis test were used for comparison. P value <0.05 was considered statistically significant.

Results: The diastasis value for the transected ligament scenario (2.47 ± 0.51 mm) was greater than those after all three fixation methods without distraction (2.02 ± 0.5 for flexible fixation, 1.72 ± 0.63 mm for metal screw fixation and 1.67 ± 0.77 mm for biointegrative screw fixation). The transected ligament diastasis was also greater than that for metal screw (1.61 ± 1.31mm) and biointegrative screws (1.69 ± 0.64 mm) with distraction ($p<0.001$). The area at the level of the ligament showed higher values for transected ligament (32.7 ± 13.08 mm2) than the three fixatives (30.75 ± 7.42 mm2 for flexible fixation, 30.75 ± 17.13 mm2 for metal screw fixation and 29.53 ± 9.15 mm2 for biointegrative screw fixation; $p<0.05$).

Conclusion: Metal screws, flexible fixation and biointegrative screws showed comparable effectiveness intra-op, in the correction of diastasis created as a consequence of Lisfranc injury.

Level of evidence: V

Keywords: Biomaterials, Bioabsorbable implant, Biointegrative implant, Tarsometatarsal joint

Introduction

Lisfranc fracture-dislocations constitute 0.2% of all body injuries.[1] They can occur following high-energy trauma leading to widely displaced injuries or low-energy trauma that can produce subtle instabilities.[2,3] Lisfranc injuries may be osseous, ligamentous or a combination of the two.[4] Most often, there is involvement of bony components that requires anatomic reduction and rigid internal fixation to prevent subsequent arch collapse and midfoot arthritis, chronic pain, and activity modification. Open reduction and internal fixation (ORIF)

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has been shown to have poorer outcomes for purely ligamentous injuries.[5] For such lesions, different fixation methods have been introduced, but choosing the best method relies on the patient's condition and the surgeon's preference.[3,6] These methods include rigid fixation using solid screws, staples, plating, and flexible fixations. However, each one of these methods has its own features and limitations.[7,8] One of the responsibilities of the surgeons is to assess the condition of the patients including the injury condition, past medical history particularly the presence of any disabling or chronic musculoskeletal diseases, and the socioeconomic characteristics in the decision-making process. The end goal is to choose the best treatment plan with the highest effectiveness and lowest rate of complication to provide a better quality of care for these patients.

Determination of the appropriate fixation method depends on its ability to achieve and maintain anatomic reduction, while not being susceptible to a high risk of complications. Metal screws provide a rigid and stable fixation and are currently the most used type of fixation. However, the need to remove them after the healing process in most cases can also bring about more complications and financial burden, which has remained a concern for the patients and the providers.[8,9] Surgeons have also suggested various removing times for these screws ranging from 8 weeks to 3 years in the literature.[2,10,11] Given the complications during the removal surgery such as breaking or being countersunk at the index surgery, early extraction can also lead to Lisfranc diastasis and the possibility of recurrent instability.[8,12] This limitation of metal screws is not associated with flexible fixation use. Flexible fixation resolves the need for removal re-operation and provides satisfactory fixation based on the previous literature.[13,14] However, this method is more costly than using metal screws, harder to use based on surgeons' opinions, and can end up with more displacement and diastasis in the Lisfranc joint compared to rigid fixation under initial load but not the cycling loads.[8,11,15] Hence, combining the solid nature and user friendliness of the metal screws with the feature of not needing to remove the implant in flexible fixations, can lead to more efficient fixation techniques that can outperform the current methods.

Biointegrative implants have received much attention as an alternative or even a replacement for the current metal implants in foot and ankle surgery given the fact that they don't need removal surgery and they can maintain the stability of the fixation until healed.[8,12,16] While there have been previous studies examining the use of bioabsorbable implants for various lower extremity conditions such as anterior cruciate ligament rupture in the knee or syndesmotic instability in the ankle in a cadaver experiment, to the best of our knowledge no study has been conducted on the biomechanical resistance and technical pros and cons of using these implants in Lisfranc instability. Previous work from our lab has also demonstrated the accuracy and reliability of using C1-M2 distance as a proxy for diagnosis and successful management of isolated Lisfranc injuries using a purely ligamentous injury model.[17]

We therefore asked: (1) If biointegrative screws were effective methods of correction of joint diastasis created in isolated Lisfranc instability and compare them to existing methods of fixation such as flexible fixation and solid screws (2) the surgeons' feedback on the experience of using biointegrative screws.

