Reproductive Care Center

Informed Consent for Fresh Embryo Transfer

The number of embryos to be transferred should be agreed upon by the couple and their physician. Based on our experience at the Reproductive Care Center (RCC) and the guidelines set forth by the American Society for Reproductive Medicine (ASRM), the number chosen should optimize the chance for achieving a pregnancy while minimizing the likelihood of higher order multiple pregnancy. Multiple gestations (particularly triplet and higher order multiple pregnancy) are an undesirable consequence of assisted reproductive technologies. Multiple gestations lead to an increased risk of significant complications in both the fetuses and the mother. Patients should also be aware that even though the likelihood is low (<2%) it is possible for an embryo to split into "identical twins". Thus even with the transfer of 1 embryo, twins could develop. Although multifetal pregnancy reduction can be performed to reduce fetal number, the procedure does not completely eliminate the risks associated with multiple pregnancies and can have adverse psychological consequences. We do not perform this procedure but can refer patients if needed. Fetal reduction may result in the loss of all fetuses (usually <5% risk) and even successful reductions may have adverse psychological consequences. If multifetal pregnancy reduction is not an acceptable option, we would usually recommend that you not transfer more than two embryos.

Embryos are cultured until ready for transfer, which is usually for three to six days. After culturing for 3 days the embryos have typically developed to the 6-8 cell stage and are called "cleavage stage" embryos. Two good cleavage stage embryos have usually been transferred on day 3 for many years at RCC with excellent pregnancy rates.

As the embryos continue to develop, they pass through several stages including blastocyst formation. Blastocysts are typically "stronger" than day 3 embryos. The strongest, and most fit, embryos will survive the additional two days in culture. Blastocysts have a higher implantation rate and are more likely to implant than day 3 embryos. Because of this increased viability, fewer blastocysts need to be transferred, thus potentially lowering the rate of high order (>2) multiple births.

However, even with the advantages of increased viability and lower multiple birth rates, blastocyst transfer is not for every couple (cycle). The longer the embryos are cultured the fewer the embryos that will remain viable for transfer (and or cryopreservation). For example, there are usually more embryos on day 1 than on day 3 or day 5 as some embryos stop growing or their growth slows during the culturing process. In addition, some studies of blastocyst transfer suggest there is an increased risk of identical twinning, including situations where the fetuses are in the same fluid filled sac. When the fetuses are in the same sac (monochorionic and monoamnionic) there is an increased risk for miscarriage and late in pregnancy complications such as twin-twin transfusion can occur. Fortunately, this occurs in less that 5% of the cases.

There must be enough viable embryos on day 3 to "risk" culturing to day 5. For example, if only two embryos are present on day 3, one or both could stop growing by extending culture to 5 or 6 days, which would result in the loss of the cycle. On the other hand, if more than 3 good 8 cell cleavage stage embryos are available on day 3, the chances are high that 2 or more will survive to day 5 making blastocyst transfer feasible. Whether or not the couple plans to cryopreserve some of their embryos will also influence the decision on whether to extend the culture.

The best comparative research studies demonstrated equivalent pregnancy rates and multiple birth rates to conventional IVF when transferring 2 blastocysts versus 3-4 embryos on day 3 after egg retrieval. The main difference between the two groups was that transfer of 2 blastocysts rarely resulted in triplets.

Unfortunately, embryos unpredictably develop to the blastocyst stage. Approximately 40-50% of embryos successfully develop into blastocysts. If the starting number of embryos is low (less than 6 embryos), then we face a higher chance that none of the embryos remain viable by day 5-6. RCC may recommend embryo

transfer on day 3 rather than attempting blastocyst transfer when the embryo number is low or the quality is poor to avoid the possibility of no embryos for transfer on day 5.

The Reproductive Care Center cannot guarantee improved pregnancy rates or that any pregnancy will result from using blastocyst embryo transfer. IVF fails to produce any blastocysts in as many as 5-10% of cycles. It is generally assumed (but not known for sure) that embryos that die in laboratory culture would not have developed into normal pregnancies if they had been transferred into the uterus at an earlier stage.

The following updated guidelines were recommended by ASRM in 2006.

