

# **BALLOON CARPAL TUNNEL-PLASTY**

The clinical study of a new surgical treatment for carpal tunnel syndrome

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**Abstract:**

A procedure termed, “Balloon Carpal Tunnel-Plasty”, has been developed to expand the transverse carpal ligament to increase the spatial diameter of the carpal tunnel and relieve pressure on the median nerve, alleviating the symptoms of carpal tunnel syndrome. The procedure utilizes a balloon catheter device with custom designed nerve protector, hand holder and pressure gauge monitor. This paper analyses the results of the balloon carpal tunnel-plasty procedure performed by the authors. The procedure was developed with cadaver study, and clinical evaluation studies. One-hundred-and-thirty balloon carpal tunnel-plasty procedures were performed on one- hundred-and-fourteen patients. The average length of follow-up was two years. The over-all satisfaction of the patients in the study was 92%.

# Balloon Carpal Tunnel-Plasty

## The clinical study of a new surgical treatment for carpal tunnel syndrome

Carpal tunnel syndrome is a common painful condition of the hand characterized by a decrease in median nerve sensibility with paresthesias of the fingers, nocturnal pain, clumsiness, and weakness of grasp and pinch. It is the most common nerve entrapment syndrome of the upper extremity.

Historically, carpal tunnel syndrome has been treated non-surgically by splinting of the affected hand and wrist, oral anti-inflammatory medication and local steroid injection. If non-surgical methods are unsuccessful, surgical intervention is indicated.

Learmonth, in 1933 described open surgical decompression of the carpal tunnel by division of the transverse carpal ligament. The open procedure entails a curved longitudinal incision ulnar to and parallel to the thenar crease. Taleisnik described an incision along the ulnar border of the ring finger axis.<sup>1</sup> After division of the skin and subcutaneous tissue, the transverse carpal ligament is identified and divided along its ulnar border to avoid and prevent injury to the median nerve or its recurrent branch.

In recent years, endoscopic techniques have been utilized to incise and divide the transverse carpal ligament.<sup>2 3 4 5</sup> Attempts have been made to decrease the size of the surgical incision with the benefit of decreasing post-operative morbidity.<sup>6</sup> Refinements of the technique of endoscopic release of the carpal ligament have been evolving but complications with this procedure have been reported. The complications include: neuropraxia of the median and or ulnar nerve; digital nerve neuropraxia or laceration; laceration of palmar blood vessels; laceration of flexor tendons; neuropraxia or laceration of the palmar cutaneous branch of the median nerve; palmar hematoma; adhesions of tendons; perineural fibrosis; bow-stringing of flexor tendons with loss of grip strength; incomplete transection of the carpal ligament with recurrence of symptoms and painful hypertrophic scar.<sup>7</sup> A dual incision technique has been developed with the attempt to further increase the safety and efficacy of the endoscopic procedure but the potential complications of surgically transecting the transverse carpal ligament remain evident.<sup>4</sup>

The author (LB), after personally performing open carpal tunnel release for many years, observing, performing and researching the endoscopic techniques and reviewing the literature has developed a new procedure, termed “Balloon Carpal Tunnel-Plasty” to decompress of the median nerve in the carpal tunnel without cutting the transverse carpal ligament.

Balloon Carpal Tunnel-Plasty utilizes a balloon catheter device with a custom designed nerve protector, hand holder and pressure gauge monitor. The balloon catheter is inserted within a nerve protector device into the carpal tunnel of the hand. The balloon catheter stretches and expands the transverse carpal ligament, increasing the diameter of the carpal tunnel, relieving compression of the median nerve and alleviating the symptoms of carpal tunnel syndrome.

### Equipment

In order to perform balloon carpal tunnel-plasty, specialized custom designed equipment is required. The equipment facilitates the safe and effective expansion of the transverse carpal ligament with protection of the contents of the carpal tunnel.



