

# Influence of organ transplant controversies on corneal donation rates

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## Abstract

**Aim:** This study aimed to investigate the influence of organ transplant controversies on corneal donation rates at the University Hospital Tübingen.

**Methods:** Data from all hospital deaths from 2009 to 2015 were analyzed. During the 7-year period two vast German organ donor controversies occurred in the end of 2012 and 2014. An ophthalmic resident handled on a full-time basis the corneal donor procurement with stable methods. The rates of corneal donation were examined and evaluated.

**Results:** Among the 5712 deaths, consent for corneal donation was obtained in 711 cases. The mean annual corneal donation rate was 12.4% (range: 8.7% - 17.8%). Since 2009, the donation rate per year could be increased with exception of 2013 and 2015. In the end of 2012 and 2014 two vast German organ donor controversies received worldwide attention. In the following years 2013 and 2015 corneal donation rate decreased significantly ( $P=0.02$  and  $P=0.0006$ ).

**Conclusion:** German law regarding tissue collection is based on previous informed consent from the donor through a standard donor card or through verbal or written consent. In its absence, the next of kin may give his or her consent, but may not oppose any known wishes of the donor. Our study showed that organ donation controversies may influence the corneal donation rate significantly.

## Introduction

Keratoplasty has been performed for over 110 years successfully and has been the most frequently performed transplant procedure worldwide [1]. Nonetheless in most countries there is a severe shortage of donor corneas [2]. It consists a rising demand for corneal grafts due to the older population and the increasing trend to endothelial keratoplasty procedures [3,4].

Particularly, the procurement of donor cornea depends on functioning network between intensive care units and cornea bank [5], the availability of suitable donors [6,7] and the previous informed consent from the donor through a standard donor card or through verbal or written consent [8].

Confronted with the serious shortage of donor corneas we decided to investigate the influence of organ transplantation controversies on corneal donation rate at the University Hospital Tübingen from 2009 to 2015. In the end of 2012 [9] and 2014 [10] media reported on multiple German *organ donation controversies* including physicians in Germany [9-13]. These organ donor controversies received worldwide attention [11].

To the best of our knowledge, this is the first study about the influence of organ transplant controversies on corneal donation rates.

## Materials and methods

Data from all hospital deaths at our University Hospital with 1500 beds from 2009 to 2015 were analyzed. No donor age limits were set and enucleation times up to 72 hours postmortem were accepted. The consent had been recorded. From 2009 to 2015 an *ophthalmic resident* handled on a full-time basis the donor screening, interviews with the next of kin, *corneal donor* procurement and *retrieval*. The

rates of corneal donation were calculated and examined. This study was approved by the institutional review board of the University of Tübingen and adhered to the tenets of the Declaration of Helsinki.

## Statistical analysis

Statistical analysis of the data was conducted using the Statistical Packages for the Social Science (SPSS 18.0). Quantitative variables were expressed as mean  $\pm$  standard deviation (SD).  $P < 0.05$  was considered to be statistically significant.

## Results

This retrospective study included 5712 hospital deaths. Consent for corneal donation was obtained in 711 cases. The male:female ratio was 61:39. Mean donor age was 70 years (SD 14, range 16-93). The mean annual corneal donation rate was 12.4 % (range: 8.7% - 17.8%). The male:female ratio was 61:39. Mean donor age was 70 years (SD 14, range 16 - 93). In 2014, the highest corneal donation rate of 17.8 % was achieved in contrast to the lowest in 2009 (8.7%). Since 2009, the donation rate per year could be increased with exception of 2013 and 2015. In the end of 2012 and 2014 multiple German organ donor controversies received worldwide attention. In the following years 2013 and 2015 corneal donation rate decreased significantly ( $P=0.02$  and

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$P=0.0006$ ). Figure 1 presents annual corneal donation rate from 2009 - 2015. Table 1 shows the number of cornea donors and deaths per year and the rate per 100 deaths.

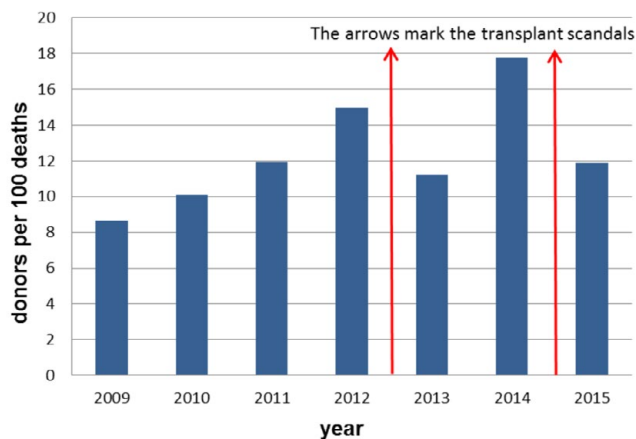
## Discussion

Our study showed the influence of organ transplant controversies on corneal donation rate in 711 consecutive consent cases at the University Hospital Tübingen during a 7-year period.

