attributable to breast cancer were 21,361,784, 2,421,698, and 533,598 respectively. Regions with the highest incidence/prevalence/DALY’s were South Asia, Southeast Asia, and Latin America/Caribbean. These numbers superseded those of high-income North America. Countries in South Asia demonstrated the greatest increase in welfare lost to breast cancer over this time from 0.05% to 0.08% of GDP. In 2015, welfare lost to breast cancer was greatest in the US at 0.22% of GDP with minimal change over the 10-year study period.

CONCLUSIONS: Although epidemiological indicators of breast cancer remain stably high in the US, the burden of disease and economic impact are rising significantly in LMICs. Efforts to improve access to surgical care for women with breast cancer could reduce mortality, and mitigate the social and financial consequences of this disease in LMICs. These findings may also be relevant to interventions focused on improving access to care in low-resource settings in the United States as well.

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04

One Stage Versus Two-Stage Microsurgical Arteriovenous Loop Reconstructions - A 10-Year Experience On 103 Cases from a Single Center

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PURPOSE: A paucity of healthy recipient vessels in microsurgical reconstructions may be managed by the placement of arteriovenous (AV) loops, which enable microvascular anastomoses of free flaps. The optimal time for flap anastomosis to an AV loop still remains a topic of controversy in the literature. A recently published meta-analysis yielded a higher rate of major complications and flap failures in two-stage compared to one-stage AV loop reconstructions (Knackstedt et al. 2017). These data, however, were derived from heterogeneous case series with low sample sizes, the largest of which included 52 patients (Cavadas et al. 2008). Evidence is also lacking on whether perforator flaps are suitable for AV loop based reconstructions and lead to outcomes comparable with large-pedicle muscle or fasciocutaneous flaps. Here, we present the largest cohort of AV loop reconstructions in the literature performed at a single microsurgical center.

METHODS: Medical records from 103 patients undergoing AV loop reconstructions (76 one-stage, 27 two-stage) at our institution between 2007 and 2017 were reviewed. One-stage and two-stage reconstructions as well as different types of free flap reconstructions were compared with respect to postoperative complications and outcomes.

RESULTS: Rates of flap thrombosis did not show significant differences between one- and two-stage reconstructions (14.47% vs. 11.11%, p=1.00). Also, no significant differences between one- and two-stage reconstructions were found for major wound complications (30.26% vs. 25.93%, p=0.67) and flap failure (10.53% vs. 7.41%), p=1.00. For two-stage reconstructions, the length of the time interval between AV loop placement and flap anastomosis was identified as a predictor for thrombotic events by logistic regression analysis (Odds Ratio: 1.31; p<0.05), yielding high thrombosis rates for intervals of > 10 days. Anterolateral thigh perforator (ALT) flaps in conjunction with AV loops (n=12) showed higher rates of flap failure compared to latissimus dorsi (LD, n=35) (33.33% vs. 8.57%, p=0.059) and combined LD and parascapular flaps (LD/PSC, n=15) (33.33% vs. 0%, p<0.05). Thrombosis rates were higher in ALT flaps compared to LD (33.33% vs. 17.14%, p=0.25), LD/PSC (33.33% vs. 0%, p<0.05), and tensor fasciae latae flaps (TFL, n=12)(33.33% vs. 0%, p=0.09).

CONCLUSIONS: Our data indicate that two-stage AV loop reconstructions do not lead to increased postoperative complications compared to one-stage reconstructions and may be favorable in selected complicated cases due to an increased safety of the staged procedure and shorter operative times. To avoid increased thrombosis rates, flap anastomosis should
not be delayed beyond 10 days in two-stage reconstructions. ALT flaps are not suitable for AV loop reconstructions since they have a significantly higher resistance and therefore cause a reduced flow rate in the vein graft. This may explain higher flap thrombosis and failure rates.

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05

Efficacy of Phase 1 Clinical Trial of Autologous Quality and Quantity Cultured Vascular and Tissue Regenerative Cell Therapy for Diabetic Patients with Chronic Non Healing Ulcer

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BACKGROUND AND OBJECTIVE: Non-healing wounds are a major cause of morbidity and mortality in diabetic patients. Recently, we have reported the novelty of endothelial progenitor cell (EPC) therapy with serum free ex vivo expansion system called Quantity and Quality Culture System (QQc) using peripheral blood mononuclear cells (PbMNC) as non-invasive and effective new generation cell therapy. After demonstrating high vasculogenic and wound healing potential of this technology with murine and porcine animals, thus obtaining permission under the law of regenerative therapy in Japan, we have begun enrolling diabetic patients with chronic wounds in a prospective phase I/II clinical trial. The objective of this study is to investigate the safety and efficacy of QQ cultured PbMNC on diabetic non-healing wounds.

MATERIAL AND METHODS: 200ml of peripheral blood was drawn from Type 2 diabetic patients with chronic (>3 months) ischemic foot ulcers in an outpatient basis. Mononuclear cells were isolated and cultured in QQc for one week without passaging or media changes. Under local anesthesia, 2x10⁷ cells were injected within 20 cm² of the chronic wound and wound healing was monitored by photometrically. The adverse effects were evaluated according to the National Cancer Institute Common Terminology Criteria for Adverse Events. Wound closure, VAS scale, skin perfusion pressure (SPP), TcPo2, laser doppler, thermography and angiography were performed to evaluate efficacy post 2,4,8 and 12 weeks therapy.

RESULTS: A total of seven patients, eight limbs were enrolled. The age ranged from 64 to 74 years old. Six males and one female. Six patients had diabetes with renal failure and one with collagen disease as past medical history. Blood sugar levels were controlled for all patients, and hbA1C was below 8.0%. All of the wounds extended into bone or tendon and were located in the digits of the foot. Case one with adverse effect underwent infection from injection site with alternative ulcer which had later healed. All patients were ambulant but wounds of two patients, three limbs did not heal. There was no death, other serious adverse events, or major amputation seen 12 weeks following transplantation. Increased vascular perfusion with decrease in VAS scale were seen in all patients. Interestingly, SPP significantly increase post therapy. (27.1±11.7mmHg pre-therapy vs 55.5±9.5 at 2 weeks, 54.3±12.1 mmHg at 4 weeks, 65.4±20.8mmHg at 12 weeks)

CONCLUSION: The outcomes of this prospective clinical study indicate the safety and feasibility of MNC-QQc cell therapy in patients with diabetic ischemic nonhealing wounds. This methodology will allow us to transplant highly vasculogenic EPCs from small amount of blood draw. This will be the world’s first non-invasive and effective peripheral blood vascular stem cell therapy for diabetic limb salvage.

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06

Expediting Tissue Expansion in Implant Based Breast Reconstruction: A Comparative Study of Prepectoral and Subpectoral Expander Placement

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