### Equipment Required

Custom designed hand holder with guide locking mechanism

Custom grooved nerve protector

Specialized balloon catheter

Pressure gauge monitor

### **Balloon Catheter**

The balloon catheter is specially designed for smooth easy atraumatic entry, expansion and withdrawal. A low-profile shaft, narrowed in diameter underneath the balloon, provides for easy placement of the device within the protective grooved director, which protects the median nerve, and contents of the carpal tunnel during the procedure. The distal tip on the catheter fits securely into the grooved nerve protector, preventing migration of the balloon. The balloon is manufactured of non-compliant high-strength material that consistently inflates to and maintains its stated diameter. Burst pressure of the balloon is rated at 12 ATM. Balloon pressure is monitored by a pressure gauge monitor that is attached to the balloon catheter. After expansion is performed, the balloon is easily deflated and refolds itself tightly for easy, smooth, atraumatic withdrawal from the carpal tunnel.

### **Cadaver Study**

Prior to commencing the study, the balloon carpal tunnel-plasty procedure and the specialized equipment required to perform the surgery were tested in fresh cadaver studies. These studies included: gross anatomical dissection, compartment pressure measurements before and after the balloon carpal tunnel-plasty, measurement of the amount of expansion of the transverse carpal ligament by the balloon, and measurement of the amount of increase of the cross sectional area of the carpal tunnel after the procedure was performed. The condition of the contents of the carpal tunnel (the osseous ligament attachments of the transverse carpal ligament, the median nerve and its branches, the flexor tendons and their synovial bursa, the vascular structures and the carpal bones) was carefully examined pre and post surgically.

The cadaveric studies were performed to demonstrate the anatomy of the carpal tunnel in the hand, the surgical technique, the instrumentation required and the safety of the procedure. The results of the dissection revealed that the instrumentation involved is easily placed into the carpal tunnel in much the same fashion as an endoscopic carpal tunnel release, however, without requiring a second distal incision. Its correct anatomical position was verified upon dissection. Inflation of the balloon catheter with measurements taken on the carpal ligament revealed that the carpal ligament does indeed stretch under 10 atmospheres of pressure, and that after balloon deflation and stretching of the ligament, it does not return to

its original pre-stressed length. This indicated the potential for this procedure in lengthening the carpal ligament and creating additional space in the carpal tunnel without division of the ligament itself. Compartment pressure studies provided objective evidence of the effectiveness of balloon carpal tunnel-plasty in decreasing the pressure in the carpal canal by stretching the transverse carpal ligament and increasing the volume of the carpal canal. The post expansion compartment pressures were not significantly different from open release in our study, and similar to those obtained with endoscopic and open release published by other authors. A 71% decrease occurred in the carpal canal pressure measured after dilation of the ligament and a 69% increase in the size of the measuring dilator, which the canal could accommodate. The histology demonstrated no disruption of the ligament from its bony attachment or within its substance. The dissection revealed that the structures within the carpal tunnel were protected by the instrumentation and were undamaged on gross anatomic inspection. The balloon catheter grooved nerve protector and custom hand holder with stop guide effectively shielded the underlying structures, including the median nerve.

The cadaveric investigation revealed that the Balloon Carpal Tunnel-Plasty procedure might be efficacious in safely decompressing the carpal ligament. We believe the procedure holds promise in decompressing the carpal tunnel and median nerve with minimal disruption of anatomy, minimal alteration of biomechanics and minimal scar formation associated with division of the carpal ligament.

The cadaver studies were documented with photographs as well as videotape.



## **Materials and Methods**

### **Criteria for participation in the Study:**

A clinical study of the surgical procedure for the treatment of carpal tunnel syndrome termed; “Balloon Carpal Tunnel-Plasty” was initiated in February 1991. The Balloon Carpal Tunnel-Plasty technique was performed on 130 hands. There were a total of 114 patients, of which 98 had the procedure performed on one involved (98 hands); 16 patients had the balloon-plasty procedure performed on both hands with bilateral carpal tunnel syndrome (32 hands); this equals a sum of 130 hands included in the study. One-hundred-and-sixteen Balloon Carpal Tunnel-Plasty procedures were performed at St. Joseph’s Hospital and Medical Center, nine procedures at Wayne General Hospital, and five procedures at Beth Israel Hospital.