Materials and Methods

Experiment setup

The protocol of this study was approved by the institutional review board (IRB no. 2016P001295). Eight fresh-frozen cadaver specimens amputated from mid tibia (mean age at time of death: 57 years, range: 34-78) were provided and preserved at -20°C temperature. The specimens were completely thawed at room temperature for 24 hours prior to the experiments.[18] Eight fellowship trained foot and ankle surgeons performed the surgical procedures on the cadavers independently. Before the surgical procedures on each specimen baseline anterior-to-posterior (AP) and lateral radiographs were taken to enable the authors to have baseline measurements of the Lisfranc joint including the distance between the first cuneiform bone and the second metatarsal base (C1-M2) and between C1 and second cuneiform bone (C1-C2) using a previous reported method.[17] Next, in order to apply distraction force on the lisfranc joint in intact status (Listract test) an incision was made on the dorsal surface of the foot in each specimen, a K-wire was drilled and passed through C1 coming out of the plantar surface of the foot. Another K-wire was drilled into the base of M2 parallel to the first K-wire.[19] A static distraction force of 50 N was exerted in opposite directions aligned with the direction of the C1-M2 ligament [Figure. 1].[19] In order to reassure the consistency and accuracy of the pulls the 50N forces were applied using fishing wires that could tolerate >100N weight and 5kg weights were hanged from the fishing wires on both sides using two pulleys to change the direction of forces from vertical to horizontal AP and lateral radiographs under distraction force were obtained to have a baseline measurement of the C1-M2 and C1-C2 distances in the intact status of the joint in this condition [Figure1]. Thereafter, the C1-M2 ligament was dissected thoroughly from the dorsal to the plantar surface by each surgeon in each of the specimens. Although the C1-C2 ligament was not dissected in this study, we used the baseline measurement of C1-C2 to compare with that of C1-C2 after complete dissection to reassure the intactness of the C1-C2 ligament. The instability of the C1-M2 joint was confirmed by the surgeon after dissecting the ligaments. In the next step, the surgeon was asked to fix the joint using three fixation methods including flexible fixation using mini-Tightrope (Arthrex Inc., Naples, FL, USA), biointegrative 4.0 mm cannulated screws (Ossio Inc., Woburn, MA, USA), and metal 4.0 cannulated screws (Depuy Synthes, PA, USA) sequentially on a cadaver. We used the same cadaver for all the fixation methods to reduce the performance bias. After conducting each fixation method, AP and lateral radiographs were obtained with and without Listract test and the distance and the area between C1-M2 were measured by three orthopaedic clinical research fellows. To perform the measurements ImageJ software (National Institutes of

Health, MD, USA) was utilized.

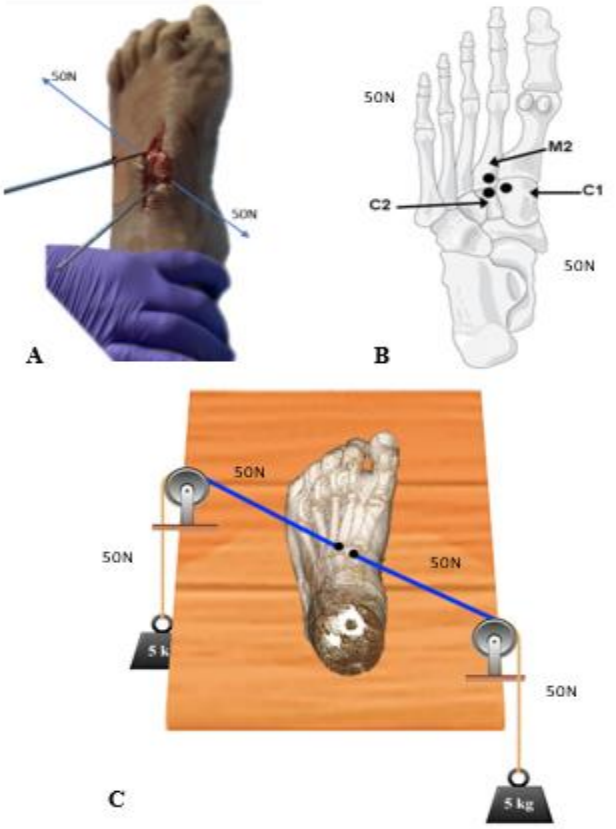

Figure 1. Listract test; a mechanical distraction test exerted in alignment with the direction of the C1-M2 ligament to assess the stability of the joint. (A) – (B) View of cadaveric foot and diagram of skeletal anatomy of foot with the force vectors representing the direction and amount of force applied across C1-M2 (C) A schematic view of the position of the foot and the pulleys positions in order to change the direction of the force from vertical to horizontal

To assess the pros and cons of each technique using expert foot and ankle surgeons' points of view, each surgeon was asked to complete a post-procedure survey and give scores on a scale of one to five for satisfaction of the technique (higher score means more satisfaction), difficulty of the technique (higher score shows more difficulty), and difficulty of removal of implant (higher score means more difficult). In addition, they were asked to suggest pros, cons, and improvement tips for improvement of each method using an open-ended question. The outcomes are provided in a descriptive manner.

