Clinical Application of PLGA Resorbable Screw Fixation in Forefoot Surgery

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Bioresorbable fixation has been utilized for over 25 years in the fixation of osteotomies in the foot and ankle. One of the most common indications today for the use of bioresorbable fixation is for first ray surgery. Multiple studies have shown the effectiveness of resorbable fixation in bunion surgery including Hirvensalo, et al in 1988 who described the use of Poly-glycolic Acid (PGA) pins in Chevron osteotomies (1,2) and Brunetti et al in 1991 where he described the use of Poly-Paradiaxone (PDS) pins for the same osteotomies (3). The trouble that developed with pure PGA or PDS fixation was that swift resorption of the polymer and dyes led to complications that included inflammatory reactions as well as osteolysis. These events were most common in the pure PGA implants (4-10).

The development of pure Poly-Lactic Acid (PLLA) fixation including pins and screws showed greater promise with a number of studies showing minimal osteolysis and foreign body reactions (11-12). The dilemma with the pure PLLA implants is the very long absorption time of up to 5 years (12,14, 15).

Newer implants combining Poly-Lactic Acid and Poly-Glycolic Acid known as PLGA implants, have great promise for offering strength equal to the pure PLLA fixation but with a quicker resorption time that is controlled over a period of 18 months while still having a minimal incidence of inflammatory reactions (16-27).

The RFS Screw which is a mixture of 85% Poly-Lactic Acid and 15% Poly-Glycolic Acid gives a high mechanical and shear strength (Figure one), as well as stiffness, while delivering reliable resorption characteristics. In addition, the screw offers a torque limiting AO compatible insertion driver for ease of insertion, and once the driver is removed a low profile screw head is exposed. This low profile head provides for minimal soft tissue prominence (Figure two).

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Financial Disclosure: This Clinical Case Study is Sponsored by Tornier
Figure One

![In Vitro Comparison of Shear Strength](image)

Figure Two (A&B)

Photograph of AO Compatible Driver and RFS Screw (A) Depicts the AO compatible inserter, and (B) Depicts the low profile head of the RFS screw

Case Study

A 40 year old health care worker with a long standing bunion deformity failing conservative care for many years, elected for a bunionectomy. After careful consideration and even a search of the literature the patient decided on resorbable fixation as her fixation of choice for the procedure.

The patient underwent a long arm chevron bunionectomy with a hallux osteotomy. The patient spent two weeks in a splint and then transitioned to a cam-walker and returned to work at the hospital weightbearing in the cam walker. After six weeks she went into tennis shoes, then returned to full activity shortly after and returned to her exercise regimen by week 12. The patient had no incidence of any type of inflammatory soft tissue reaction, nor was there any osteolysis seen on x-ray on long term follow up(Figure Three-Seven)
Figure Three (A&B)

Intraoperative photograph of Long Arm Chevron Osteotomy (A) and (B). Depict a Long Arm Chevron after moving the capital fragment for correction and temporary fixation with a kirschner wire.

Figure Four (A&B)

Intra-Operative photographs of insertion of PLGA RFS screw (A) and (B) This photo depicts compatible hexagonal torque limiting head for ease of screw insertion. The removable metallic head is then detached when satisfactory screw purchase is achieved and be replaced back on PLGA screw for further screw tightening as needed by surgeon.
Figure Five (A&B)

Intra-Operative photographs of PLGA screws after insertion. (A) and (B) depicts the resorbable screw with firm purchase in the underlying long arm chevron, with very low profile head for minimal soft tissue prominence.

Figure Six (A&B)

Intra-Operative photographs of PLGA screws after insertion. (A) and (B) depicts the resorbable screw with firm purchase in the underlying phalanx osteotomy which was also performed again note very low profile head for minimal soft tissue prominence.
Figure Seven (A-C)

X-Rays Pre-Operative and Post-Operative (A) depicts x-rays of patient prior to bunionectomy with double osteotomy (B) depicts long term post-operative x-ray after bunionectomy with long arm chevron and hallux osteotomy, note good bone healing and lack of osteolysis around screws

Conclusion
Resorbable screws are an excellent option for fixation in bunion surgery. Although there are many absorbable materials available for implantation, a combination of Poly-Lactic Acid and Poly-Glycolic Acid may be the best option combining strength and controlled resorption. A long term IRB approved prospective study looking at the RFS screw in bunion surgery is currently underway to help further elucidate the safety of this implant.
References


References

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