Dental occlusion ties: A rapid, safe, and non-invasive maxillo-mandibular fixation technology

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ABSTRACT

Maxillo-mandibular fixation (MMF) establishes dental occlusion to treat mandible fractures. Current treatment risks sharps injury, consumes operating room time, and inflicts gingival trauma. There is a need for an efficient, safe, and non-invasive MMF solution.

An iterative prototyping process was used to invent dental occlusion ties to meet this need. Rapid prototyping, cadaver testing, and engineering design resulted in devices worthy of clinical feasibility testing.

In the first clinical application of these devices, they secured MMF successfully in management of unilateral and bilateral mandible fractures as well as displaced maxilla fractures.

This feasibility study establishes proof of concept for establishing intra-operative MMF using dental occlusion ties.

Dental occlusion ties offer a non-invasive solution featuring operating room time efficiency, minimized sharps risk, and less bony and soft tissue trauma than current commercialized solutions.

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Disclosure:
Dental occlusion ties were invented in the University of Minnesota's Senior Innovation Fellowship in Medical Devices.

Alan W. Johnson is the lead inventor of the technology which has been licensed to a medical device company for commercial development.

INTRODUCTION

Maxillo-mandibular fixation (MMF) establishes dental occlusion to treat mandible and maxilla fractures. For decades, Erich arch bars have been the standard to establish MMF. While reliable, the approach risks sharps injury, consumes operating room time, and inflicts gingival trauma. Newer technologies including screw-based techniques and "hybrid" techniques have improved MMF by reducing sharps injuries and operating room time, but risk injury to tooth roots, nerves, and gingiva.

The need remains for an efficient, safe, and non-invasive MMF solution.

METHODS

Dental occlusion ties were invented at the University of Minnesota's Medical Device Center through an iterative prototyping process. (*figure 1*). Development included 3D printed models, cadaver prototype testing, human apical embrasure dimensioning, and ultimately non-significant risk human clinical trial testing (*figure 2*). Institutional review board approval was obtained at Altru Health System for a feasibility clinical trial. The devices were applied to mandible and maxilla fracture candidates with fractures amenable to intra-operative MMF and open reduction with internal fixation. The ties were removed prior to extubation. Pre-teens, comminuted fracture patients, and patients requiring post-operative MMF were excluded.

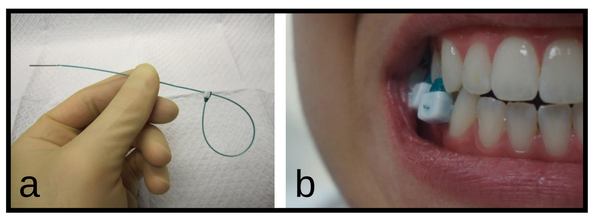

Figure 1. a) An individual dental occlusion tie. b) Two example dental occlusion ties applied in establishing maxillo-mandibular fixation.

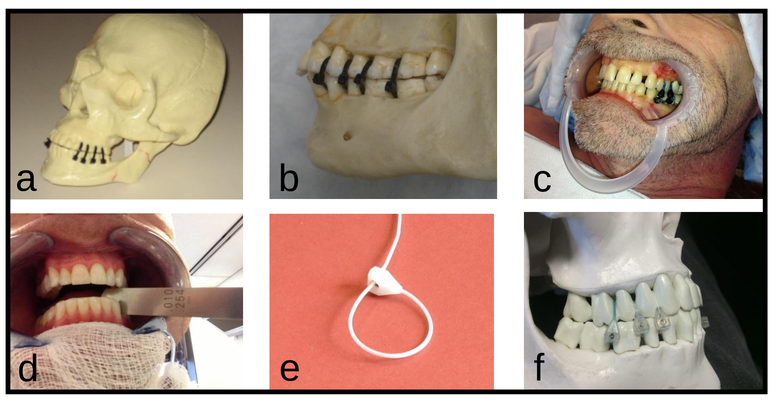

Figure 2. Development process. a) Model prototype. b & c) Cadaver prototype applications. d) Human embrasure sizing. e) Early device design. f) Manufactured prototypes applied to dental occlusion model.

RESULTS

Fully-optimized and manufactured prototypes achieved MMF successfully in management of unilateral and bilateral mandible fractures as well as displaced maxilla fractures. To date, four patients have been treated in this early feasibility trial. Two candidates were excluded due to comminuted fracture patterns. All four patients reported correction of pre-operative malocclusion. Application times were 12-15 minutes for a single surgeon to achieve MMF. Patients incurred negligible gingival trauma from the technology as the ties require no screw or wire penetration for application. One patient incurred a chipped tooth a week after surgery; it is uncertain if this was related to his treatment or injury. One experienced a transient marginal mandibular branch weakness, believed to be a traction injury from a retro-mandibular approach. Six-month follow-up revealed durable results and no new concerns. An example of one patient's care is detailed in *figure 3*.

DISCUSSION

This feasibility study of dental occlusion ties establishes clinical proof of concept for intra-operative MMF. Future larger studies are planned in level 1 trauma centers. The devices are undergoing FDA clearance testing currently. Future studies and testing will include multi-week applications for fracture management with and without use of internal fixation. The ease of application of these devices promises faster intra-operative management. Future studies may establish that these minimally-invasive devices can enable clinic-based, non-operative management of non-displaced or minimally-displaced mandible fractures.

CONCLUSIONS

Dental occlusion ties offer a non-invasive solution featuring operating room time efficiency, minimized sharps risk, and less bony and soft tissue trauma than current commercialized solutions.

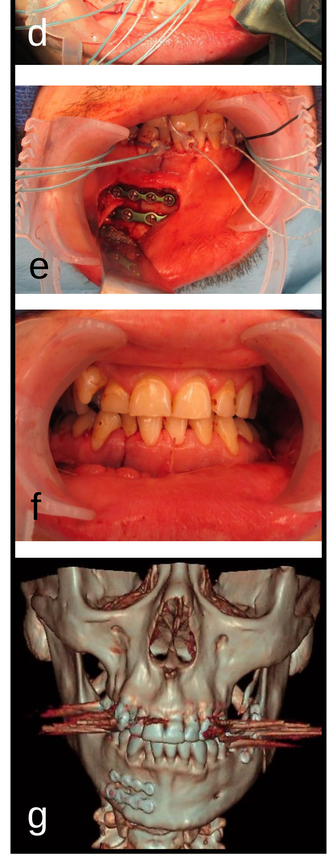

Figure 3. Treatment of bilateral mandible fractures with dental occlusion ties and internal fixation.
a) Pre-operative CT.
b) Pre-operative image.
c) Intra-operative MMF and reduction.
d & e) Plating.
f) Post-operative occlusion.
g) Post-operative CT.

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