Laryngoscope Investigative Otolaryngology

Dental Occlusion Ties: A Rapid, Safe, and Non-Invasive Maxillo-Mandibular Fixation Technology

Alan W. Johnson, MD, MS

Objectives: For decades, Erich arch bars have been a standard in establishing maxillo-mandibular fixation (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. This study aims to establish the application, strengths, and limitations of dental occlusion ties as a novel alternative in maxillo-mandibular fixation.

Study Design: Prospective, non-blinded, human feasibility clinical trial.

Materials and Methods: An iterative prototyping process was used to invent dental occlusion ties (brand name: Minne Ties). Development included 3D printing, cadaver prototype testing, human apical embrasure measurement, and ultimately non-significant risk human clinical trial testing. In the IRB-approved feasibility clinical trial, the devices were applied to mandible and maxilla fracture candidates with fractures amenable to intra-operative MMF with 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.

Results: Manufactured, sterile prototypes secured MMF successfully in management of unilateral and bilateral mandible and maxilla fractures. All patients reported correction of pre-operative malocclusion. Application times were typically 12–15 minutes for a single surgeon to achieve MMF. Patients incurred negligible gingival trauma from the technology as the ties require no tissue penetration for application.

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

Key Words: mandible, maxilla, maxillary fractures, dental occlusion, fracture fixation, internal, Minne Ties, mandible fracture, maxillomandibular fixation.

Level of Evidence: Therapeutic, IV

INTRODUCTION

Maxillo-mandibular fixation (MMF) establishes dental occlusion to treat mandible and maxilla fractures. While MMF is necessary for other cares, such as orthognathic surgery, MMF is most commonly employed for treating mandible fractures. For the last century, wire-based techniques such as Ivy loops and Erich arch bars have remained a standard of care.[1] In 1943 John B. Erich co-authored *Traumatic Injuries of Facial Bones (An Atlas of Treatment)*. His use and description of arch bars were popularized worldwide. In coming decades, Erich arch bars became the leading option to establish MMF.[2] While reliable and versatile, Erich arch bar technique has many limitations: the approach risks "wire stick" sharps injuries,[3,4] consumes valuable operating room time,[5,6] inflicts extra gingival trauma to the patient, limits dental hygiene,[7] and constrains nutritional options if worn for weeks of treatment.[8] Newer techniques including screw-based techniques[9–11] and "hybrid" techniques[12–14] have improved MMF by reducing sharps injuries and operating room time, but risk injury to tooth roots, nerves, and gingiva.[7,15]

The need remains for an efficient, safe, and non-invasive MMF solution. This feasibility clinical trial aims to define the clinical application, strengths, and limitations of one novel option: dental occlusion ties.

MATERIALS AND METHODS

Study Design

Dental occlusion ties (future brand name: *Minne Ties*; Summit Medical, Inc., St. Paul, MN) were studied in a prospective, non-controlled feasibility trial. One study objective was to obtain initial clinical data to confirm the design and operating specifications of this new technology. Additionally, the trial was

From the Altru Health System, Grand Forks, North Dakota; and Department of Surgery, University of North Dakota School of Medicine & Health Sciences, Grand Forks, North Dakota.

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Financial Disclosure/Conflict of Interest Statement:
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. He has not received any financial benefit from the company producing the devices, but he is entitled to a percentage share of royalties per the University of Minnesota's Regent's policy.

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Send correspondence to Alan W. Johnson, Altru Professional Center, Department of Otolaryngology–Head & Neck Surgery, 4440 S. Washington St., Grand Forks, ND 58201. E-mail: alanwellingtonjohnson@gmail.com

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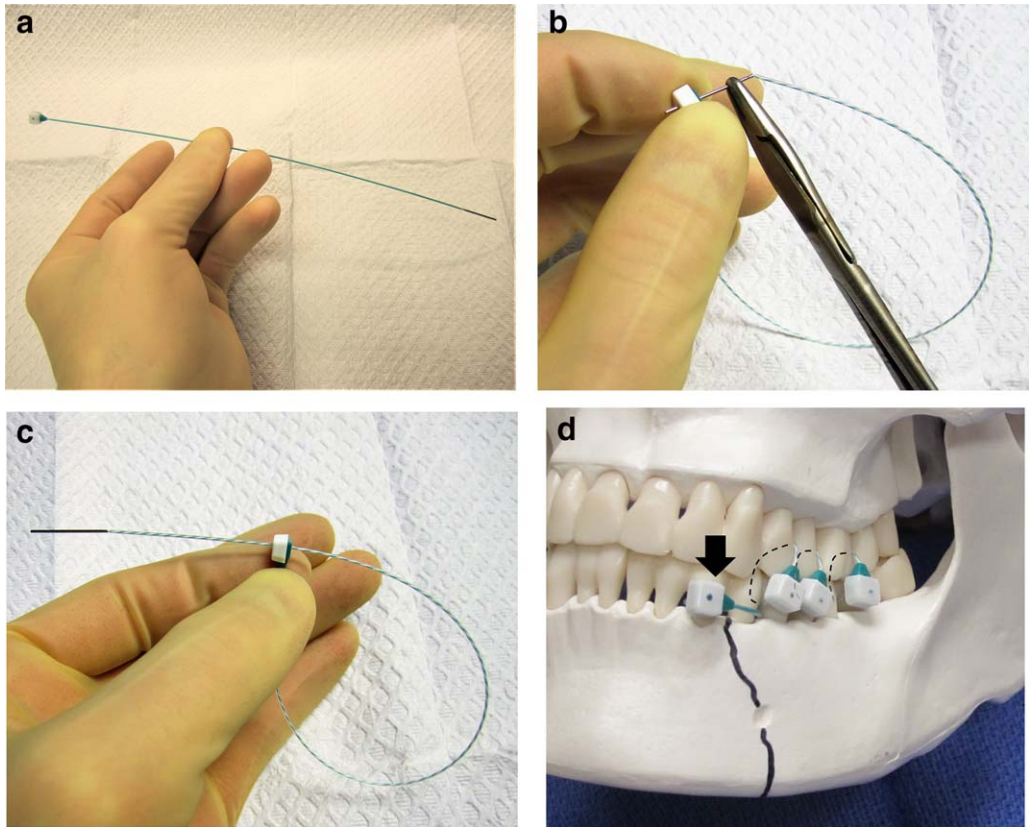

Fig. 1. Dental occlusion ties: model application. a) Individual dental occlusion tie; b) Dental occlusion tie with blunt needle entering clasp; c) Dental occlusion tie ("looped" outside the mouth/dentition for visualization purposes) ready to be tightened; and d) Four dental occlusion ties applied to model dentition–one (arrow) applied as a "bridle wire" to two teeth straddling the fracture (black line), 3 establishing occlusion/maxillo-mandibular fixation.

designed to establish the clinical application, strengths, and limitations of this novel technology. The enrollment (from August 2015 to October 2016) was intentionally small, with an anticipated enrollment of 5 to 10 patients. The study population included those presenting to a rural level II trauma hospital serving eastern North Dakota and northern Minnesota.

Data Collection

Objective data including: 1) patient age, 2) sex, 3) fracture types, 4) operating room times, 5) dental occlusion ties application times, 6) number of ties used per patient, and 7) device "failures" were recorded on an intra-operative data collection form. "Failure data" included mechanical failures of the devices and anatomic failures in which the devices did not engage the dentition in the intended fashion. As an early clinical trial/feasibility study, this device failure data was shared with the sponsoring company, allowing for minor design changes to the devices. Importantly, the company remained blinded from all other trial data. Additional follow-up data was collected on a patient data collection form and a post-treatment data collection form. These forms requested subjective, narrative data from the patients and surgeon with the intent of aiding in future clinical studies design. Standard clinical data such as clinical histories, CT scans, and post-operative exams were collected. Data was de-identified with patient-specific letter codes (i.e., patient A) and stored in a secure fashion in compliance with HIPAA. Pictures of the patients' dentition were obtained during clinic visits and in the operating room. All pictures included a minimal view of the patient's face for confidentiality and all patients consented to this level of photography prior to any involvement in the study.

