BALLOON CARPAL TUNNEL PLASTY: FIRST COMPARATIVE CLINICAL STUDY

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INTRODUCTION

About half a million carpal tunnel release surgeries are performed annually in the United States [1]. Transecting the transverse carpal ligament (TCL), whether by open or endoscopic release, is the standard surgical treatment of carpal tunnel syndrome. Although carpal tunnel release provides excellent results by most measures, complications associated with ligament transection are common. The TCL is an important anatomical, biomechanical and physiological structure, and hand function would be compromised when it is cut. Balloon Carpal Tunnel Plasty (BCTP), invented by a co-author (LB), is a minimally invasive method to decompress the median nerve in the carpal tunnel while preserving the TCL. The purpose of this study was to evaluate BCTP efficacy in comparison to the gold standard open carpal tunnel release (OCTR).

METHODS

The BCTP system is composed of a unidirectional balloon built within an integral nerve protector (i.e. the balloon probe), the hand holder restraint, sterile saline syringe for inflation, and pressure gauge monitor (Figure 1). During surgical treatment, a one-cm incision is made at the volar wrist crease identical to uniportal endoscopic release. The balloon probe is placed through the custom hand restraint guide then inserted under the TCL and advanced to the distal margin of the ligament. The stop guide of the hand restraint is engaged to lock the balloon probe in place with the balloon facing upward, and to prevent any downward deflection of the probe or balloon protecting the median nerve and contents of the carpal tunnel. The position of the balloon probe is confirmed by digital palpation, tightened and locked in place with the set screw on the hand restraint guide and the balloon is then inflated. Three sequential inflations and deflations are performed at 30 second intervals each time further tightening the set screw as the ligament expands. After the ligament is stretched and expanded the balloon is deflated and removed with the balloon probe. The expansion of the ligament is then directly visualized and the contents of the carpal tunnel including the median nerve can be directly inspected visually or with endoscopic assistance and interoperative photos can be obtained for documentation. The skin incision is closed with sutures and dressing applied.

***Figure 1**. A demonstration of BCTP with the hand in the restraint device together with the ligament stretching accessories.*

A randomized prospective clinical trial enrolled 81 surgical patients: 45 patients/hands were treated with OCTR and 36 patients/hands were treated with BCTP. The treatment outcomes were evaluated using Levine Symptom and Function scores [2], grip strength, pinch strength, and medication usage. Patients were evaluated pre-op and post-op at 1, 2, 4, 8, 16, and 24 weeks intervals. Repeated measures two-way ANOVAs were used to test the effects of time and treatment factors. Only the Levine scores are reported in this abstract.

RESULTS

The average scores are summarized in Table 1. OCTR or BCTP significantly improved both the Symptom and Function scores ($p < 0.001$). The improvement after BCTP was 56% for symptom and 40% for function at post-op 1 week, and the improvement retained 49% for symptom and 49% for function at the post-op 24 weeks. The two treatments were not significantly different in improving the Symptom score ($p = 0.141$) despite a trend to lower BCTP scores. The treatments were significantly different in improving Function score ($p < 0.01$). For example, at 1 week the Function score after BCTP was 32% better than that after OCTR. Also, the interaction between the time and treatment factors was significant for both the symptom and Function scores ($p < 0.001$), which means that the change of scores over time were non-parallel for the BCTP and OCTR.

***Table 1**. Symptom and function scores, mean (SD), pre- and post-op up to 24 weeks.*

Time	PRE	1	2	4	8	16	24
				Symptom			
OCTR	3.49 (0.69)	1.99 (0.59)	1.91 (0.55)	1.76 (0.63)	1.71 (0.77)	1.59 (0.86)	1.32 (0.36)
BCTP	3.50 (0.69)	1.55 (0.52)	1.53 (0.55)	1.53 (0.59)	1.54 (0.54)	1.65 (0.60)	1.78 (0.65)
				Function			
OCTR	2.82 (0.64)	2.44 (0.92)	2.20 (0.64)	1.83 (0.68)	1.60 (0.60)	1.92 (0.67)	1.23 (0.27)
BCTP	2.75 (0.71)	1.66 (1.03)	1.48 (0.68)	1.32 (0.50)	1.33 (0.48)	1.38 (0.51)	1.43 (0.62)

DISCUSSION

BCTP improved the symptom and function and was more effective than OCTR in improving hand function in the evaluated post-op period of 24 weeks. Similar accelerated recovery was previously shown with endoscopic carpal tunnel release but with a higher complication rate [3]. Absence of iatrogenic injury in this study and in a previous study with 68 hands treated by BCTP [4] is likely attributed to absence of TCL cutting. The current data demonstrates the potential of BCTP as an alternate carpal tunnel syndrome treatment that offers quick and safe recovery.

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