*In literature multiple factors contribute to loss of potential cornea donors: the imperfect identification of potential donors, the donor family has not been asked and the denial of consent by the potential donors family [14]. Muraine et al. [15] reported that potential donor identification and reaching relatives for verification the last will of the deceased implies a high degree of organization and a sufficient staff level [15].*

Different studies demonstrated that measures can be taken to improve consent rates. It was recommended the interviewer did complete specific communication training and had more clinical experience [16,17]. A high positive response can be obtained from the donor's family when a trained and motivated interviewer manages the post-mortem cornea donation request [18,19]. Potential corneal donor identification is based on a functioning network between intensive care units and a cornea bank [5]. Regular advancement training intensifies this relationship. To the best of our knowledge, this is the first study about the influence of organ transplant controversies on corneal donation rates.

German law regarding tissue collection is based on previous informed consent from the donor through a standard donor card or through verbal or written consent. In its absence, the next of kin may give his or her consent, but may not oppose any known wishes



**Figure 1. Annual corneal donation rate from 2009 to 2015:** The mean annual corneal donation rate was 12.4 % (range: 8.7 % - 17.8 %). Since 2009, the donation rate per year could be increased with exception of 2013 and 2015. In the end of 2012 and 2014 multiple German organ donor scandals received worldwide attention. The arrows mark the organ donor scandals. In the following years 2013 and 2015 corneal donation rate decreased significantly ( $P = 0.02$  and  $P = 0.0006$ ).

**Table 1. Number of cornea donors and deaths per year:** The table shows the number of cornea donors and deaths per year and the rate per 100 deaths. This study included 5712 hospital deaths. Consent for corneal donation was obtained in 711 cases. The mean annual corneal donation rate was 12.4 % (range: 8.7 % - 17.8 %).

Year	2009	2010	2011	2012	2013	2014	2015	Total
Donors	64	79	93	124	96	150	105	711
Deaths	738	783	779	829	856	844	883	5712
Rate per 100 deaths	8.7	10.1	11.9	15.0	11.2	17.8	11.9	12.4

of the donor. Under ideal circumstances, face to face would be the preferred setting of requesting consent. However, legal postmortem time constraints limit their ability to arrange face to face meetings [20,21]. A simple solution to increase the number of families contacted is to contact them by telephone [16]. The use of telephone increased overall cornea donation rates, mainly because of logistic improvements [20,21]. Furthermore, Geissler *et al.* [22] reported, that consent rates for cornea donation obtained via telephone interview increase with the interviewers' experience. Muraine reported a dramatic drop in face to face consent rates when an inexperienced ophthalmologist took part in their interviews [18] and Linyear et Tartaglia suggested that staff experience is a major contributor to a positive donation outcome [23].

Based on this knowledge since 2009 the donation rate per year could be increased with exception of 2013 and 2015. In the end of 2012 [9] and 2014 [10] multiple German organ donor controversies received worldwide attention. In the following years 2013 and 2015 corneal donation rate decreased significantly ( $P=0.02$  and  $P=0.0006$ ). Because of not changing the setting of corneal tissue procurement and without changing standards in the whole study period we suspect that the decrease had been exacerbated by *organ donation controversies* including physicians in Germany who favored several patients for different reasons [9,11]. Hoisl *et al.* [12] reported that several hundred articles, which focused on the transplantation scandal, were published in the leading German newspapers between the end of 2012 and early 2013. This seems to be responsible for the decrease of the donation rate in 2013.

At the German *Heart Institute of Berlin* a new scandal was uncovered and the topic flared up again in the media in the end of 2014. Physicians manipulated waiting lists. Incorrect statements were made about medical conditions and medicine wrongly prescribed so that patients appeared sicker than they were [13]. Jox *et al.* [24] showed a significant decrease in the number of organ donations in Germany caused by the transplant controversies. Especially between the end of 2012 and early 2013 and between the end of 2014 and early 2015 the media reported about the controversies. In the following years 2013 and 2015 the number of cornea donors at the University Hospital in Tübingen decreased significantly.

Nevertheless some points should be considered before drawing hasty conclusions. The main limitation of our evaluation is the limited comparability of these data with previous publications on the corneal donation rate. Almost all of our donors coming from cadaver deaths of the University Hospital in Tübingen with exception of few brain dead organ donors. Other cornea banks originating their donors from hospitals partially far away or from cadavers who died outside hospitals, what means that the donors died under uncontrolled conditions. Therefore they had a vast heterogeneity of the study population without stable methods of procedures and without stable contact persons. Sometimes they changed the methods during the study period, for example *in situ* corneoscleral disc excision versus whole globe enucleation. These facts could have an influence on the donation rate.

In our opinion the corneal donation rate may be influenced by sufficient staff levels of the eye banking team, a specific training of the eye bank resident performing the consent with the next of kin, motivation and experience of the resident, empathy in the grieving process and actual organ donation controversies.

In conclusion, our study showed that organ donation controversies may influence the corneal donation rate significantly.

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## Competing interests

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