Technology Development

Dental occlusion ties were invented at the University of Minnesota's Medical Device Center through an iterative prototyping process. Development included 3D printed models, cadaver prototype testing, human apical embrasure measurements, and ultimately non-significant risk human clinical trial testing. Prior experiments including the use of prototype devices applied to plastic jaw models, cadaver skulls, fresh cadavers including oral soft tissues (gums) were completed in anticipation of this study. The technology was described in an invention disclosure at the University of Minnesota and a patent application was filed. The technology was subsequently commercially licensed to Summit Medical, Inc., St. Paul, MN. The devices were further developed, manufactured, and packaged in sterile kits for study. An example device and example application is displayed in Figure 1. Institutional review board (IRB) approval was obtained at Altru Health System (Grand Forks, ND) for a non-significant risk[16] feasibility clinical trial of the devices.

Patient Selection

Patients sustaining fractures of the upper (maxilla) and/or lower (mandible) jaw were considered for the minimally invasive technology evaluated in this study. Patients were offered standard care including arch bars applied with wires or the polymer-based "zip tie"-like dental occlusion ties to be studied.

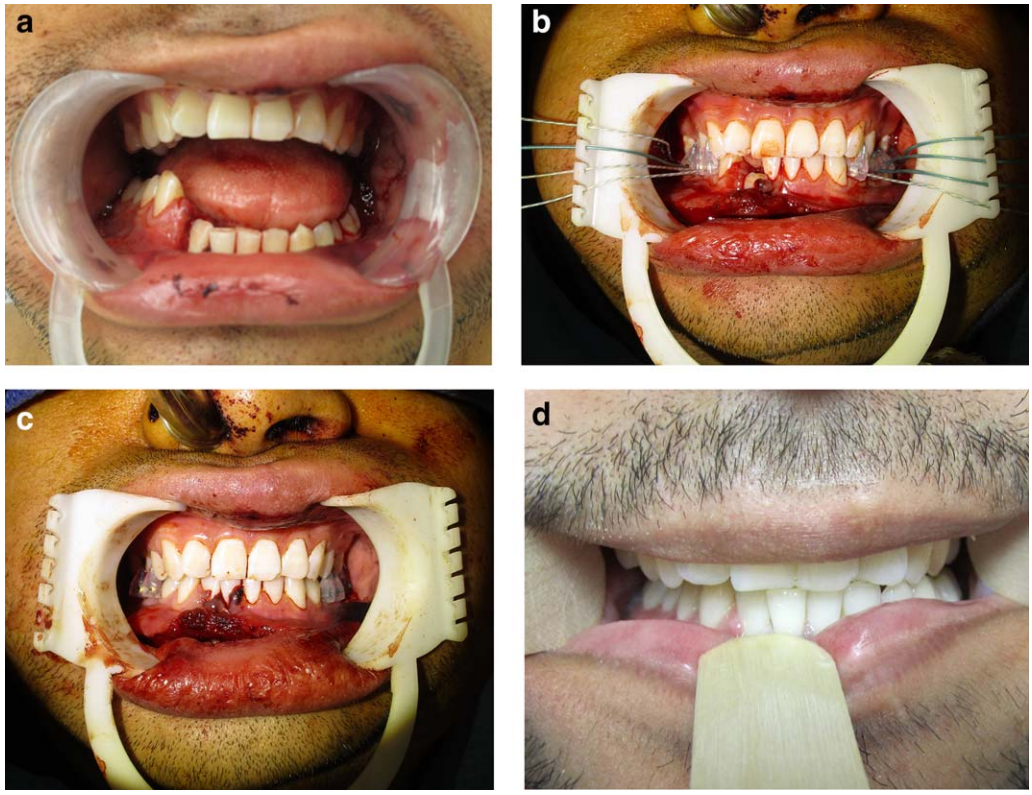

Fig. 2. Dental occlusion ties: trauma patient application. a) Example mandible fracture (patient E); b) Dental occlusion ties applied with organizing cheek retractor; c) Dental occlusion ties cut flush at the clasp for improved oral access; d) Post-operative dental occlusion result/appearance.

Written consent with an explanation of arch bar technique versus this experimental approach was obtained from each patient. As mandible and maxilla fractures are treated under general anesthesia in the operating room, the devices were applied to the patient's dentition while under general anesthetic. The devices established and maintained anatomic dental occlusion, achieving a similar function to arch bars. This allowed the surgeon to treat the fractures with standard internal fixation techniques. The experimental devices were used solely as an alternative to wire-based arch bar techniques to achieve an immobile, stable jaw. Accordingly, if for any reason the forces needed for fracture stabilization were deemed inadequate with the experimental devices, standard steel wire techniques such as arch bars or interdental wires[6] were to be employed.