Primary and Secondary Outcomes

The C1-M2 distance and area measurements taken for the four conditions were the primary outcomes of interest. The objective and subjective feedback collected from the surgeons post each experiment served as the secondary variables of interest.

Statistical Analysis

The measurements were presented as the median and interquartile range (IQR). Wilcoxon Signed-rank test was used to compare the C1-M2 distance and area measured after the three fixation methods with the intact ligament (stable) and dissected C1-M2 ligament (unstable) conditions. The measurements of C1-M2 with and without Listract test were also compared using paired t-test in each stage on the images. Statistical analysis was performed using SSPS for Windows (version 26.0, Armonk, NY, USA). Significance was set at p-value < 0.05.

To evaluate inter-observer reliability three observers independently performed all measurements in three randomly selected specimens. Inter-observer reliability was assessed using the intraclass correlation coefficient (ICC). Interpretation of the ICC values was calculated according to the guidelines proposed by Shrout as follows: 0.00–0.10, virtually none; 0.11–0.40, slight; 0.41–0.60, fair; 0.61–0.80, moderate; 0.81–1.00, substantial.

Results

The mean age of cadavers (at time of death) was 57 years (range: 34 - 78 years) and there were 4 males (67%) and 2 females (33%).

As seen in Table 1, the difference between the recorded diastasis for transected ligament and all three interventions was significant without Listract test [Table 1]. This significance was preserved for metal screw fixation and biointegrative screws intervention once the Listract test was applied, implying considerable effectiveness of these interventions, even under distraction. The Lisfranc joint area measurements of all three fixation methods were found to be significantly lower than the transected values, with and without Listract test, suggesting successful correction of instability in neutral and weight-bearing conditions.

Table 1. The measurement of the C1-M2 in intact Lisfranc joint, dissected C1-M2 ligament, and fixed with flexible fixation (Mini-tightrope), biointegrative cannulated screws, and metal cannulated screws

C1-M2 DISTANCE MEASUREMENTS *Median (IQR), mm*									
Listract Test	Intact	Dissected		Flexible Fixation		Metal Screw		Biointegrative Screw	
	Measured	Measured	P value#	Measured	P value#	Measured	P value#	Measured	P value#

Table 1. Continued

Absent	1.61 ± 0.27	2.47 ± 0.51	<0.001	2.02 ± 0.5	0.009	1.72 ± 0.63	<0.0001	1.67 ± 0.77	<0.0001
Present	1.82 ± 0.57	2.75 ± 0.52	<0.001	2.82 ± 0.63	0.3	1.61 ± 1.31	0.0002	1.69 ± 0.64	<0.0001
P value†	<0.001	<0.001		<0.001		0.04		0.03	
C1-M2 AREA MEASUREMENTS *Median (IQR), mm²*									
Listract Test	Intact	Dissected		Flexible Fixation		Metal Screw		Biointegrative Screw	
	Measured	Measured	P value#	Measured	P value#	Measured	P value#	Measured	P value#
Absent	26.8 ± 6.21	32.7 ± 13.08	0.009	30.75 ± 7.42	0.03	30.75 ± 17.13	0.014	29.53 ± 9.15	0.005
Present	31.3 ± 11.06	41.8 ± 14.32	0.07	29.9 ± 6.8	<0.0001	31.13 ± 9.75	0.005	31.8 ± 19.19	0.003
P value†	<0.001	0.002		0.86		0.002		0.08	

† Wilcoxon Signed-rank test was used for comparison between the Listract test present and absent measurements.
# Wilcoxon Signed-rank test was used to compare the measured value of dissected condition and the measurement in the three fixation conditions.
P<0.05 considered statistically significant.

It was noted that the difference in diastasis with and without Listract was significant at baseline values of intact and transected ligament as well as on application of all three fixation methods. On assessment of the area measurements, this significance was lost for the flexible fixation and metal screw fixation methods, signaling possibly to a greater strength of fixation with these interventions [Table 1].