### **To be part of our study group, the following criteria were required:**

A volunteer patient

A patient between the ages of 20 and 85 years

A positive history of symptoms consistent with the diagnosis of carpal tunnel syndrome

Symptoms of pain and numbness of the hand and fingers of over three months duration

A detailed medical history, including a list of any previous medical illness, previous surgery, medications, allergies, and history of any familiar illness

A physical examination documenting positive clinical findings associated with carpal tunnel syndrome

Recent (no more than 4 months old) positive electrodiagnostic studies confirming compression of the median nerve at the level of the carpal tunnel

Each of the patients was examined and treated by the author (LB). The clinical diagnosis of carpal tunnel syndrome was made based on the patient's history, physical examination and electro-diagnostic studies. All patients volunteered to participate in the study and were required to sign a detailed informed consent, explaining the procedure and study, which had been prepared by the Hospital Investigational Review Board. The patient's pre-operative symptoms were at least three months duration. Each patient's symptoms had failed to respond to non-operative treatment, such as rest from activity, ergonomic controls and activity modification, medication, injection of the carpal canal, splinting of the hand and wrist, or physiotherapy. Contraindications for inclusion in the study included previous fracture of the hand or wrist, history of open or endoscopic carpal tunnel surgery, metabolic disorder, such as diabetes, thyroid dysfunction, renal failure, or pregnancy.

The history included the patient's age, sex, involved hand, handedness, the length of symptoms, and any previous treatment of the condition. The patient's activities of daily living, occupation, and whether a workman's compensation claim was involved were documented. Pre-operative pain, tingling or numbness of the digits, night symptoms, dropping objects and fine dexterity loss was recorded. Phalen's test and Tinel's test were performed pre-operatively.<sup>8</sup> Sensation was measured by Semmes-Weinstein monofilament testing and two-point discrimination in all patients. Grip strength was measured with a grip strength meter and recorded. Thenar atrophy and strength of thumb abduction was assessed. Radiographs of the carpal tunnel of the affected hand of each patient were taken and reviewed. Electro-diagnostic studies were performed on each patient by an independent neurologist. A delay of the distal sensory latency above 4.5 milliseconds confirmed the diagnosis.

### **Operative Procedure**

The author, LB, performed all procedures. Each case was performed as a same-day procedure in the hospital operating room. 78 procedures were performed under local 1% plain xylocaine, 52 procedures were performed with the use of regional anesthesia (Bier block or axillary block). During the study, it was evident that the procedure could be performed comfortably and easily with local anesthetic and in less than twenty minutes of operative time. The local procedure was safer than the use of a regional block in many ways. It reduced the tourniquet time; allowed the patient to actively move the fingers immediately post-operatively as no motor block is involved, and provided good pain relief during and after the surgery.



### **PROCEDURE**

## **BALLOON CARPAL TUNNEL-PLASTY**

The hand is prepped and draped in the usual surgical fashion. After exsanguination of the hand, forearm, and elbow a pneumatic tourniquet applied to the patient's arm is inflated. The hand is comfortably positioned in the custom designed hand holder, which is required to perform the procedure. The procedure can be performed with the use of 1% local xylocaine (lidocaine) without epinephrine or with regional anesthesia. A one-centimeter size incision is made at the level of the volar wrist crease ulnar to the palmaris longus and radial to the flexor carpi radialis tendons in line with the fourth ray. The incision is similar to that which surgeons are familiar with performing endoscopic carpal tunnel release. The incision is carried through the skin by sharp dissection. The subcutaneous tissue is bluntly dissected to the level of the distal antibrachial fascia. A small aperture is made in the distal antibrachial fascia with a #15 blade and the most proximal portion of the transverse carpal ligament is identified. A synovial elevator is utilized to bluntly clear the synovial membrane from the undersurface of the transverse carpal ligament. The striations of the undersurface of the ligament are palpated with the elevator. The diameter of the carpal tunnel can be measured prior to the balloon expansion with a calibrated measuring device and recorded.