Inclusion/Exclusion Criteria

The devices were applied to mandible and maxilla fracture candidates with fractures amenable to open reduction with internal fixation and MMF, applied solely intra-operatively; the ties were removed prior to extubation. Patients with inadequate dentition including edentulous patients, patients with minimal or overly mobile dentition, and patients with concomitant mandibular and maxillary fractures were excluded. Pre-teens, comminuted fracture patients, and patients requiring post-operative MMF were also excluded.

Device Application Technique

Dental occlusion ties are thin, smooth, "zip tie"-like devices that are handled similar to a straight needle suture (see Fig. 1b). The needle segment of the device is swedged to a polymer-based "suture segment" that ends with a secure clasp. Using a needle driver, a surgeon drives the blunt needle segment through the apical embrasure between two adjacent teeth, similar to how embrasure wires are applied. Like embrasure wires, dental occlusion ties can be selected for the ideal diameter to harness the contact point between teeth. Manufactured dental tie diameters of 0.5, 0.7, and 1.0 mm are comparable to wire gauges of 24, 21, and 18, respectively. Typically, the largest tie permitted through the apical embrasures is chosen to maximize the stability of the tie in the embrasure.

Ties can be applied in a horizontal fashion around 2 adjacent teeth straddling a fracture in the mandible; this is a similar approach to applying a "bridle wire" for fracture reduction (see Fig. 1d). If a tooth is unstable due to its fracture proximity, a bridle wire tie can be applied to an embrasure further from the fracture.

To achieve maxillo-mandibular fixation, a balanced series of ties are applied to both sides of the maxilla and mandible, starting with the posterior dentition and progressing anteriorly. Commonly, 3 to 4 ties can be applied per side. An example application is depicted in Figure 2. To achieve maxillo-mandibular fixation as in Figure 2, a secure loop is created by first passing through an embrasure in the maxilla in the buccal-to-lingual direction, followed by passing through a corresponding mandibular embrasure in the lingual-to-buccal direction (as depicted in Fig. 1d with dashed lines). The blunt-tipped needle segment is passed through the clasp (see Fig. 1b) and the loop is left open until all the intended tie loops have been introduced. The resting loops can be secured by holding them with a specialized cheek retractor, included in the set. The

TABLE I.
Post-Operative Results Summary

Patient	Age (yrs)	Fracture Mechanism	Fracture pattern/location	Plating employed	Application time	# ties used	Device "failures"	Patient comments
A	26	Boat accident	Right body, left parasymphyseal	2 mini plates at each fracture	40 minutes*	10	2 ties "flossed out"; one needle broke at swedge	"I am very happy with my teeth."
B	26	Horse kick	LeFort I and II maxilla fractures	3 L-shaped plates on buttresses	12 minutes	6	None	"No problems occurred after use of the ties."
C	45	Assault/ punch	Left subcondylar, unstable	1 mini plate, retromandibular	13 minutes	6	One needle broke at swedge	(Omitted)
D	29	Assault/ punch	Right parasymphyseal, left angle	1 angle plate, 2 plates at parasymphyseal	15 minutes	8	One needle broke at swedge	"Painful first couple of months."
E	25	Punch/ boxing	Right parasymphyseal, left angle	1 angle plate, 2 plates at parasymphyseal	12 minutes	8	1 tie "flossed out", 2 clasps were loose	"Recovered quickly; didn't have any problems."
G**	28	Pathologic	Parasymphyseal	1 reconstruction plate	12 minutes	5	3 needles broke at the swedge	"I feel like I have a regular jaw."

*Application extended to 40 minutes for patient A due to time needed to discard comminuted bone fragments that were preventing acceptable reduction.

**Patient F was initially considered a candidate but later was excluded for inadequate dentition.

mandible and maxilla are then placed in contact with care taken to re-establish pre-morbid dental occlusion. Note that the devices should typically be applied to matching embrasures in the maxilla and mandible to create a net force vector reinforcing anatomic occlusion. Attention to the patient's pre-morbid occlusion (type I, II, or III) is necessary at this juncture to ensure that dental cusps and grooves are in pre-morbid orientation. The ties are then tightened, similar to a commercial zip tie/cable tie. Note that the dental occlusion ties can be organized in the specialized cheek retractor throughout this process (see specialized cheek retractor in Fig. 2b in contrast to standard cheek retractor in Fig. 2a). Final tightening of the ties can be achieved with the help of a pickle fork to stabilize the clasp while pulling on the suture segment. The suture segments can be cut flush to the clasp (see Fig.1d and 2c) with an iris scissors or a scalpel, providing ample access to the fractures and incisions.