The inter-observer reliability for the C1M2 distance and area measurements was moderate (ICC=0.636, 95% CI=0.528-0.732; ICC=0.796, 95% CI=0.724-0.855 respectively).

Regarding the scores and feedback provided by the surgeons on the three different fixation methods, the median (IQR) satisfaction rates with the use of the implants given to the flexible fixation, the biointegrative screws, and metal screws were 2.75 (2-4), 4 (3-5), 4 (3.5-4.5), respectively. The median rates for the difficulty of the procedure using flexible fixation, the biointegrative screws, and metal screws were 3 (2-4), 1 (1-2.25), and 2 (1.75-2), respectively. The median scores for the difficulty of removal of the implants for flexible fixation, the biointegrative screws, and metal screws were 2 (1.5-2.5), 2 (1.5-2.5), and 2 (2-2), respectively. None of the scores showed significant difference when comparing the three fixation methods. The following comments were made by the surgeons after they were asked to provide their feedback on the pros and cons of using biointegrative fixation method (if a point was repeated, we did not re-mention it):

"Given the similar performance with biointegrative screws and the ability to avoid removal operation give them superiority over the current methods"
"We need to have a properly outlined technique which avoids potentially increased risk of stripping the material during insertion or removal"
"Con: The lack of assessment using the fluoroscopy because they do not have any radiopaque marker. Pro: easy to use, similar technique to metal screws, and avoids a second procedure for removal"
"Allows for MRI in the future; however, hard to remove the hardware if buried in the tissue"
"Difficult to assess the outcome of operation and maybe difficult to remove after a while"
"Easier to use compared to flexible fixation (Mini-Tightrope)"
"Adding radio opaque markers to the biointegrative screw can be an added value for further assessment. Moreover, providing screws in varied sizes and thread options can help a lot"
"The screw can bend during the procedure and hard to remove due to radiolucency"

Discussion

This study showed that the biointegrative screws could perform as effectively as metal screws and partly better than the flexible fixation for Lisfranc instability according to the outcome of radiographic measurements and surgeons' opinions in the intraoperative period. The measurements performed on radiographs of the C1-M2 showed that biointegrative screw fixation can stabilize the joint and reduce the diastasis similar to the performance of the currently used methods including metal screws and flexible fixation using metallic buttons. Moreover, surgeons' opinions on the difficulty of the technique, difficulty of removal, and satisfaction rate using biointegrative screws were relatively similar to the metal screws as the gold standard treatment and superior to the flexible fixation. However, our expert foot and ankle surgeons proposed a number of opinions toward improving the performance of biointegrative screws in this study as mentioned in the result section.

Several studies have advocated for using biointegrative implants in foot and ankle pathologies. Thordarson et al. have used polylactic acid (PLA)-based 3.5 mm and 4.5 mm fully threaded cortical absorbable screws for fixation of Lisfranc instability in fourteen patients. They reported mild to moderate pain in the majority of the patients in follow up visits with no sever pain among all. Moreover, no soft tissue reaction, no long-standing infection, no evidence of osteolysis, loss of reduction, or significant arthrosis was seen in follow up radiographs. They observed asymptomatic palpable screw head along the mid-medial border of one patient's foot after 2 years.11 Ahmad et al., in a randomized trial, compared twenty patients treated with bioabsorbable screws with twenty who were treated with metal screws.8 They reported no significant difference regarding pain and function of the patients based on 10-point visual analog scale (VAS) of pain and Foot and Ankle Ability Measures (FAAM) in short-term follow ups (up to 1 year). Saxena et al., in a study on fifteen athletes used PLA screws for fixation of Lisfranc instability. The average follow-up times of the patients was 36±18 months (range:12–62 months). Patients were evaluated with weight-bearing foot radiographs and American Orthopedic Foot and Ankle Society's (AOFAS) midfoot scoring system questionnaires.15 The preoperative and postoperative AOFAS scores were 35.4±25.0 and 92.7±7.7, respectively (p<.001). The average time to return to regular activities including sports and normal shoe wear was 4.2 months. They had to convert the implant to a metal screw in one patient due to the unsatisfactory reduction of the PLA screw in the operation room. Given the previous reports and the remained gaps concerning the application of biointegrative implants for Lisfranc fixation, in the present study using a novel biointegrative screws for Lisfranc fixation, we showed that these implants could effectively reduce the Lisfranc joint and tolerate the joint tension that the patient might undergo during daily routine activities. The performance of biointegrative screws was similar to that of the metal screws in reducing the Lisfranc instability based on our radiographic findings.