The balloon catheter held within the grooved nerve protector device is placed through the custom hand support stop guide, then carefully inserted underneath the transverse carpal ligament and advanced to the most distal margin of the transverse carpal ligament just proximal to the level of Kaplan's oblique line. The stop guide of the hand holder is then set securing the balloon, which is held within nerve protector guide in proper position protecting the underlying contents of the carpal tunnel. The nerve protector is positioned in the carpal tunnel in line with the fourth ray and lies ulnar to the median nerve. The position of the grooved nerve protector is confirmed by digital palpation. The balloon catheter is attached to the pressure monitor. Sterile saline solution is then injected into the catheter and the balloon is expanded. The position of the radio opaque catheter and balloon is digitally palpated or can optionally be reconfirmed by image intensification or radiographs. The carpal tunnel-plasty is performed by serially inflating and deflating the balloon catheter held in the nerve protector device intermittently along the course of the carpal tunnel from distal to proximal, stretching and expanding the transverse carpal ligament.

Balloon pressure measurements are taken throughout the procedure. The grooved nerve protector device serves to direct the balloon catheter in the carpal tunnel and protect the median nerve and underlying structures. The stop guide of the hand holder prevents any downward deflection of the nerve protector when the balloon is inflated. After expansion of the transverse carpal ligament, the balloon is deflated and the catheter and nerve protector device is removed. The expansion of the transverse carpal ligament and the increase size of the carpal tunnel can be visualized. The post-dilation diameter of the carpal tunnel can be measured with a calibrated measuring device. The tourniquet is released. The wound is irrigated with sterile saline solution. The skin is closed with one or two #5.0 nylon sutures. A sterile dressing is applied to the wound.

### **Postoperative Patient Evaluation**

All surgery was performed in the operating room of the hospital as a same-day procedure. Post operatively, all patients were given simple home care instructions. Analgesics were kept to a minimum, as there was little post-op pain associated with the procedure. All patients were evaluated by the authors at a predetermined post-op evaluation schedule at week 1, 2, 4, 6, 12, 24, 36, 48 and further to document the progress of the patient. A detailed post-op protocol was performed which included completion of a documentation data form. The form included the patients employment status, return of hand to activities of daily living, improvement of symptoms: pain, tingling, weakness, numbness, night symptoms, dropping items and fine dexterity skills. The clinical data included grip strength measurement and Semmes- Weinstein sensory testing of the thumb, index, long and ring fingers. Phalen's test and Tinel's test were performed and the findings noted. Motor testing of thumb abduction was performed. The patient was also evaluated for scar tenderness that was rated zero-to-five (0 non-tender→5 very painful). Radial and ulnar pillar tenderness was also rated on the same scale. The patient's outcome satisfaction was also noted on each postoperative visit.

## **Results**

### **Study Population**

Balloon Carpal Tunnel-Plasty was performed on one-hundred-and-fourteen patients in 130 hands. The study was performed from February 1991, through October 1995 (4 years eight months). The average length of follow-up was two years. There were sixty-four women and fifty men. The average age of the patients was fifty-three (53.0) (range: twenty-five to eighty-five years). The right hand was involved in seventy cases; the left hand was involved in fifty-three cases. Sixteen patients had involvement of both hands. The average duration of the symptoms before the operation was twenty-eight months (range, four months to one-hundred-and-eighty months). 85 patients were gainfully employed and 29 patients worked at home or had retired. 34 patients were covered by Worker's Compensation. 6 patients had had a previous open procedure on the opposite hand.

The occupations of the patients represented a broad spectrum of the general population. Included in the study were doctors, nurses, secretaries, computer operators, factory workers, truck drivers, a nun, a hairdresser, an orchestra conductor, musician, actor, radio announcer, electrician, carpenter, postman, fireman, and a physiotherapist, as well as other occupations.

### **Outcome of Study**

Balloon Carpal Tunnel-Plasty provided marked improvement of symptoms in the majority of patients. One-hundred-and-six patients had marked clinical improvement with relief of pain (**92.9%**). Sixteen patients had noticeable relief of pain but still had mild residual numbness of one or more digits (14%). The residual numbness was more frequent in those patients over 60 years of age and patients with symptoms of greater than 24 months duration. Patients with marked prolongation of the distal motor latency on electrodiagnostic studies, especially those with thenar atrophy and weakness of thumb abduction tended to have mild residual numbness. However, even in the patients who had residual numbness, there was generally relief of pain and night symptoms and an increase in grip strength and activities of daily living. Interestingly, 16 patients who had Balloon Carpal Tunnel-Plasty performed on one hand returned to have the procedure performed on the other affected hand.