RESULTS

Prototype dental occlusion ties (manufactured and sterile) were applied successfully in intra-operative management of unilateral and bilateral mandible fractures as well as displaced maxilla fractures. From August 2015 to October 2016, 14 patients presented with mandible fractures. Six patients, all male, met inclusion criteria with fractures amenable to intra-operative MMF with no need for post-operative MMF. Eight candidates were excluded: 3 due to comminuted fracture patterns (>2 fractures); 4 due to non-displaced, favorable fractures managed solely with soft diet modification, and 1 for insufficient dentition (3 total maxillary teeth). All 6 enrolled patients reported correction of dental malocclusion with return to their pre-morbid occlusion. Application times were commonly 12–15 minutes for a single surgeon to achieve MMF. Patients incurred negligible gingival trauma from the dental occlusion ties as the ties slide smoothly through the apical embrasures between teeth. (This contrasts with screws and wires which commonly penetrate gingiva.) Post-operative follow-up, (typically 6 weeks duration) revealed durable results and no new concerns. All 6 patients treated with intra-operative dental occlusion ties achieved full recovery with subjective confirmation of normal/pre-morbid occlusion. Post-operative CT scans confirmed reduction of fractures and appropriate internal fixation. None of the six needed revision surgery for dental occlusion concerns. One patient needed extraction of a titanium plate placed to treat a mandibular angle fracture after a screw loosened 8 months post-op. One patient reported a chipped tooth 10 weeks after surgery, unlikely to be related to occlusion as he had reported normal occlusion after surgery. One patient reported temporary marginal mandibular nerve weakness that corrected before 6-month follow up, believed to be a retraction injury from the retromandibular approach to plating his displaced subcondylar fracture. None of these post-operative management issues were believed to be related to the use of dental occlusion ties. Regarding the intended use of the devices, the devices provided the intended forces on the teeth the majority of the time. The two most common modes of failure were: 1) a device "flossing out" (defined as applying a device to an intended embrasure with the device pulling through the dental contact point upon tightening) and 2) a device needle component detaching from the body of the dental occlusion tie. An example of one patient's care is detailed in Figure 2. Patient data including fracture types, plating techniques, application times, device failures, and patient comments are shown in Table I.

DISCUSSION

Dental occlusion ties were successful in establishing intra-operative occlusion for open reduction with internal fixation. They add to a growing number of approaches to achieve MMF and feature a number of clear advantages: speed of application and removal with associated cost savings, improved intra-oral access, reduced sharps injury risk for the surgical team, and reduced gingival trauma.

Application and Removal Efficiency

Application requires approximately 12–15 minutes in an uncomplicated fracture–longer if there are multiple fractures requiring bony debridement or complicated stabilization. This speed is comparable to screw-based techniques and newer "hybrid" techniques.[9,13] Dimitroulis et al. determined that arch bar application typically required an hour (58.3 minutes) of extra operative time to achieve MMF with Erich arch bar application versus manual reduction technique. Engelstad et al., employing embrasure wires versus Erich arch bars, calculated an average difference of 23.0 minutes, although this retrospective study's time difference compared somewhat different fracture patterns in each cohort. Farber et al. calculated an average time savings of 59 minutes when comparing MMF screws technique to traditional arch bars. They calculated the extra cost of the screw-based system to be comparable to the cost of the extra time spent in the operating room.[17] Similarly, Kendrick et al. demonstrated a similar overall cost when comparing a hybrid system to arch bars, assuming an average arch bar application time of 54.2 minutes.[13]

The aforementioned studies demonstrate convincingly that the effort invested to achieve MMF can be timely and costly, as any facial trauma surgeon can attest. During the study, removal of ties was uniformly less than a minute, which is also definitively faster than arch bar/wire removal. With combined application and removal time on the order of 15 minutes, dental occlusion ties show a time savings comparable to MMF screw techniques and hybrid techniques.[9–13]

Intra-Oral Access

One further efficiency identified with the devices stems from their low-profile interface with the teeth (see Figs. 1d and 2c). Unlike arch bars with associated tabs and wires, the dental occlusion ties had no surfaces to catch suture when sewing an incision. They also minimally obstructed access to posterior fractures. Angle fractures were readily accessible with no interference from the devices.