In the past, bioabsorbable screws (whether for syndesmosis, fusions, etc.) have been problematic because of technical issues (limited lengths, need to cut screws, need to tap, etc.).20,21 Thus, we wanted to have our foot and ankle surgeons give feedback on their experience using the biointegrative screws and the current standards of care, focusing on a comparison between the two. To this effect, we gathered expert surgeons' opinions on the pros and cons of the biointegrative screws that could further enlighten implant developers on the needs and concerns of clinicians for this fixation method. Lack of visibility of the screws on radiographs was a commonly observed limitation, in addition to the increased risk of stripping of screw material during retrieval which in turn made removing the screw a challenging process. Addition of radiotracer loop around the head of the screw or radiopaque markers at the tip and ensuring availability of an ideal range of screw sizes were few of the suggestions made by our expert surgeons.

There have been various reports on the shortcomings of the current Lisfranc open reduction and internal fixation (ORIF) methods. Reviewing the recent literature, Jin et al., compared K-wire (on 29 cases), metal screws (on 31 cases), and steel plate (on 32 cases) for ORIF.22 Their outcomes showed a significantly better joint recovery, pain VAS score after one month, post-treatment axial displacement, and total incidence of complications in the screw and steel plate groups compared to the K-wire treated group. Regarding the time to remove the metalwork, there are controversies among clinicians and there is no definite consensus for the time of removal. Moreover, a recent systematic review by Rhodes et al., concluded that there is lack of studies comparing the outcomes and complications of various plans for hardware removal in Lisfranc injuries.23 Cho et al., in a clinical study comparing the flexible fixation (suture button; 31 patients) with metal screws (32 patients), assessed the clinical and radiologic outcomes pre-operatively, at 6 months and one year postoperatively, and the last follow-up visit. Plantar foot pressure at 6 months and postoperative complications were also evaluated. While the AOFAS score and VAS score for pain were significantly lower in short-term follow-up in the flexible fixation group, in 1-year follow-up session, the differences were not noticeable between the two treatments. Before the removal of the metal screws, plantar pressure was increased at the great toe and first metatarsal head. Of notice, two patients with flexible fixation had recurrent instability compared to one case in the screw group. Overall, the outcomes of both methods in their study in long term were similar.7 Compared to metal screws, flexible fixation seems to be less costly and to resolve the need for re-operation for hardware removal; however, the odds for re-dislocation, re-instability, and thus, re-operation seem to be higher.24–26 Existing literature gives a divided view of the usefulness of flexible fixation, solid screws, and other methods of ORIF in Lisfranc injuries. This necessitates the need for future clinical studies comparing the short- and long-term outcomes of these methods that include not only the clinical findings but also patient-reported outcomes, patients' socioeconomic factors, knowledge, attitude, and

skills of the surgeons.

This study had several limitations to be mentioned. First, our biomechanical evaluation was not comprehensive and did not assess the mechanical properties of the implants in various ways including torque and force in different directions. While our method of distraction (Listract test) was effective in cadaver testing, it is previously untested and not validated to accurately detect differences between two correction methods used and may not replicate all the forces seen across the tarsometatarsal joint in vivo. Moreover, all the procedures by each surgeon were conducted on one specimen that could affect and bias the outcomes. A solution to that would be having paired specimens or specimens with similar weight, age, bone condition, and characteristics which was hard to achieve at this point. To reduce this bias, we planned to perform the flexible fixation first as we believe it would affect the structure of the bones to a lower extent compared to biointegrative screw and then metal screw. Lastly, all measurements were conducted only one time intraoperatively at the time of using the fixation methods (i.e time zero) and we lack long-term data for these comparisons. This limits the translation of our results to clinical scenarios where patients are often followed-up and the quality of repair thus tested over time.

Conclusion

Biointegrative screws, due to no need for hardware removal, few complication and adverse effects, and satisfactory performance for reduction and fixation of the Lisfranc joint, were shown to be a promising treatment as an alternative or replacement for the current techniques including metal screws and flexible fixation in a simplified biomechanical model. Accessibility, providing an imaging technique to enable the surgeon to assess the position of the screw and follow up, and also increasing the variety in the threads and length, can improve the quality and performance of these implants. Moreover, future clinical studies should focus on the short- and long-term evaluation of these patients regarding the outcomes of the method and possible complications.

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