The over-all satisfaction of the patients in the study was **92%**.

**Functional Outcomes**

Scar and Pillar Tenderness	No significant scar or pillar tenderness in any of the 130 hands
Recovery of Strength	Average pre-op grip strength 16.5kg (range 3-52kg) Average post-op grip strength 27.0kg (range 12-58kg) (61.1% increase pre vs post-op)
Activities of Daily Living	Average = 4 days (range 1-7 days)
Return to Work	Average = 10 days (range 1-28 days)
Time and Cost	Average surgical procedure < 25 minutes Operating room time < 45 minutes Anesthesia - most procedures can be performed under local anesthetic
Complications	(None) there were no inter-operative or post-operative complications No wound infections No nerve or vascular injuries

## Discussion

Balloon Carpal Tunnel-Plasty is a procedure for the treatment of carpal tunnel syndrome that is safe, easy to perform and offers many potential advantages over open surgical carpal tunnel release or endoscopic carpal tunnel release.

The primary advantage of Balloon Carpal Tunnel-Plasty is that the technique avoids transection of the transverse carpal ligament, which we believe serves a protective purpose in the palm and is important for maintenance of grip strength. With operative procedures that cut the transverse carpal ligament we believe there is a disruption of the normal anatomy of the hand. It has been shown that standard carpal tunnel release produces an average widening of the transverse carpal arch of 2.7 mm. There is a direct relationship between widening of the carpal arch and decreased grip strength.<sup>9</sup> With balloon carpal tunnel-plasty, the transverse carpal ligament is expanded. The transverse carpal arch remains stabilized preventing bow stringing of the flexor tendons. When the balloon catheter device is inflated, the protective grooved director has been designed, with the use of the custom hand holder, to prevent compression of the median nerve and underlying structures. By not transecting the transverse carpal ligament, post-operative scar formation in the carpal tunnel and perineural fibrosis around the median nerve that commonly occurs with open or endoscopic procedures may be reduced. The normal relationship of the carpal tunnel and its contents are maintained.

The operation requires a small incision and is performed under local anesthetic as a hospital outpatient surgical procedure. The one-centimeter size incision provides a very cosmetic result. The procedure can be performed with or without endoscopic assistance. Balloon pressure measurements can be taken and monitored throughout the procedure.

In a study comparing open and endoscopic carpal tunnel release, open carpal-tunnel release provided relief of pain and paresthesias in 64% of patients by eighty-four days. Thirty-three percent had mild residual symptoms and 3% had no improvement. Endoscopic carpal-tunnel release provided complete relief in 74% by eighty-four days. 25% had mild symptoms at eighty-four days and 1% had no improvement. The over-all satisfaction of the patients with the operative procedure was similar for the open and endoscopic-release groups: **84%** compared with **89%** at eighty-four days.<sup>10</sup>

This clinical study, initiated in February 1991, provided the opportunity to evaluate the Balloon Carpal Tunnel-Plasty procedure for the treatment of carpal tunnel syndrome. The outcome results of the balloon carpal tunnel-plasty study offer potential functional advantages over the open or endoscopic procedures. There was no significant scar or pillar tenderness in any of the 130 hands. Relief of pain and numbness was comparable to the other procedures. Recovery of grip strength was rapid and one of the major objectives of the procedure. The average pre-op grip strength was 16.5kg (range 3-52kg); the average post-op grip strength was 27.0kg (range 12-58kg). This represents a 61.1% increase in grip strength pre vs post-op. The return to the patients activities of daily living was rapid (average = 4 days, range 1-7 days.) Return to work averaged 10 days (range 1-28 days.) The over-all satisfaction of the patients in the study was 92%.

With Balloon Carpal Tunnel-Plasty, the patient has little post-operative pain, a quick recovery time and early return to activities of daily living. The clinical results of this technique show promise as a less invasive, safer and more physiologic treatment of carpal tunnel syndrome.

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