Sharps Injury Risk Reduction

Numerous studies cite the risk to surgeons and surgical staff from "wire sticks."[2–4] The blunt-tipped needle of dental occlusion ties avoids this risk. The tip is comparable to the common blunt-tipped needle used for drawing medications into a syringe. While the needle component of a dental occlusion tie is capable of tearing a glove, it is far less likely to penetrate a fingertip or hand. No sharps injuries occurred during this study. Larger studies are needed to assess if there is a true risk reduction statistically. Similar to using a large blunt 18-gauge syringe needle, however, the risk of skin penetration is intuitively less.

Gingival Trauma Assessment

While gingival trauma was not objectively assessed, subjectively the tissue trauma was definitively less than arch bar and other wire-based techniques, with the possible exception of embrasure wires.[5] Traditional wire-based techniques such as Ernst ligatures and Ivy loops[1] as well as arch bars employ circumdental wiring that compresses individual teeth and can strangle surrounding gingiva. Apical papillae are commonly pierced with sharp stainless steel wire. This creates considerable periodontal trauma, especially evident to any trauma surgeon upon removal of the devices. Gingival bleeding is the norm, whether wires are removed in the operating room or clinic. Similarly, screw-based approaches (MMF screws and hybrid systems) impose gingival trauma and occasionally stimulate mucosal overgrowth of the screws. This mucosal/gingival trauma is less than arch bars, but still can require travel back to the operating room for removal. Dental occlusion ties, in contrast to screws and wires, showed negligible bleeding during application or removal. The associated bleeding was only slightly more than the scant bleeding that can occur with dental flossing.

Device Failure Analysis

Dental occlusion ties were successful in establishing maxillo-mandibular fixation in all study patients. Individual device failures did not compromise care because there is inherent redundancy in applying a balanced 3 to 4 ties to each side of the dentition. Five to 8 ties were successfully employed in the study patients. Initial intent was to apply up to 8 ties total–4 per side. As some patients were missing a few teeth or had adjacent teeth that did not make tight contact, a number less than 8 was typical. Despite this lessor number, stable maxillo-mandibular fixation was still always achieved. When a needle component broke from the body of the device, the device was discarded and a new device was selected. If a 0.7 mm tie "flossed out," a 1.0 mm device was commonly successful in securing the intended embrasure. Thus, a kit of devices including 12 dental occlusion ties had an appropriate number of extra ties to compensate. Device failures were shared with the company for improved future manufacturing/engineering. The swedge failures have been replicated and corrected.

CONCLUSIONS

This feasibility study marks the first clinical application of dental occlusion ties (future brand name: *Minne Ties)*. The study generated important proof-of-concept data to enable future larger studies that can compare dental occlusion ties to traditional approaches. Future larger studies may validate or refine this study's conclusions. They may also focus on questions such as:

1. Can in-office/clinic application suffice for non-displaced fractures or fractures not amenable to open fixation? Can in-office removal be achieved routinely?
2. Can dental occlusion ties provide a durable construct for patients needing postoperative MMF (i.e., 3–6 weeks)?
3. How do dental occlusion ties compare to other techniques in terms of comfort, mobility, and need for re-application?
4. How do dental occlusion ties affect the cost of mandible fracture care overall?
5. What is the minimal number of teeth or apical embrasures needed for application?

Dental occlusion ties were proved a viable alternative for MMF. With future questions still to be answered, the technology clearly demonstrated distinct operating room time efficiency, minimized sharps risk, and less bony and soft tissue trauma than current commercialized solutions. The ease of application of these devices establishes fast intra-operative management and promises simplified post-operative management. Future studies may establish that these minimally-invasive devices can enable clinic-based removal as well as potential clinic-based management of non-displaced or minimally-displaced mandible fractures with closed reduction techniques. The devices are undergoing FDA assessment currently. Future studies will help to answer these questions.

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