1. In patients under the age of 35, no more than two embryos should be transferred in the absence of extraordinary circumstances. For patients with a favorable prognosis, consideration should be given to transferring only a single embryo. The patients having the most favorable prognosis include those who are undergoing their first cycle of IVF, have good quality embryos as judged by morphologic criteria (appearance), and have embryos of sufficient quality and quantity to warrant cryopreservation (freezing). The patients who have had previous success with IVF should also be considered the most favorable prognostic category.
2. For patients between 35 and 37 years of age having a favorable prognosis, no more than two embryos should be transferred. All others in this age group should have no more than three embryos transferred. After extended culture no more than 2 blastocysts should be transferred.
3. For patients between 38 and 40 years of age with a favorable prognosis, no more than 2 blastocysts or 3 cleavage stage embryos should be transferred. For patients in this age group having a less favorable prognosis, no more than three blastocysts or 4 cleavage stage embryos should be transferred.
4. For most patients greater than 40 years of age, no more than three blastocysts or five cleavage stage embryos should be transferred.
5. For the patients with two or more previously failed IVF cycles and those having a less favorable prognosis, additional embryos may be transferred according to individual circumstances after appropriate consultation.
6. In donor egg cycles, the age of the donor should be used to determine the appropriate number of embryos to transfer.

We understand that we fit into category #_____ listed above. Special considerations for our case, if any, include (none) _____

We understand that transferring multiple embryos entails the risk of multiple pregnancies, which have much higher risks than single pregnancies. We have had an opportunity to discuss these risks with an RCC physician and accept the risks involved with this decision. We understand that transferring more than two embryos requires physician discussion.

RCC usually recommends that the couple plan to culture the embryos to day 5 or 6 after the egg retrieval and then transfer blastocysts if there are an adequate number of good quality embryos available on day 3. A day 2 transfer may be recommended if the number of embryos available for transfer is the same as the number of embryos desired for transfer (usually 2).

Please choose one option from the following two options:

Option 1 day 3 (circle) – Yes No

We desire a day 3 embryo transfer (do not want a day 5 (blastocyst) transfer and we plan to transfer the following number of cleavage stage embryos:

____ One cleavage stage embryo.
____ Two cleavage stage embryos.
____ Three cleavage stage embryos, if one is of poor quality.

Option 2 day 5-6 (circle) – Yes No

If in the opinion of RCC physicians and embryologists there is an **inadequate number** of quality embryos for extended culture we plan to transfer the following number of cleavage stage embryos on day 2 or 3:

____ One cleavage stage embryo.
____ Two cleavage stage embryos.
____ Three cleavage stage embryos, if one is of poor quality.

The following options are not usually recommended (extended culture would be preferred):

____ Four cleavage stage embryos, if two are of poor quality.
____ Three good quality cleavage stage embryos.
____ All cleavage stage embryos available.

If in the opinion of RCC physicians and embryologists there is an **adequate number** of quality embryos for extended culture we plan to transfer the following number of blastocysts on day 5 or 6:

____ One blastocyst.
____ Two blastocysts.
____ Three blastocysts **(not usually recommended at RCC).**

_____ _____
Wife's Signature Date

_____ _____
Husband's Signature Date

_____ _____
Physician's Signature Date

To be completed on the day of embryo transfer:

Based on updated information provided on the day of embryo transfer, we desire to change the number of embryos transferred on this cycle to: _____.

We desire that extra embryos of adequate quality (#____) be cryopreserved today (circle): Yes No
We desire that assisted hatching be performed today (additional cost): Yes No
We desire that extra embryos undergo extended culture (at additional cost) and if at least _____ blastocyst(s) of adequate quality develop we desire that they be cryopreserved (circle): Yes No
We desire that the embryos be frozen (circle): In groups (with no more than #____ in a group) Individually

We request that RCC dispose of bodily fluids or tissues, including any unfertilized or abnormally fertilized eggs, developmentally arrested, abnormal or undesired embryos. Photographs may be made of any discarded tissues or fluids and may be used anonymously for presentation or publications. We also consent to allow RCC to use any bodily fluids, tissues, unfertilized or abnormally fertilized eggs, as well as any developmentally arrested, abnormal or undesired embryos that would otherwise be discarded, for medical research, quality control, training or teaching purposes.

_____ _____
Wife's Signature Date

_____ _____
Husband's Signature Date

_____ _____
Physician's Signature Date: